

Florida Laws, Rules and Medical Ethics

Jason D. Winn, PA, Attorney at Law - 850/222-7199

jwinn@jwinnlaw.com

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Disclosure Statement

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

Educational Objectives

Florida Laws, Rules and Medical Ethics

- 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.
- What constitutes medical ethics?
- Why should I be concerned about medical ethics?

Why Laws, Rules and Medical Ethics?

- Recently the Board of Osteopathic Medicine amended their rules for osteopathic physicians in Florida – changing the required CE hours for renewal to NOW include 2 hours of Prescribing Controlled Substances as a mandatory course and MUST be completed by January 31, 2019 if you are licensed in Florida and hold are authorized by the DEA to prescribe CS.
- Also, the Board combined the one hour for laws and rules with the one hour for medical ethics.
- There are still **5 mandatory hours** for each biennium – this course, Medical Errors 2 hours, and Prescribing Controlled Substances 2 hours

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 at midnight, Eastern Time, on 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- Domestic Violence is required every third biennium

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
• Florida Laws, Rules and Medical Ethics	1	Must be live
• Prescribing of Controlled Substances	2	Does not have to 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>		

Reports to CE BROKER

- REPORT THE HOURS YOU RECEIVE HERE TODAY TO CE BROKER! CE BROKER IS THE STATEWIDE CLEARING HOUSE FOR ALL CONTINUING EDUCATION HOURS FOR HEALTH CARE PROFESSIONALS.



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.—

(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.

(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.

456.44 Florida Statute (not complete statute)

(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).

(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).

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.

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.

459.025, FS

Formal supervisory relationships, standing orders, and established protocols; notice; standards.

1) NOTICE.—(a) When a physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. [401.27](#), which relationship or orders contemplate the performance of medical acts, or when a physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts set forth in s. [464.012](#)(3) and (4), the physician shall submit notice to the board. The notice shall contain a statement in substantially the following form:

I, (name and professional license number of physician), of (address of physician) have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with (number of persons) emergency medical technician(s), (number of persons) paramedic(s), or (number of persons) advanced registered nurse practitioner(s).

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

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

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.

PDMP or Eforcse

www.floridahealth.gov/statistics-and-data/e-forcse/

Welcome to E-FORCSE®, Florida's Prescription Drug Monitoring Program

The Florida Prescription Drug Monitoring Program, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program), was created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida.

IMPORTANCE NOTICE:

We are pleased to announce that the NEW E-FORCSE® PMP AWA_Rx_E platform is now available at: <https://florida.pmpaware.net>.

To create an account, navigate to <https://florida.pmpaware.net> and click “Create an Account.”

For technical assistance, please call 1-877-719-3120. If you have questions specific to state policy, you may contact E-FORCSE® at 850-245-4797 or by e-mail at e-forcse@flhealth.gov.

MEDICAL MARIJUANA



Medical Ethics – Why should I be concerned?

AOA Code of Ethics

The American Osteopathic Association has formulated this Code to guide its member physicians in their professional lives. The standards presented are designed to address the osteopathic physician's ethical and professional responsibilities to patients, to society, to the AOA, to others involved in health care and to self.

Further, the American Osteopathic Association has adopted the position that physicians should play a major role in the development and instruction of medical ethics.

What is Medical Ethics?

Medical ethics involves examining a specific problem, usually a clinical case, and using values, facts, and logic to decide what the best course of action should be.

Some ethical problems are fairly straightforward, such as determining right from wrong. But others can also be more perplexing, such as deciding between two "rights"—two values that are in conflict with each other—or deciding between two different value systems, such as the patient's versus the doctor's.

Doctors may deal with a great variety of perplexing ethical problems even in a small medical practice. Here are some common problems identified in a 2016 Medscape survey, where at least some physicians held different opinions

What are the Basic Principles of Medical Ethics?

Autonomy

Requires that the patient have autonomy of thought, intention, and action when making decisions regarding health care procedures. Therefore, the decision-making process must be free of coercion or coaxing. In order for a patient to make a fully informed decision, she/he must understand all risks and benefits of the procedure and the likelihood of success. Because ARTs are highly technical and may involve high emotions, it is difficult to expect patients to be operating under fully-informed consent.

Justice

The idea that the burdens and benefits of new or experimental treatments must be distributed equally among all groups in society. Requires that procedures uphold the spirit of existing laws and are fair to all players involved. The health care provider must consider four main areas when evaluating justice: fair distribution of scarce resources, competing needs, rights and obligations, and potential conflicts with established legislation. Reproductive technologies create ethical dilemmas because treatment is not equally available to all people.

Beneficence

Requires that the procedure be provided with the intent of doing good for the patient involved. Demands that health care providers develop and maintain skills and knowledge, continually update training, consider individual circumstances of all patients, and strive for net benefit.

Non-maleficence

Requires that a procedure does not harm the patient involved or others in society. Infertility specialists operate under the assumption that they are doing no harm or at least minimizing harm by pursuing the greater good. However, because assistive reproductive technologies have limited success rates uncertain overall outcomes, the emotional state of the patient may be impacted negatively. In some cases, it is difficult for doctors to successfully apply the do no harm principle.

Examples of medical ethics scenarios

- Withholding treatment to meet an organization's budget, or because of insurance policies;
- Accepting money from pharmaceutical or device manufacturers;
- Upcoding to get treatment covered;
- Getting romantically involved with a patient or family member;
- Covering up a mistake;
- Reporting an impaired colleague;
- Cherry-picking patients;
- Prescribing a placebo;
- Practicing defensive medicine to avoid malpractice lawsuits;
- Dropping insurers; and
- Breaching patient confidentiality owing to a health risk.

Medical ethics issues?

The Medical Practice Act defines unprofessional conduct in each state. Although laws vary from state to state, some examples of unprofessional conduct include the following:

Physician abuse of a patient

Inadequate record keeping

Failing to meet the standard of care

Prescribing drugs in excess or without legitimate reason

Failing to meet continuing medical education requirements

Dishonesty

Conviction of a felony

Delegating the practice of medicine to an unlicensed individual

Minor fee disagreements and poor customer service are not considered unprofessional conduct.

456.059 Communications confidential; exceptions.

- Communications between a patient and a psychiatrist, as defined in s. 394.455, shall be held confidential and shall not be disclosed except upon the request of the patient or the patient's legal representative. Provision of psychiatric records and reports shall be governed by s. 456.057. Notwithstanding any other provision of this section or s. 90.503, where:
 - (1) A patient is engaged in a treatment relationship with a psychiatrist;
 - (2) Such patient has made an actual threat to physically harm an identifiable victim or victims; and
 - (3) The treating psychiatrist makes a clinical judgment that the patient has the apparent capability to commit such an act and that it is more likely than not that in the near future the patient will carry out that threat,
- the psychiatrist may disclose patient communications to the extent necessary to warn any potential victim or to communicate the threat to a law enforcement agency. No civil or criminal action shall be instituted, and there shall be no liability on account of disclosure of otherwise confidential communications by a psychiatrist in disclosing a threat pursuant to this section.

456.063 Sexual misconduct; disqualification for license, certificate, or registration

- (1) Sexual misconduct in the practice of a health care profession means violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical sexual activity outside the scope of the professional practice of such health care profession. Sexual misconduct in the practice of a health care profession is prohibited.
- (2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant has:
 - (a) Had any license, certificate, or registration to practice any profession or occupation revoked or surrendered based on a violation of sexual misconduct in the practice of that profession under the laws of any other state or any territory or possession of the United States and has not had that license, certificate, or registration reinstated by the licensing authority of the jurisdiction that revoked the license, certificate, or registration; or
 - (b) Committed any act in any other state or any territory or possession of the United States which if committed in this state would constitute sexual misconduct.

For purposes of this subsection, a licensing authority's acceptance of a candidate's relinquishment of a license which is offered in response to or in anticipation of the filing of administrative charges against the candidate's license constitutes the surrender of the license.

- (3) Licensed health care practitioners shall report allegations of sexual misconduct to the department, regardless of the practice setting in which the alleged sexual misconduct occurred.

Patient Boundaries Case Study

Physician saw patient in his office as a patient.

Then he started calling her, multiple times, to offer a job.

Later he called back and was “breathing heavily and his tone of voice had changed”.

He proceed to stated inappropriate things

to the patient regarding her body and how he wanted to touch her.

Action taken:

Revocation

Its only my ethics, Right?

456.072(1)(i) Except as provided in s. 465.016, failing to report to the department any person who the licensee knows is in violation of this chapter, the chapter regulating the alleged violator, or the rules of the department or the board. However, a person who the licensee knows is unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material, or as a result of a mental or physical condition, may be reported to a consultant operating an impaired practitioner program as described in s. 456.076 rather than to the department.

456.072(1) other ethical violations

- (n) Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.
- (u) Failing to comply with the requirements of ss. 381.026 and 381.0261 to provide patients with information about their patient rights and how to file a patient complaint.
- (v) Engaging or attempting to engage in sexual misconduct as defined and prohibited in s. 456.063(1).

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

AOA Code of Ethics

Section 1. The physician shall keep in confidence whatever she/he may learn about a patient in the discharge of professional duties. Information shall be divulged by the physician when required by law or when authorized by the patient.

Section 2. The physician shall give a candid account of the patient's condition to the patient or to those responsible for the patient's care.

Section 3. A physician-patient relationship must be founded on mutual trust, cooperation, and respect. The patient, therefore, must have complete freedom to choose her/his physician. The physician

must have complete freedom to choose patients whom she/he will serve. However, the physician should not refuse to accept patients for reasons of discrimination, including, but not limited to, the patient's race, creed, color, sex, national origin, sexual orientation, gender identity or handicap. In emergencies, a physician should make her/his services available.

Section 4. A physician is never justified in abandoning a patient. The physician shall give due notice to a patient or to those responsible for the patient's care when she/he withdraws from the case so that another physician may be engaged.

AOA Code of Ethics

Section 5. A physician shall practice in accordance with the body of systematized and scientific knowledge related to the healing arts. A physician shall maintain competence in such systematized and scientific knowledge through study and clinical applications.

Section 6. The osteopathic medical profession has an obligation to society to maintain its high standards and, therefore, to continuously regulate itself. A substantial part of such regulation is due to the efforts and influence of the recognized local, state and national associations representing the osteopathic medical profession. A physician should maintain membership in and actively support such associations and abide by their rules and regulations.

Section 7. Under the law a physician may advertise, but no physician shall advertise or solicit patients directly or indirectly through the use of matters or activities which are false or misleading.

Section 8. A physician shall not hold forth or indicate possession of any degree recognized as the basis for licensure to practice the healing arts unless he is actually licensed on the basis of that degree in the state in which she/he practices. A physician shall designate her/his osteopathic school of practice in all professional uses of her/his name. Indications of specialty practice, membership in professional societies, and related matters shall be governed by rules promulgated by the American Osteopathic Association.

AOA Code of Ethics

Section 9. A physician should not hesitate to seek consultation whenever she/he believes it advisable for the care of the patient.

Section 10. In any dispute between or among physicians involving ethical or organizational matters, the matter in controversy should first be referred to the appropriate arbitrating bodies of the profession.

Section 11. In any dispute between or among physicians regarding the diagnosis and treatment of a patient, the attending physician has the responsibility for final decisions, consistent with any applicable hospital rules or regulations.

Section 12. Any fee charged by a physician shall compensate the physician for services actually rendered. There shall be no division of professional fees for referrals of patients.

Section 13. A physician shall respect the law. When necessary a physician shall attempt to help to formulate the law by all proper means in order to improve patient care and public health.

Section 14. In addition to adhering to the foregoing ethical standards, a physician shall recognize a responsibility to participate in community activities and services.

Section 15. It is considered sexual misconduct for a physician to have sexual contact with any current patient whom the physician has interviewed and/or upon whom a medical or surgical procedure has been performed.

AOA Code of Ethics

Section 16. Sexual harassment by a physician is considered unethical. Sexual harassment is defined as physical or verbal intimation of a sexual nature involving a colleague or subordinate in the workplace or academic setting, when such conduct creates an unreasonable, intimidating, hostile or offensive workplace or academic setting.

Section 17. From time to time, industry may provide some AOA members with gifts as an inducement to use their products or services. Members who use these products and services as a result of these gifts, rather than simply for the betterment of their patients and the improvement of the care rendered in their practices, shall be considered to have acted in an unethical manner.

SECTION 18. A physician shall not intentionally misrepresent himself/herself or his/her research work in any way.

SECTION 19. When participating in research, a physician shall follow the current laws, regulations and standards of the United States or, if the research is conducted outside the United States, the laws, regulations and standards applicable to research in the nation where the research is conducted. This standard shall apply for physician involvement in research at any level and degree of responsibility, including, but not limited to, research, design, funding, participation either as examining and/or treating provider, supervision of other staff in their research, analysis of data and publication of results in any form for any purpose.

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!

Jason D. Winn, Esq.

Jason D. Winn, PA, Attorney at Law

2709 Killarney Way, Suite 4, Tall., FL 32301

jwinn@jwinnlaw.com 850/222-7199

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