Florida Laws & Rules

2015 Annual FSACOFP Convention
Hilton Bonnet Creek - Orlando
August 2, 2015 – 10 a.m.

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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.
CURRENT LICENSES EXPIRE MIDNIGHT, EASTERN TIME, MARCH 31, 2016.

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.
# 2014-2016 Requirements

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<th>REQUIRED SUBJECT</th>
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<td>General Hours*</td>
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<td>General Hours*</td>
<td>15</td>
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<td>Medical Errors</td>
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<td>Professional &amp; Medical Ethics</td>
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<td>Florida Laws and Rules</td>
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<td>Federal &amp; State Laws Related to the Prescribing of Controlled Substances</td>
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<th>IMPORTANT INFORMATION</th>
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<td>These hours can be AOA or AMA</td>
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**TOTAL HOURS** 40**

* Licensees must obtain 2 hours of domestic violence every third renewal period
FSACOFP Reports to CE BROKER

• THE FSACOFP 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 AND THE PCOMS 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 Generals 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)
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.
FS 459.012 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)
64B15-14.007 Standard of Care for Office Surgery (not complete Rule)

(3) Level I Office Surgery.
(a) Scope. Level I office surgery includes the following:
4. Anesthesia is local, topical, or none, and preoperative medicines are limited to a single anxiolytic drug not in the opiate class. The cumulative dose of the anxiolytic drug shall not exceed the maximum recommended dose (as per the manufacturer’s recommendation).
Amended 5/24/2015; Different than MD Rule presently; Ongoing meetings of the joint committee of BOOM and Bd of Medicine - Office Surgery Rule
DEPARTMENT OF HEALTH (DOH) INVESTIGATIONS

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

B. Notice of Investigation – letter of investigation.
Exceptions = Criminal charge or DOH thinks notice will be detrimental to investigation
The Phone Call After the Letter

A. You need to fully understand your rights.

B. After you receive written notification about investigation, you may receive a phone call from a Department Investigator.

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

D. Try to convince you there is nothing to this matter – “Tallahassee” will close it out.
E. At this point, you SHOULD HAVE an attorney – sound legal advice

F. DOH – MUST promptly furnish a copy of complaint or document which resulted in investigation

G. Within 45 days – you MUST submit written response - MUST be considered by probable cause panel for the Board of Osteopathic Medicine

✓ An attorney may be able to extend the response timeframe through properly filed motions
A. Constitutional right to remain silent

B. You **DO NOT** have to respond to any questions by DOH investigator

C. **ALL** communications - through your attorney
EXAMPLE OF WHY TO REMAIN SILENT and/or RETAIN COUNSEL

• Physician receives letter of investigation into improper advertising because she failed to conspicuously identify herself by name in the advertisement or failed to conspicuously identify herself as an osteopathic physician.

• Physician decided not to remain silent but to write the DOH on her own behalf….result?
• Physician writes letter to DOH on letterhead that does not correctly identify herself as a D.O., only – Dr. Jane Doe
• Dr. Doe now gets a second complaint for failing to identify herself as a D.O.!!!!!
• If letter written by Attorney – NO SECOND COMPLAINT
A. Investigative Subpoena’s
   1. Supported by Affidavit
   2. Departments initiative or request by probable cause
   3. The validity may be challenged
      a. Was unlawfully issued
      b. It is unreasonably broad in scope
      c. Requires production of unreasonable materials

B. Investigative Depositions
   1. Be aware – using deposition at subsequent formal hearing against you
   2. Department may take depositions – own initiative or request probable cause panel; They **DO NOT** have to notify you
When Investigation is Concluded:

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

B. Presented to probable cause panel - to determine whether probable cause should be found and an administrative complaint issued
A. Passed by Florida Legislature in 1989 – could preclude matter from going to probable cause

B. Board of Osteopathic Medicine calls these “Citations”
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.
Citations (cont.)

I. Issuance – alternative to the submission of an investigative report to the probable cause panel.

(s. 455.225 (3), FS, 1989)

A. Know the list of Citations – not on list, then not a minor violation.

RULE 64B15-19.007(a-o)
Citations (cont.)

B. Due Process considerations:

1. Without an opportunity for a hearing
2. May not take corrective action
3. Choice is yours
4. Be aware – finding of the minor violation remains on the departments records as a violation
C. Each licensing board shall establish by rule those minor violations under this provision that do not endanger the public health, safety and welfare and which do not demonstrate a serious inability to practice the profession.

D. The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of Section 456.073(3), F.S., to be followed.

• MUST take action within 15 days
• Get a call – request written notice
• Failure – issuance of formal complaint
• Finding – remains on department record as a violation
Citation Example - Advertising

- 64B15-14.001(2)(k) Fails to conspicuously identify the osteopathic physician by name in the advertisement or fails to conspicuously identify the osteopathic physician referred to in the advertising as an osteopathic physician.
- CITATION is an option for NAME not DO
- 64B15-19.007(3)(f) Failure to conspicuously list the name of the osteopathic physician in an advertisement as required in paragraph 64B15-14.001(2)(k), F.A.C. The fine shall be $500.
Citation Example – CE HOURS

• 459.008(4) – 40 hours of CME every biennium
• Statute gives authority to Board to write rule:
• 64B15-19.007(3)(d) Failure of the licensee to satisfy continuing education hours. The fine shall be $75 for each hour not completed or completed late. In addition, the licensee shall make up all hours not completed, and such hours shall not be counted toward the current renewal cycle.
Citation Example –
CE HOURS (cont.)

- 40 hours every biennium
- Only completed 20 hours total.
- First time violation receive citation.
- Citation results:
  - 20 hours x $75.00 = $1,500.00
  - 20 hours
PROBABLE CAUSE PANEL

64B15-9.006 Probable Cause Determination
Your professional license is not officially placed in jeopardy until a determination of probable cause has been made.

A. Licensing Board function or department function

1. Board of Osteopathic Medicine makes it a Board Function – 456.73, Florida Statutes

2. BOOM Probable Cause Panel – At least 2 members and not more than 3.

3. BOOM Board member, up to 2 may be professional and consumer board member and no more than 1 may be a lay member.
Consideration of the investigative report by probable cause panel (s. 456.073(4) FS, 2008)

A. Majority vote – two/three - member panel

B. Exempt from “Sunshine Law”
   1. You CANNOT be present
   2. Some boards do it without notice to licensee under investigation
   3. Notice is not given when it could be detrimental to the investigation
   4. Panel may request the department to provide additional investigative information
Recording of the probable cause panel proceedings – “Public Records Law” (s. 286.011, FS)

A. Electronically record all proceedings

B. Recorded by a certified court reporter

C. Transcripts may be obtained from the court reporter
D. Request copy of transcript of the probable cause panel proceeding

E. Transcript is also important – must meet test of being “meaningful”
   1. Must be some evidence to reasonably indicate
   2. The Department must justify actions
   3. Not just “rubber stamp” recommendation
   4. Transcript - the best place to start
WHY GET TRANSCRIPT of PROBABLE CAUSE PANEL?

• Discussion of facts and evidence
• Discussion of possible defenses
• Discussion of other licensed professionals and whether they agree/disagree with your actions
• DISCUSSION, DISCUSSION, DISCUSSION!!!
Submission of a letter of concern or filing of formal charges

A. Letter of concern
   1. Violation exists – formal charges not being filed
   2. Issued without an opportunity for hearing or to refute or dispute allegations
   3. Becomes public record
   4. Unclear – considered disciplinary actions

B. Formal charges – The formal charges take the form of an administrative complaint.
• **THE ADMINISTRATIVE COMPLAINT AND YOUR ELECTION OF RIGHTS**
Administrative Complaint

• States clearly that it is an administrative complaint, should not be ignored, is always served and includes an election of rights.
Election of Rights Timetable

A. Filed within 21 days of service
B. Failure to file – licensee in default
C. Extension of time from department

D. Three ways to proceed:
   1. Formal hearing
   2. Informal hearing
   3. Settlement agreement
**The Formal Hearing**

A. Formal hearing before a hearing officer
   Division of Administrative Hearings

B. Full evidentiary hearing – department must meet its burden of proving up the material
   - Quite similar to a criminal or civil case
   - Absolute fool - try and go this route WITHOUT legal assistance
A. **DO NOT** dispute the material factual allegations.
   ✓ *If you dispute then YOU ARE NOT GOING INFORMAL.*

B. Informal hearing – held before full board of Osteopathic Medicine

C. Mitigate

D. Go informal – take a calculated risk

E. **NEVER** – without conferring with a lawyer
The Stipulated Settlement

A. Avoid both formal and informal – “stipulated settlement agreement”

B. Agreement between the licensee and the Department and Board

C. Must fully and completely agree upon all terms
   ✓ CANNOT unilaterally bring proposal before regulatory board
   ✓ Must be a joint settlement proposal
D. Usually enclosed with administrative complaint

- Department’s offer of settlement
- Negotiate and modify proposal
- The Department must agree – or there is NO settlement agreement

E. Board has various options:

- Accept the agreement
- Reject the agreement
- Counteroffer
F. Certain advantages in seeking a stipulated settlement before filing an “election of rights form”

✓ Immediate reaction from Department
✓ Resolve matter – without sizeable legal bill
PROSECUTIONS OF ADMINISTRATIVE COMPLAINTS
Your constitutional rights... a brief review.

A. 5\textsuperscript{th} & 14\textsuperscript{th} Amendments to the US Constitution

B. Your license...is a property right

C. Due process of law
D. Due process means such things as:

✓ Proper and adequate notice
✓ Adequate time
✓ See agency’s investigative file
✓ Discovery
✓ Subpoena
✓ Counsel
✓ Examine and cross examine witnesses
✓ Etc.

E. You MUST understand what your due process rights are…
Imposition of Penalties

A. The Board of Osteopathic Medicine adopted such a rule: Rule 64B15-19.002

B. Know the range of penalties
JUDICIAL REVIEW AND STAYS OF FINAL AGENCY ORDERS
Administrative Proceedings

Generally, one of the parties is unhappy with final action.

- You will be the unhappy party
- Rarity – Department feels need to appeal the decision

A. Seek judicial review – District Court of Appeal.

- Five District Court of Appeals
- Each has jurisdiction to hear appeals from licensing boards
B. Stays

C. If agency suspends or revokes license – petition for a stay granted as a matter of right

The burden of proof is on the agency to prove probable danger
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
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.
DISCIPLINARY TRENDS - Example 1

- Allegations of Complaint: 459.015(1)(x)- malpractice (2 counts); 459.015(1)(t)- inappropriate prescribing (2 counts); 459.015(1)(pp)- violating a law or rule of the board (2 counts); 459.015(1)(o)- medical records violation (2 counts)
- Dr. was present and represented
- Settlement Agreement accepted by Board
DISCIPLINARY TRENDS
Example 1 (cont.)

Terms

• Reprimand

• $15,000.00 fine to be paid within 2 years of the Final Order - Costs of $12,170.00 to be paid within 2 years

• Completion of the Prescribing Controlled Drugs: Critical Issues and Common Pitfalls of

• Prescribing course sponsored by the University of Florida in 12 months

• Completion of the Quality Medical Record Keeping for Health Care Professionals course sponsored by the FMA within 12 months

• Completion of 5 hours of Risk Management continuing education within 12 months
Terms (cont.)

- Quality assurance consultation/risk management assessment - initial review to be completed within 60 days and compliance with all recommendations within 6 months of the Final Order
- Permanent Practice Restriction: may not own, operate, or work in a Pain Management Clinic
- Prohibited from prescribing any controlled substances until compliance with the risk management review
- The settlement agreement was orally amended with respect to the sponsor of the medical records course. Both parties accepted the oral amendments for the record.
Example 2

- Allegations of Complaint: 459.0137(2)(a)1- practicing in an unregistered pain management clinic
- Dr. was not present or represented by counsel.
- Settlement Agreement accepted by Board with terms as follows:
  - Letter of Concern
  - $5000.00 Fine to be paid within 1 year of the Final Order
  - Costs of $1660.09 to be paid within 1 year of the Final Order
  - Completion of the Legal and Ethical Implications in Medicine: A Physician’s Survival Guide- Laws and Rules course within 1 year of the Final Order
  - Completion of the Prescribing Controlled Drugs: Critical Issues and Common Pitfalls of Prescribing course sponsored by the University of Florida in 12 months
Example 3

- Allegations of Compliant: 459.015(10(g) - fail to perform a legal obligation; 459.015(1)(t) - inappropriate prescribing; 459.015(1)(x) - malpractice
- Board rejected proposed settlement agreement and proposed an alternative settlement agreement with the following terms:
  - Reprimand
  - $10,000.00 fine
  - $10,292.55 in costs
  - CME - 4 hours in the prevention of medical errors and 10 hours in medical ethics
  - Probation for 2 years to include: appearances at the first and last meeting once probation commences; indirect supervision, reports, etc.
  - Practice restriction - shall not use any non-FDA drugs or devices
  - Lecture or article - must do a one hour lecture pedigree papers and internet ordering - the lecture must be approved by the Chair prior to the presentation and a list of attendees must be submitted; or, draft an article on the same topic suitable for publication in a medical journal - article must also be approved by the Chair
Example 4

- Allegations of Complaint: 459.015(1)(x)- malpractice; 459.015(1)(o)- medical records violation
- Board rejected settlement agreement as presented offered the following counter settlement agreement:
  - Reprimand
  - $5,000.00 fine
  - $5,000.00 in costs
  - Completion of the FMA “Quality Medical Record Keeping for Health Care Professionals” course
  - Must undergo a risk management evaluation (to be completed by a licensed healthcare risk manager); must comply with all terms and recommendations of the review within 6 months; the chair has delegated authority to review the evaluation; if deficiencies are found a complaint is to be filed
  - Both parties agreed to the terms of the counter offer.
Example 5

- Allegations of Complaint: 459.015(1)(x)- malpractice; 459.015(1)(t)- inappropriate prescribing; 459.015(1)(o)- medical records violation; 459.015(1)(pp)- violating a law or rule of the board
- Dr. was present and represented by counsel in informal hearing.

OUTCOME –
- Reprimand
- $10,000.00 fine to be paid within 30 days of the Final Order
- Costs of $12,777.55 to be paid within 30 days of the Final Order
- Permanent Practice Restriction: may not own, operate, or work in a Pain Management Clinic
- Permanent Practice Restriction: may not prescribe or dispense any controlled substance
- The motion passed unanimously.
Searching the Web!!!
Thank you for your time!

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KNOW YOUR LEGAL RIGHTS AND HOW TO PROTECT THEM