

Florida Laws & Rules Osteopathic Medicine

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Disclosure Statement

I have no financial relationship
in regard to the content of this
presentation - JDW

Educational Objectives

Florida Laws and Rules

- Understanding of applicable Laws & Rules for licensed Osteopathic Physicians.
- Knowledge of the disciplinary process.
- Learning of rights afforded to physicians in licensure disciplinary cases.
- Ability to locate applicable statutes and rules through online resources.
- How to protect their right to practice.

What Fla Statute applies to ALL health care practitioners?

- A. Florida Statute 459
- B. Florida Statute 456
- C. Florida Statute 484 Part II
- D. Rule 64B15

LICENSE RENEWAL

Osteopathic Physician

Current licenses expire midnight, Eastern Time, March 31, 2020.

To ensure you receive your renewal notification from the department, your current mailing address must be on file. Failure to renew an active or inactive license by the expiration date will result in the license being placed in delinquent status. Failure by a delinquent licensee to renew before the expiration of the current licensure cycle renders the license null and void without any further action by the board or the department.

A licensee who remains on inactive status for more than two consecutive biennial licensure cycles and who wishes to reactivate the license may be required to demonstrate the competency to resume active practice by sitting for a special purpose examination or by completing other reactivation requirements.

If you are reactivating your license, please refer to the Laws & Rules governing your practice for additional requirements.

The department will renew your license upon receipt of:

Completed renewal application, Required fees, Updated Practitioner Profile, Completed Physician Workforce Survey, Completed Financial Responsibility Form

NOTE- Osteopathic Physicians licensed after July 1 of the second year of the biennium (odd year), are only required to complete the HIV/AIDS, Florida Laws and Rules, Professional & Medical Ethics, Federal & State Laws Related to the Prescribing of Controlled Substances and Prevention of Medical Errors courses (NOTE TO NOTE: YOU MUST COMPLETE THE 2 HOUR CE COURSE ON PRESCRIBING, AND SOON THE OTHER FIVE WILL BE MODIFIED TO 3...WAIT FOR IT AT THE END OF LECTURE!)

2018-2020 Requirements Osteopathic Physician

REQUIRED SUBJECT AREA	REQUIRED NUMBER OF HOURS	IMPORTANT INFORMATION
• General Hours*	20	20 must be AOA 1-A
• General Hours*	15	These hours can be AOA or AMA
• Medical Errors	2	Must be live
• Professional & Medical Ethics	1	Must be live
• Florida Laws and Rules	1	Must be live
• Federal & State Laws Related to the Prescribing of Controlled Substances	1	Must be live
• TOTAL HOURS	40**	
• * Licensees must obtain 2 hours of domestic violence <u>every third renewal period</u>		
• <u>Of the 15 general hours, only 8 can be home study</u>		

FSACOFP FOMA

Reports to CE BROKER

- THE FOMA REPORTS THE HOURS YOU RECEIVE HERE TODAY TO CE BROKER ON YOUR BEHALF! CE BROKER IS THE STATEWIDE CLEARING HOUSE FOR ALL CONTINUING EDUCATION HOURS FOR HEALTH CARE PROFESSIONALS. FOMA REPORTS FOR YOU!



Who's on First?

- Dept. of Health (DOH) – licenses health care practitioners
- Board of Osteopathic Medicine (Board) – rulemaking, and disciplinary hearings
- Attorney General's Office (AG) – provide an Attorney for the Board as Gen Counsel
- Also, provide Attorney(s) from Prosecution Services Unit to represent DOH during prosecution of discipline before Board
- District Court of Appeal (DCA) – court hears appeals from Board and DOAH
- Div. of Admin. Hearings (DOAH)– court hears Formal hearings for disciplinary cases

I. Laws and Rules for Osteopathic Physicians

Florida Statutes (F.S.): *Laws*

- Chapter 459: Osteopathic Medicine
- Chapter 456: Health Professions and Occupations: General Provisions
- Chapter 120: Administrative Procedure Act

Florida Administrative Code (F.A.C.): *Rules*

- Rules: Chapter 64B15: Board of Osteopathic Medicine, F.A.C.
- Rules: Chapter 64B: Division of Medical Quality Assurance, F.A.C.

FS 456 GENERAL PROVISIONS

HEALTH PROFESSIONS AND OCCUPATIONS:

- 456.001 Definitions
- THROUGH
- 456.50 Repeated Medical Malpractice

GENERAL HEALTH CARE PROVISION FOR ALL LICENSED
HEALTH CARE PROVIDERS

456.44 Florida Statute (not complete statute)

(1) DEFINITIONS.—

(e) “Chronic nonmalignant pain” means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(2) REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

- (a) Designate himself or herself as a controlled substance prescribing practitioner on the physician’s practitioner profile.
- (b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure. (a)-(g)

456.067 Florida Statute

Penalty for giving false information

- In addition to, or in lieu of, any other discipline imposed pursuant to s. 456.072, the act of knowingly giving false information in the course of **applying for or obtaining** a license from the department, or any board thereunder, with intent to mislead a public servant in the performance of his or her official duties, or the act of attempting to obtain or obtaining a license from the department, or any board thereunder, to practice a profession by knowingly misleading statements or knowing misrepresentations **constitutes a felony of the third degree**, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- History.—s. 71, ch. 97-261; s. 24, ch. 99-7; s. 86, ch. 2000-160; s. 27, ch. 2000-318.

456.054 Kickbacks prohibited

- 1) As used in this section, the term “kickback” means a remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items, when the payment is not tax deductible as an ordinary and necessary expense.
- (2) It is unlawful for any health care provider or any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.
- (3)(a) It is unlawful for any person or any entity to pay or receive, directly or indirectly, a commission, bonus, kickback, or rebate from, or to engage in any form of a split-fee arrangement with, a dialysis facility, health care practitioner, surgeon, person, or entity for referring patients to a clinical laboratory as defined in s. [483.803](#).
- (b) It is unlawful for any clinical laboratory to:
 1. Provide personnel to perform any functions or duties in a health care practitioner’s office or dialysis facility for any purpose, including for the collection or handling of specimens, directly or indirectly through an employee, contractor, independent staffing company, lease agreement, or otherwise, unless the laboratory and the practitioner’s office, or dialysis facility, are wholly owned and operated by the same entity.
 2. Lease space within any part of a health care practitioner’s office or dialysis facility for any purpose, including for the purpose of establishing a collection station where materials or specimens are collected or drawn from patients.
- (4) Violations of this section shall be considered patient brokering and shall be punishable as provided in s. [817.505](#).

456.069 Authority to inspect

In addition to the authority specified in s. [465.017](#), duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours:

- (1) Any pharmacy; or
- (2) Any establishment at which the services of a licensee authorized to prescribe controlled substances specified in chapter 893 are offered,

for the purpose of determining if any of the provisions of this chapter or any practice act of a profession or any rule adopted thereunder is being violated; or for the purpose of securing such other evidence as may be needed for prosecution.

FS 459 Osteopathic Medicine

OSTEOPATHIC MEDICINE

- 459.001 Purpose.
- THROUGH
- 459.026 Reports of adverse incidents in office practice settings.

STATUTE APPLIES TO ALL DO's and Physician assistants & Anesthesiologist Assistants.

459.0152 Specialties

An osteopathic physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the osteopathic physician has successfully completed the requirements for certification by the American Osteopathic Association or the Accreditation Council on Graduate Medical Education and is certified as a specialist by a certifying agency approved by the board. However, an osteopathic physician may indicate the services offered and may state that his or her practice is limited to one or more types of services when this accurately reflects the scope of practice of the osteopathic physician.

459.012 Florida Statute

Itemized patient statement

- Whenever an osteopathic physician licensed under this chapter renders professional services to a patient, the osteopathic physician **is required, upon request**, to submit to the patient, the patient's insurer, or the administrative agency for any federal or state health program under which the patient is entitled to benefits **an itemized statement of the specific services rendered and the charge for each**, no later than the osteopathic physician's next regular billing cycle which follows the fifth day after the rendering of professional services. An osteopathic physician **may not condition the furnishing of an itemized statement upon prior payment of the bill**. Whenever the itemized statement is submitted to the patient's insurer or the administrative agency, **a copy of the itemized statement shall simultaneously be provided to the patient**. Such copy of the itemized statement which is sent to the patient shall, in boldfaced letters, state that: "THIS IS A DUPLICATE COPY OF A STATEMENT SUBMITTED TO YOUR INSURER OR OTHER AGENCY."
- History.—s. 4, ch. 79-198; s. 2, ch. 81-318; ss. 13, 27, 29, ch. 86-290; s. 4, ch. 91-429.

Rule 64B15 Osteopathic Medicine

- 64B15-6 PHYSICIAN ASSISTANT(19)
- 64B15-7 ANESTHESIOLOGIST ASSISTANTS (14)
- 64B15-9 PROCEDURE (6)
- 64B15-10 FEES (12)
- 64B15-12 EXAMINATIONS AND LICENSURE (10)
- 64B15-13 CONTINUING EDUCATION (6)
- 64B15-14 PRACTICE REQUIREMENTS (16)
- 64B15-15 MEDICAL RECORDS (5)
- 64B15-16 RESIDENT INTERNSHIP (2)
- 64B15-18 PRESCRIPTIONS OF CERTAIN MEDICINAL DRUGS BY PHARMACISTS (4)
- 64B15-19 DISCIPLINARY GUIDELINES (10)
- 64B15-20 FINANCIAL RESPONSIBILITY (3)
- 64B15-22 REGISTRATION OF HOSPITAL RESIDENTS AND INTERNS (4)

MEDICAL MARIJUANA RULES

Emergency rules in place NOW!

To access the medical marijuana **consent form** visit:

- <http://flboardofmedicine.gov/forms/medical-marijuana-consent-form.pdf>

To access the medical marijuana statutorily **required documentation** form visit:

- <http://floridasosteopathicmedicine.gov/forms/statutorily-required-documentation.pdf>

64B15-19.007 Citations

- (1) As used in this rule, “citation” means an instrument which meets the requirements set forth in Section 456.077, F.S., and which is served upon a licensee or certificate holder for the purpose of assessing a penalty in an amount established by this rule.
- (2) In lieu of the disciplinary procedures contained in Section 456.073, F.S., the Department is hereby authorized to dispose of any violation designated herein by issuing a citation to the subject for a complaint that is the basis for the citation.
- (3) The following violations with accompanying fines may be disposed of by citation.
If it is not listed as a citation, then it is handled through a **FORMAL COMPLAINT**

II. Investigations

Florida Department of Health (DOH)

How can an investigation begin?

- 1) Upon written complaint signed by complaining individual;
- 2) Anonymous Complaint; 3) Confidential Informant complaint; and 4) DOH.

Does the Department tell me if I am being investigated?

Notice of Investigation – letter of investigation.

Exceptions = Criminal charge or DOH believes notice will be detrimental to investigation

Due Process Rights

Constitutional right to remain silent

5th Amendment Due Process right to remain silent as applied to the Federal Government

14th Amendment Due Process right to remain silent as applied to the States

You DO NOT have to respond to any questions by DOH investigator

ALL communications - through your attorney

WHAT RIGHTS?

Question: What exactly does it mean when an officer says, "You have the right to remain silent?"



Right to Remain Silent Contact by DOH

You need to fully understand your rights.

After you receive written notification about investigation, you will receive a phone call from a Department Investigator

He/She will try to convince you he/she is your friend

Often DOH Investigators will try to convince you there is nothing to this Complaint – talk to us and we will close it out! (not always a true statement)

Why should I invoke my right to remain silent?

Physician receives letter of investigation for improper advertising, the physician failed to conspicuously identify the osteopathic physician by name in the advertisement or failed to conspicuously identify the osteopathic physician referred to in the advertising as an osteopathic physician. 64B15-14.001(2)(k), FAC

*Violation is considered a Citation 64B15-19.007(2)(f) FAC

Physician decided not to remain silent but to write the DOH on his own behalf....result?

Why should I invoke my right to remain silent?

Response?

Physician writes letter to DOH on letterhead without correctly identifying himself as DO., only – Dr. John Doe

Physician received initial letter for failing to identify Dr. as DO and in letter to DOH he again failed to identify himself on letterhead as DO. – so, Dr receives a second complaint!!!!

If letter written by Attorney No Second Violation, letter by Dr. and because second complaint it is NO LONGER a Minor Violation



MR. CHAFFETZ
CHAIRMAN

C-SPAN
c-span.org



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CHAIRMAN

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Letter from DOH

At this point, you **SHOULD HAVE** an attorney – sound legal advice
DOH – **MUST** promptly furnish a copy of complaint or document
Within 45 days – you **MUST** submit a written response - it **MUST** be
considered by probable cause panel for the Board of Osteopathic
Medicine

An attorney is able to extend the response timeframe through
properly filed motions

DOH Resources

Investigative Subpoena's

Supported by Affidavit

Departments initiative or request by probable cause

The validity may be challenged – Was it unlawfully issued?

It is unreasonably broad in scope or Requires production of unreasonable materials

Investigative Depositions - Be aware – using deposition at subsequent formal hearing against you DOH may take depositions – own initiative or request probable cause panel; DOH gives you NO NOTICE

Investigation Conclusion

Entire investigative report with all exhibits is forwarded to Departments legal section in Tallahassee –

**If a Citation or Minor Violation, then case does NOT go to PCP – licensee receives notice of Citation or Notice of Noncompliance. Physician then either accepts and complies; or, does not accept and then regular disciplinary process resumes.*

Case then presented to PCP to determine whether probable cause exists and an administrative complaint issued. If no finding of probable cause – case dismissed.

PCP = Probable Cause Panel

III. 64B15-19.007 Citations

- (a) - Falsely certifying compliance with required continuing medical education hours for the purpose of renewing a license or certificate. The fine shall be \$2,000.
- (b) - Failure to keep current mailing or practice address on file with the Board. The fine shall be \$250.
- (c) - Failure to register as a dispensing practitioner. The fine shall be \$500.
- (i) Failure to timely provide medical records, upon request to a patient or a patient's legal representative. The fine shall be \$500.00.
- (j) Charging copying fees for patient records in violation of Rule 64B15-15.003, F.A.C. The fine shall be \$750.00.

Affect of Citations

If the subject does not dispute the matter in the citation in writing within 30 days after the citation is served by personal service or within 30 days after receipt by certified mail, the citation shall become a final order of the Board..

Failure to pay the fine and costs within the prescribed time period constitutes a violation of F.S., which will result in further disciplinary action. All fines and costs are to be made payable to “Department of Health – Citation.”

(5) Once the citation becomes a final order, the citation and complaint become a public record pursuant to Chapter 119, F.S., unless otherwise exempt from the provisions of Chapter 119, F.S. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions.

IV. Probable Cause Panel (PCP)

456.073, FS (4) The determination as to whether probable cause exists shall be made by majority vote of a probable cause panel of the board, or by the department, as appropriate. Each board may provide by rule for multiple probable cause panels composed of at least two members. Each board by rule establishes members of PCP.

64B15-9.006 (1) The probable cause panel shall be composed of at least two (2) members and not more than three (3) members. *1 BOOM Board Member, 2 may be professional or former consumer board member, and no more than 1 lay member.*

(4) The determination as to whether probable cause exists that a violation of the provisions of Chapters 456 and 459, F.S., and/or the rules promulgated pursuant thereto, has occurred shall be made by a majority vote of the probable cause panel of the Board.

Recordings of PCP

Electronically record all proceedings; Recorded by a certified court reporter

Transcripts may be obtained from the court reporter, Request copy of transcript of the probable cause panel proceeding – must meet test of being “meaningful” – Discussion of evidence by PC members

Must be some evidence to reasonably indicate finding of PC

The Department must justify actions but board may Not just “rubber stamp” recommendation

Transcript - the best place to start

Findings of PCP

NO Probable Cause = Case dismissed or receipt of Letter of concern

Violation exists – formal charges not being filed

Issued without an opportunity for hearing or to refute or dispute allegations

Becomes public record

Unclear – considered disciplinary actions

YES Probable Cause = Formal charges – Administrative Complaint

V. Administrative Complaint and Election of Rights

Administrative complaints are sent to a licensee after conclusion of the investigation, presentation to the probable cause panel, and sent with a form titled – Election of Rights.

The sending of the Administrative Complaint by DOH is deemed served upon the licensee after mailing, and should never be ignored.





Election of Rights

Once received, you must file within 21 days and Failure to file – licensee in default and license may be suspended by the DOH

Extension of time from department through legal counsel or request

Three ways to proceed (must choose only one way to proceed):

- Formal hearing

- Informal hearing

- Settlement agreement

Election of Rights

Formal Hearing before a hearing officer DOA Hearings

Full evidentiary hearing – DOH must meet its burden of proving up the material

Quite similar to a criminal or civil case

Absolutely foolish – to go this route **WITHOUT** legal assistance

Election of Rights

- Informal Hearing – before the Board of Osteopathic Medicine.
 - Physician MUST NOT dispute the facts of the alleged complaint.
 - Physician goes before BOOM and presents testimony/evidence requesting for leniency in their penalties for the violation.
 - BOOM can reduce penalties, keep the penalties as offered by the Prosecutor, increase the penalties, or go as far as reduce the charges or dismiss the complaint.
 - Physician should go with counsel, or at the least, after consultation with counsel.

Election of Rights

- Settlement Agreement – presented by the Prosecutor to resolve the matter.
 - Physician will have to appear before the BOOM for the Board to accept.
 - Physician's appearance will be after agreeing to the Prosecutor's negotiated penalties for the alleged violations in the complaint.
 - BOOM may accept the Agreement, or reject the Agreement. If BOOM rejects, they will make a counter-offer to resolve the matter. The physician can either accept the counter-offer immediately, or up to 7-14 days later; or reject the counter-offer and go to either a Formal or Informal Hearing (likely to have same result at Informal Hearing as the counter-offer).

Prosecution of Administrative Complaint

Licensee has due process PROPERTY rights, including, but not limited to:

Right to Remain Silent

Proper and adequate notice and adequate time to respond

See agency's investigative file, called discovery including subpoena's issues, depositions

Right to Counsel with Right to Examine and cross examine witnesses

Prosecution of Administrative Complaint

Attorney's from the Attorney General's office presents the case to the Full Board of Osteopathic Medicine for Informal Hearings or Settlement Agreements & to the Administrative Law Judge for Formal Hearings

After completion of the case, and a finding of guilt by either the Board or ALJ, an Order is entered with penalties:

Penalties can include a reprimand, probation, practice restrictions, or revocation of licensure.

Prosecution Penalties

64B15-19.002(4) False, deceptive or misleading advertising. (459.015(1)(d)FS) 1st offense letter of concern to reprimand and \$1k fine, 2nd offense probation and up to \$5k fine, 3rd offense up to 1 yr suspension followed by probation up to \$5k fine

(11) Kickbacks and unauthorized fee arrangements. (459.015(1)(j)FS) 1st offense probation or suspension and up to \$5k fine or denial, 2nd offense denial, revocation, or suspension followed by probation up to \$10k fine.

(35) Presigning blank prescription forms. (459.015(1)(ee), FS) 1st offense reprimand or suspension and \$5k fine, 2nd offense probation/revocation up to \$10k fine

Judicial Review and Stays of Final Order

Upon Order, one party wins – one party loses. If you lose, you can file a Motion to Stay the Order while you Appeal! The burden of proof is on the agency to prove probable danger to the community.

You will be the unhappy party; **Rarity** – Department feels need to appeal the decision!

Seek judicial review – District Court of Appeal.

Five District Court of Appeals

Each has jurisdiction to hear appeals from licensing boards final orders

VI. DEA Changes in Laws and Rules

Determination Transfer Hydrocodone Combination Products (HCPs) to Schedule II

DEA rescheduled hydrocodone Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of HCPs. As such, the DEA has rescheduled HCPs as a schedule II controlled substance under the CSA.

DEA Changes in Laws and Rules

Placement of Tramadol Into Schedule IV

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of tramadol. As such, the DEA is scheduling tramadol as a controlled substance under the CSA.

Based on these findings, the Deputy Administrator of the DEA concludes that tramadol, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Florida Changes in Laws

Prescription Drug Monitoring Program (PDMP)

Any physician prescribing controlled substances level II-IV should be registered through the PDMP. While not mandatory, if you prescribe a controlled substance II-IV and not view the PDMP, you may be falling below the standard of care. As of July 2014 **30.5%** of participating physicians were Osteopathic Physicians.

456.44, F.S. REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance listed in schedule II, schedule III, or schedule IV, as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

- (a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.
- (b) Comply with the requirements of this section and applicable board rules.

Florida Changes in Laws

- 456.0301 Requirement for instruction on controlled substance prescribing.
complete a board—approved 2—hour continuing education course on prescribing controlled substances offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 Credit or the American Osteopathic Category 1—A continuing medical education credit as part of biennial license renewal. The course must be completed by January 31, 2019, and at each subsequent renewal

Florida Changes in Laws

456.44 Controlled substance prescribing.

(1) DEFINITIONS. AS used in this section, the term: (a) "Acute pain" means the normal, predicted, physiological, and time—limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

1. Cancer.
2. A terminal condition. For purposes of this subparagraph, the term "terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life—sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.
3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.
4. A traumatic injury with an Injury Severity Score of 9 or greater.

Florida Changes in Laws

- **(4) STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN.***The applicable boards shall adopt rules establishing guidelines for prescribing controlled substances for acute pain, including evaluation of the patient, creation and maintenance of a treatment plan, obtaining informed consent and agreement for treatment, periodic review of the treatment plan, consultation, medical record review, and compliance with controlled substance laws and regulations. Failure of a prescriber to follow such guidelines constitutes grounds for disciplinary action pursuant to s. 456.072(1)(gg), punishable as provided in s. 456.072(2).

Florida Changes in Laws

(5) PRESCRIPTION SUPPLY? (a) For the treatment of acute pain, a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812 may not exceed a 3—day supply, except that up to a 7—day supply may be prescribed if:

1. The prescriber, in his or her professional judgment, believes that more than a 3—day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;
2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and 3. The prescriber adequately documents in the patient's medical records the acute medical condition and lack of alternative treatment options that justify deviation from the 3— day supply limit established in this subsection. (b) For the treatment of pain other than acute pain, a prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

(6) EMERGENCY OPIOID ANTAGONIST. For the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, a prescriber who prescribes a Schedule II controlled substance listed in s. 893.03 or 21 U.S.C. s. 812 must concurrently prescribe an emergency opioid antagonist, as defined in s. 381.887(1).

HB 21 – An Act Relating to Controlled Substances

On March 19, 2018 Governor Scott signed HB 21 into law to combat opioid abuse in Florida.

HB 21 increase the regulation, training, and reporting required when controlled substances are prescribed or dispensed.

Most requirements take effect July 1, 2018.

Prescribing Guidelines

HB 21 requires applicable health care regulatory boards to adopt rules establishing guidelines for prescribing controlled substances for the treatment of acute pain. The rules will include evaluation of the patient, creation and maintenance of a treatment plan, obtaining informed consent and agreement for treatment, periodic review of the treatment plan, consultation, medical record review, and compliance with controlled substances laws and regulations.

Failure to follow the Board guidelines will result in disciplinary action.

Prescribing Limitations

HB 21 limits a prescription for an opioid listed in Schedule II to no more than three days if prescribed to treat “acute pain”.

“Acute pain” = the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

The term “acute pain” specifically does not include pain related to:

- Cancer;
- A terminal condition;
- Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury; or
- A serious traumatic injury with an Injury Severity Score of 9 or greater.

Prescribing Limitations

The prescription limitation of 3 days for acute pain can be increased to 7 days if the prescriber:

Believes it is medically necessary to treat the patient's pain.

Indicates "ACUTE PAIN EXCEPTION" on the prescription.

Adequately documents in the patient's medical records the acute medical condition and lack of alternative treatment options that justify the deviation from the 3 day supply limit.

Opioid Antagonist Requirement

HB 21 requires a prescriber to co-prescribe an opioid antagonist when prescribing Schedule II controlled substances for the treatment of pain related to a traumatic injury with an injury severity score of 9 or greater.

Prescribing Limitations

- If a prescriber writes a prescription for a Schedule II opioid for the treatment of pain other than acute pain – (i.e. for **chronic non-malignant pain**, or for pain that is excluded from the definition of acute pain) the prescriber **MUST** indicate “**NONACUTE PAIN**” on the prescription.

Nonacute Pain

For treatment of pain other than acute pain the prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a schedule II.

The **NEW** Florida OPIOID Prescribing Law Mandated by the Florida Legislature (HB 21)

What you need to know:

3-Day LIMIT

- ★ Applies to treatment of acute pain for Schedule II opioids
- ★ Does not apply to:
 - ▶ Cancer
 - ▶ Terminal condition
 - ▶ Pain related with palliative care
 - ▶ Traumatic injury with ISS of 9 or higher (* see below)
- ★ When prescribing schedule II opioid for traumatic injury with an ISS score of 9 or higher, physician is required to also prescribe an emergency opioid antagonist
- ★ 7-day supply allowed if:
 - ▶ If physician determines it medically necessary
 - ▶ Script includes "Acute Pain Exception"
 - ▶ Reason for exemption documented on chart
- ★ For chronic pain patients:
 - ▶ You must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812
- You must maintain:
 - ▶ Complete Medical Record
 - ▶ Controlled Substance Agreement
 - ▶ Driver's License

PDMP

- ★ The E-FORSCE state Prescription Drug Monitoring Program (PDMP) must be consulted for every schedule II-V prescription
 - ▶ For patients 16 or older
 - ▶ Only exception is Schedule V non-opioids
- ★ PDMP may be accessed by designated staff with individual login
- ★ If the PDMP is down at the time of the script, you must document the script, time and reason you are unable to access
 - ▶ Physician may not prescribe more than a 3-day supply
- ★ A health care practitioner who fails to consult the PDMP as required is subject to a nondisciplinary citation for the initial offense. Any subsequent offense for failure to consult the PDMP may result in disciplinary action against the health care practitioner's license.
- ★ Link to the PDMP:
<https://florida.pmpaware.net/login>

CME Req.

- ★ All physicians with a Florida Medical License and a DEA License must complete a two-hour mandatory CME course before January 31, 2019
- ★ CME must be completed for each subsequent Licensure Renewal
- ★ BY LAW, the course is only available from a Florida statewide professional association of physicians accredited by the AMA or AOA to provide category 1 or 1-A credit
- ★ Takes effect beginning with renewals scheduled for January 2019

This law **TAKES EFFECT**
July 1, 2018!

This is a summary of the provisions of HB 21, provided for convenience purposes only. For complete information, please consult the text of the legislation at <https://www.flsenate.gov/Session/BILL/2018/21/BillText/er/PDF> or
Access the state mandated course at: <http://www.foma.org/opioid-prescribing-controlled-substances-2hr-course.html>



For more info contact us at
(850) 878-7364

Rule Changes 64b-15

64B15-13.0025 Requirement for Continuing Education Course on Prescribing Controlled Substances.

- (1) Pursuant to section 456.0301, F.S., **by January 31, 2019**, all physicians who **are** registered with the United States Drug Enforcement Agency **and** authorized to prescribe controlled substances **must** complete a 2-hour course on prescribing controlled substances.
- (2) The Board approves the controlled substance prescribing courses offered by the Florida Medical Association, the Florida Osteopathic Medical Association, the Florida Academy of Family Physicians, and the Florida College of Emergency Physicians, for the purpose of meeting this continuing education requirement. The course **may** be offered in a distance learning format.
- (3) The 2-hour controlled substances prescribing course **shall be included** in the total hours required for continuing education renewal purposes.
- (4) This rule requirement is **not** applicable to physician assistants licensed pursuant to section 459.022, F.S.

*Rulemaking Authority 456.0301(2) FS. Law Implemented 456.0301 FS. History—**New 7-11-18.***

64B15-13.001 Continuing Education for Biennial Renewal.

The Florida Board of Osteopathic Medicine is currently working on changes to the continuing education requirements for biennial renewal. Just last month the Board published proposed rules which modify the 5 mandatory hours to only 3 total hours, because of the 2 hour ce course that is mandated by statute, and referenced in previous slide. The 3 hours will include: 1 hour continuing medical education course in Florida Laws and Rules/Professional and Medical Ethics, and a two (2) hour course in Prevention of Medical Errors.

This rule is not yet effective.

TELEMEDICINE



Changes in Telemedicine Rule

- Beginning in 2014, the BOM and the BOOM, after promulgating Rule 64B15-14.0081, took action to repeal their existing rules and promulgate new rules for Telemedicine.
- BOM and BOOM promulgated the EXACT SAME LANGUAGE. There is no difference if you are a DO or an MD in performing Telemedicine.
- Then the BOM and the BOOM addressed the issue of ordering vs prescribing controlled substances for hospitalized patients through the use of telemedicine.
- The rule amendment does not prescribe the behavior or actions of any regulated entity or licensee but rather clarifies that physicians can indeed order controlled substances for hospitalized patients through the use of telemedicine.

Telemedicine Rule

64B15-14.0081 and **64B8-9.0141**

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- (1) “Telemedicine” means the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.
 - (2) The standard of care, as defined in Section 456.50(1)(e), F.S., shall remain the same regardless of whether a Florida licensed physician or physician assistant provides health care services in person or by telemedicine.

Telemedicine Rule

64B15-14.0081 and **64B8-9.0141**

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- (3) Florida licensed physicians and physician assistants providing health care services by telemedicine are responsible for the quality of the equipment and technology employed and are responsible for their safe use. Telemedicine equipment and technology must be able to provide, at a minimum, the same information to the physician and physician assistant which will enable them to meet or exceed the prevailing standard of care for the practice of medicine.
 - (4) Controlled substances shall not be prescribed through the use of telemedicine except for the treatment of psychiatric disorders. This provision does not preclude physicians or physician assistants from ordering controlled substances through the use of telemedicine for patients hospitalized in a facility licensed pursuant to Chapter 395, F.S.

Telemedicine Rule

64B15-14.0081 and 64B8-9.0141

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- (5) Prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances, as well as prescribing legend drugs other than in the course of a physician's professional practice.
 - (6) Physicians and physician assistants shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met:
 - (a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.
 - (b) Discussion between the physician or the physician assistant and the patient regarding treatment options and the risks and benefits of treatment.
 - (c) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B15-15.004, F.A.C.

Telemedicine Rule

64B15-14.0081 and 64B8-9.0141

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- (7) The practice of medicine by telemedicine does not alter any obligation of the physician or the physician assistant regarding patient confidentiality or recordkeeping.
 - **(8) A physician-patient relationship may be established through telemedicine.**
 - (9)(a) Nothing contained in this rule shall prohibit consultations between physicians or the transmission and review of digital images, pathology specimens, test results, or other medical data by physicians or other qualified providers related to the care of Florida patients.
 - (b) This rule **does not apply** to emergency medical services provided by emergency physicians, emergency medical technicians (EMTs), paramedics, and emergency dispatchers. Emergency medical services are those activities or services to prevent or treat a sudden critical illness or injury and to provide emergency medical care and prehospital emergency medical transportation to sick, injured, or otherwise incapacitated persons in this state.
 - (c) The provisions of this rule **shall not apply where a physician or physician assistant is treating a patient with an emergency medical condition that requires immediate medical care.** An emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.
 - (d) The provisions of this rule **shall not be construed to prohibit patient care in consultation with another physician** who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including the use of any prescribed medications, nor on-call or cross-coverage situations in which the physician has access to patient records.

64B15-14.007 Standard of Care for Office Surgery

(3) Level I Office Surgery.

(a) Scope. Level I office surgery includes the following:

4. Anesthesia is limited to minimal sedation. The patient's level of sedation is that of minimal sedation and anxiolysis and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected. Controlled substances, as defined in Sections 893.02 and 893.03, Florida Statutes, are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain.

64B15-15.004 Written Records; Minimum Content; Retention.

(1) For the purpose of implementing the provisions of Section 459.015(1)(o), F.S., osteopathic physicians shall maintain written legible records on each patient in English, with sufficient detail to clearly demonstrate why the course of treatment was undertaken. The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately. Such written records shall contain, at a minimum, the following information about the patient:

- (a) Patient histories;
- (b) Examination results;
- (c) Test results;
- (d) Records of drugs prescribed, dispensed or administered;
- (e) Reports of consultations;
- (f) Reports of hospitalizations; and,
- (g) copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.

64B15-15.004 Written Records; Minimum Content; Retention.

(2) Medical records in which compounded medications are administered to a patient in an office setting must contain, at a minimum, the following information:

- (a) The name and concentration of medication administered;
- (b) The lot number of the medication administered;
- (c) The expiration date of the medication administered;
- (d) The name of the compounding pharmacy or manufacturer;
- (e) The site of administration on the patient;
- (f) The amount of medication administered; and,
- (g) The date medication administered.

(3) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered into the record. However, office records do not need to be timed, just dated.

64B15-15.004 Written Records; Minimum Content; Retention.

(4) Whenever patient records are released or transferred, the osteopathic physician releasing or transferring the records shall maintain either the original records or copies thereof and a notation shall be made in the retained records indicating to whom the records were released or transferred. However, whenever patient records are released or transferred directly to another Florida licensed physician, or licensed health care provider it is sufficient for the releasing or transferring osteopathic physician to maintain a listing of each patient whose records have been so released or transferred which listing also includes the physician or licensed health care provider to whom such records were released or transferred. Such listing shall be maintained for a period of five (5) years.

(5) In order that the patients may have meaningful access to their records pursuant to Section 456.058, F.S., an osteopathic physician shall maintain the written record of a patient for a period of at least five (5) years from the date the patient was last examined or treated by the osteopathic physician. However, upon the death of the osteopathic physician, the provisions of Rule 64B15-15.001, F.A.C., are controlling.

Rulemaking Authority 459.005 FS. Law Implemented 456.058, 459.015(1)(o) FS. History—New 11-30-94, Amended 10-25-95, Formerly 59W-15.004, Amended 12-22-97, 9-9-13, 3-8-18.

MEDICAL MARIJUANA



Recent Board Rulings

Allegations: Count I: Section 459.015(1)(x), FS., - committing medical malpractice. Count II: Section 459.015(1)(t), FS., - legend drug outside of professional practice. Count III: Section 459.015(1)(pp), F.S., by violating Rule 64B15-14.005(3), FAC.

Action – Reprimand, \$7.5k fine, Laws Course, UF Drug Course, Risk Mgmt., Permanent restriction not own, operate or practice in Pain Mgmt Clinic, probation 2 yrs direct, 3 yrs indirect, may not prescribe 2-5 CS

Recent Board Rulings

Allegations: Section 459.015(1)(b), FS., - license to practice osteopathic medicine acted against by another jurisdiction

Action – Suspension until receipt of unencumbered license in other state, CE hours, Boundaries course

Allegations: Section 456.072(1)(c), FS., - convicted of crime related to the practice

Action – Reprimand, Permanent restriction CS II, probation for 2 yrs indirect supervision

VII. What if I don't like...

A Rule as promulgated by the Board of Osteopathic Medicine?

File for Variance or Waiver of a Rule - 120.542, FAC Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. Hearing before the Board of Osteopathic Medicine.

A Law in statute?

Requires the Florida Osteopathic Medicine Practice Act to be opened up and subject to change in all sections of the Practice Act of 459, FS. Through legislative process.

Resources

www.floridahealth.gov Florida Department of Health Home Page – Verify a License

www.floridasosteopathicmedicine.gov/ Board of Osteopathic Medicine Homepage

www.leg.state.fl.us/Statutes/index.cfm All Florida Statutes

www.flrules.org/default.asp All Florida Rules of Board, and All Boards

Thank you for your time!

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