



Florida Healthcare: Laws and Rules

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Continuing Education for Biennial Renewal

- Rule 64B15-13.001, Florida Administrative Code
 - (1)(a) "Every person licensed pursuant to Chapter 459, F.S. [Osteopathic Medicine], except those licensed as physician assistants..., shall be required to complete forty (40) hours of continuing medical education courses approved by the Board in the twenty-four (24) months preceding each biennial period.... Five of the continuing medical education hours for renewal shall include... one hour of Florida Laws and Rules."
 - (3)(c) "For purposes of this rule, Florida laws and rules means Chapters 456 and 459, F.S., and Rule Chapter 64B15, F.A.C."



Florida Law Governing Osteopaths

- Osteopathic physicians in Florida are governed primarily under two bodies of statutes and one group of regulations:
 - Chapter 456 of the Florida Statutes (Regulation of Health Professions and Occupations)
 - Chapter 459 of the Florida Statutes (Osteopathic Medicine)
 - Rule Chapter 64B15 of the Florida Administrative Code (Board of Osteopathic Medicine)



Highlights From the 2009-2010 Annual Report of the Division of Medical Quality Assurance in the Florida Department of Health

- Re: Health Care Licensure and Enforcement
- Figures for Florida professionals in osteopathic medicine
 - 5,738 licenses
 - 3,989 active in state
 - 1,054 active out of state
 - 293 new licenses were issued
 - Troublesome statistics
 - 449 complaints received
 - 185 were "legally sufficient" (i.e. if true, would "show a potential violation of Florida statutes or rules")



Highlights From the 2009-2010 Annual Report of the Division of Medical Quality Assurance in the Florida Department of Health

– Troublesome statistics

- 9 orders issued for emergency license suspension (probably due to 3 strikes rule for medical negligence or malpractice, Section 456.50, Florida Statutes)
- 1 license revoked, 1 surrendered
- 23 licenses were restricted
- 51 licensees were fined, reprimanded, or received a citation
- 32 medical malpractice claims were filed



Outline

- Healthcare Fraud and Abuse
- Mandatory Disclosures
- Prescribing Drugs
- Advertising
- Patient's Bill of Rights



Fraud & Abuse



Florida Fraud and Abuse Statutes

- Patient Self-Referral Act of 1992
 - Compare with federal Stark Law
- Florida Anti-Kickback Statute
 - Compare with federal Anti-kickback Statute
- Patient Brokering Act
- Florida False Claims Act
 - Compare with federal False Claims Act
- Fee-Splitting Statutes



Patient Self-Referral Act of 1992

- Section 456.053(5)(a), Florida Statutes

"A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest."



Patient Self-Referral Act of 1992

- Similar to Stark Law
 - Courts and Florida agencies look to Stark interpretations for guidance
- Differences

STARK LAW	SELF-REFERRAL LAW
Limited to claims submitted to Medicare and Medicaid	Applies to claims submitted to all payors
Pertains to referrals to entities with which a physician has a "financial relationship" through ownership or "compensation arrangements"	Pertains to referrals to entities in which a physician only has an ownership interest



Patient Self-Referral Act of 1992

STARK LAW	SELF-REFERRAL LAW
Prohibited referrals are only for "designated health services"	All referrals for health care services are covered
Generally referrals are prohibited to non-public commercial entities in which the physician has any ownership interest.	A referring physician may own up to 50% of the non-public entity that gets the referral, if he is the only one in his practice who can make referrals.
"In-office ancillary services" exception permits services provided by the referring physician, another physician in the same group practice, or someone supervised by either.	Direct, on-site supervision is required for "Group Practice" exception (with the physician in the office suite and "immediately available").
- Yet Medicare/Medicaid rules usually require direct on-site supervision, even if Stark does not.	



Patient Self-Referral Act of 1992

STARK LAW	SELF-REFERRAL LAW
If a self-referral is permitted, the physician's financial relationship need not be disclosed to the patient.	If a self-referral is permitted, the physician's investment interest in the service provider must be disclosed to the patient.



Patient Self-Referral Act of 1992

Section 456.053 of the Florida Statutes

- Generally prohibits healthcare providers (including osteopathic physicians) from referring patients to entities for "designated health services" if the provider or an immediate family member has an investment interest in the entity providing:
 - Clinical laboratory services
 - Diagnostic-imaging services
 - Radiation therapy services
 - Physical therapy
 - Rehabilitation



Patient Self-Referral Act of 1992

Section 456.053 of the Florida Statutes

- Group Practice Exception
 - Referrals do not include recommendations by a health care provider who is the only provider or who is a member of a "group practice" for services performed by, or under the direct supervision of, the provider or group practice.



Patient Self-Referral Act of 1992

Section 456.053 of the Florida Statutes

- Similar referrals for non-designated health services are prohibited, unless the provider's investment is:
 - In a publicly held corporation that has at least \$50 million in assets; or
 - In a non-public entity (e.g., a small business) if:
 - Investors are not required to make referrals or are not in a position to make referrals as a condition of investing;
 - No more than ½ the value of the investment interests are held by those in a position to make referrals to that entity; and
 - The investment is offered to someone who is in the position to make referrals on the same terms as someone who is not.



Patient Self-Referral Act of 1992

Section 456.052 of the Florida Statutes

- If a provider may refer a patient to an entity in which the provider is an investor – e.g., because of the Group Practice exception or because the entity is a public company -- the provider must give the patient:
 - Prior notice of the investment interest
 - Acknowledgement of the patient's right to go to another supplier or provider
 - The name and address of each such place where provider is an investor; and
 - The names and addresses of at least two other providers or suppliers



Patient Self-Referral Act of 1992

Section 456.053 of the Florida Statutes

- "No claim for payment may be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section." (§ 456.053 (5)(c))
- Any amount paid in violation must be refunded "timely."
- Any amount not refunded may subject the provider to a civil penalty of up to \$15,000 "for each such service."
- Cross-referral arrangements may subject the provider to a civil penalty of up to \$100,000.
- Violations may also subject the provider to professional disciplinary action.



Healthcare Fraud and Abuse

- Federal Kickback Law relates to federal healthcare programs
- Florida has its own counterparts
 - Florida Anti-Kickback Statute
 - Patient Brokering Act
 - Fee-Splitting Statutes
- These statutes deal with differing aspects of the same problem – making payments in order to get patient referrals



Florida Anti-Kickback Statute Section 456.054, Florida Statutes

- Healthcare providers may not offer, pay, solicit, or get a kickback (remuneration or payment that serves as an incentive or inducement) for referring or soliciting patients for services or items.
- Violations are treated under the Florida Patient Brokering Act (Section 817.505, Florida Statutes).
 - Violations constitute 3rd degree felony
 - Up to 5 years imprisonment
 - Up to \$5,000 fine
- Practitioners of osteopathic medicine may be disciplined for getting or paying a bonus, commission, kickback, or rebate, or engaging in a split-fee arrangement with a physician, organization, etc. for patients referred to hospitals, pharmacies, clinical labs, ambulatory surgery centers, etc.



Florida Anti-Kickback Statute Section 456.054, Florida Statutes

- A violation need not be willful or knowing
- In contract, the federal Anti-Kickback Statute requires that the solicitation or receipt of remuneration be made "knowingly and willfully"
- In re: Petition for Declaratory Statement, Paul J. Befanis, M.D. (August 27, 2007 Final Order)
 - An ophthalmologist proposed a marketing program through which he would donate \$10 to the patient's charity of choice if either:
 - The patient gave out information about the patient's Lasik surgery performed by the ophthalmologist; or
 - The patient referred another person to the ophthalmologist and that other person had the ophthalmologist perform Lasik surgery.
 - The ophthalmologist submitted the marketing plan to the Board of Medicine for review.
 - The Board determined that the plan would constitute a kickback or rebate, in violation of the Florida Anti-Kickback Statute.



Grounds for Disciplinary Action Section 459.015 (1), Florida Statutes

"(j) Paying or receiving any commission, bonus, kickback, or rebate, or engaging in any split-fee arrangement in any form whatsoever with a physician, organization, ... person, ... or other business entity, for patients referred to providers of healthcare goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgery centers, or pharmacies.

.....

"(r) Promoting or advertising on any prescription form of a community pharmacy, unless the form shall also state "This prescription may be filled at any pharmacy of your choice.""



Florida Anti-Kickback Statute Section 456.054, Florida Statutes

- Example of Fee-Splitting
 - Gold, Vann & White, P.A. v. Friedenstab (Fla. App. 2002)
 - Management services agreement provided that payment was made in form of:
 - Annual fee
 - 12% of net clinic revenues
 - 25% of additional managed care payments
 - The court held the 12% figure to be illegal fee-splitting.
 - The 25% figure was held to be an indirect fee for patient referrals.



Florida Anti-Kickback Statute Section 456.054, Florida Statutes

- In Harris v. Gonzales (Fla. App. 2001), a physician had entered into a contract with a nutritional supplement company
 - The contract gave the physician ½ of the company's net profit in return for his referring patients to the company "as an option for their fulfillment of their supply needs and make referrals to no other source."
 - The court held the contract void.
 - Exclusive patient referrals in return for a share of profits were seen as a kickback.



Florida False Claims Act Section 68.081 – 68.09, Florida Statutes

- Prohibits knowingly presenting (or causing to be presented) a false or fraudulent claim for payment to the State of Florida, or using a false statement in support of such a claim, or conspiring to submit a false claim or get it approved
 - "Knowingly" includes deliberate ignorance or reckless disregard of truth or falsehood
 - Damages
 - Civil penalty of \$5,500 - \$11,000
 - Treble damages



Florida False Claims Act

- Florida's Departments of Legal Affairs or Financial Services may sue, but so may an individual suing in the name of the State of Florida.
- Whistleblower suits ("qui tam actions") are filed under seal in the name of the State of Florida.
 - A copy of the complaint and of the written evidence is also sent to the Florida Attorney General and to the Chief Financial Officer of the Department of Financial Services.
 - The Dept. of Legal Affairs or the Dept. of Financial Services may decide to take over the litigation. If they decline, the person who filed suit may assume responsibility for prosecuting the suit.



Mandatory Disclosures



Mandatory Disclosures

- Reports on Professional Liability Claims
- Section 456.049, Florida Statutes
 - Practitioners of osteopathic medicine must report to the Florida Office of Insurance Regulation any claim or suit for damages for personal injury allegedly due to error, omission, or negligence while the licensee was rendering professional services.



Mandatory Disclosures

- Duty to Notify Patients

Section 456.0575, Florida Statutes

(known as Amendment 7 to Florida Constitution)

- "Every licensed health care practitioner shall inform each patient... in person about adverse incidents [or outcomes] that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section shall not constitute an acknowledgment of admission of liability, nor can such notifications be introduced as evidence."



Mandatory Disclosures

- Duty to Notify Patients (continued)
 - Thus, negative outcomes must be disclosed to the patient or the patient's legal representative (often a parent or other family member).
 - Disclosure should be as soon as reasonably possible in order to tell the patient of potential results and options for treatment.
 - This disclosure should be documented, although it need not be in the medical record.



Prescriptions



Written Prescriptions for Medicinal Drugs

- "Legible Prescription Law"
- Section 456.42, Florida Statutes
 - Written prescriptions "must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription."
 - The prescribing healthcare practitioner must sign the prescription on the day issued.
 - The prescription has to contain this information:
 - The name of the prescribing healthcare practitioner;
 - The name and strength of the drug;
 - The quantity of the drug ("in both textual and numerical formats" for controlled substances);
 - Directions for use; and
 - For controlled substances, the abbreviated month on the face of the prescription.



Advertising



Advertising

- Rule 64B15 – 14.001(2) of the Florida Administrative Code provides:

"Any advertisement or advertising shall be deemed ... false, deceptive, or misleading if it:

(b) Makes only a partial disclosure of relevant facts; or

....

(i) Represents that professional services can or will be competently performed for a stated fee when this is not the case, or makes representations with respect to fees for professional services that do not disclose all variables affecting the fees that will, in fact, be charged; or

(j) Conveys the impression that the osteopathic physician disseminating the advertising or referred to therein possess qualifications, skills or other attributes, which are superior to other osteopathic physicians, other than a simple listing of earned professional, post-doctoral or other professional achievements recognized by the Board [of Osteopathic Medicine]"



Advertising of Fees and Discounted Services Rule 64B5-4.003, Florida Administrative Code

- Subsection (2): "Any advertisement containing fee information shall contain a disclaimer that the fee is a minimum fee only."
- Subsection (5): "Any advertisement for free or discounted services must comply with the requirements of Section 456.062, F.S., and must also clearly identify the dates that free, discounted or reduced fee services will be available."



Advertising of Fees and Discounted Services Rule 64B5-4.003, Florida Administrative Code

- Section 456.062 of the Florida Statutes requires the following statement, all in caps, in advertising free or discounted services (as, e.g., in advertising a free consultation):

THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT.



Florida's Patient's Bill of Rights



Florida's Patient's Bill of Rights and Responsibilities Section 381.026, Florida Statutes

- (3) **PURPOSE.**—It is the purpose of this section to promote the interests and well-being of the patients of health care providers and health care facilities and to promote better communication between the patient and the health care provider. It is the intent of the Legislature that health care providers understand their responsibility to give their patients a general understanding of the procedures to be performed on them and to provide information pertaining to their health care so that they may make decisions in an informed manner after considering the information relating to their condition, the available treatment alternatives, and substantial risks and hazards inherent in the treatments. It is the intent of the Legislature that patients have a general understanding of their responsibilities toward health care providers and health care facilities. It is the intent of the Legislature that the provision of such information to a patient eliminate potential misunderstandings between patients and health care providers. It is a public policy of the state that the interests of patients be recognized in a patient's bill of rights and responsibilities and that a health care facility [not including nursing homes] or health care provider may not require a patient to waive his or her rights as a condition of treatment. This section shall not be used for any purpose in any civil or administrative action and neither expands nor limits any rights or remedies provided under any other law.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

(4) RIGHTS OF PATIENTS.—Each health care facility or provider shall observe the following standards:

(a) Individual dignity.—

1. The individual dignity of a patient must be respected at all times and upon all occasions.
2. Every patient who is provided health care services retains certain rights to privacy, which must be respected without regard to the patient's economic status or source of payment for his or her care. The patient's rights to privacy must be respected to the extent consistent with providing adequate medical care to the patient and with the efficient administration of the health care facility or provider's office. However, this subparagraph does not preclude necessary and discreet discussion of a patient's case or examination by appropriate medical personnel.
3. A patient has the right to a prompt and reasonable response to a question or request. A health care facility shall respond in a reasonable manner to the request of a patient's health care provider for medical services to the patient. The health care facility shall also respond in a reasonable manner to the patient's request for other services customarily rendered by the health care facility to the extent such services do not require the approval of the patient's health care provider or are not inconsistent with the patient's treatment.
4. A patient in a health care facility has the right to retain and use personal clothing or possessions as space permits, unless for him or her to do so would infringe upon the right of another patient or is medically or programmatically contraindicated for documented medical, safety, or programmatic reasons.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

(b) Information.—

1. A patient has the right to know the name, function, and qualifications of each health care provider who is providing medical services to the patient. A patient may request such information from his or her responsible provider or the health care facility in which he or she is receiving medical services.
2. A patient in a health care facility has the right to know what patient support services are available in the facility.
3. A patient has the right to be given by his or her health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, unless it is medically inadvisable or impossible to give this information to the patient, in which case the information must be given to the patient's guardian or a person designated as the patient's representative. A patient has the right to refuse this information.
4. A patient has the right to refuse any treatment based on information required by this paragraph, except as otherwise provided by law. The responsible provider shall document any such refusal.
5. A patient in a health care facility has the right to know what facility rules and regulations apply to patient conduct.
6. A patient has the right to express grievances to a health care provider, a health care facility, or the appropriate state licensing agency regarding alleged violations of patients' rights. A patient has the right to know the health care provider's or health care facility's procedures for expressing a grievance.
7. A patient in a health care facility who does not speak English has the right to be provided an interpreter when receiving medical services if the facility has a person readily available who can interpret on behalf of the patient.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

(c) Financial information and disclosure.—

1. A patient has the right to be given, upon request, by the responsible provider, his or her designee, or a representative of the health care facility full information and necessary counseling on the availability of known financial resources for the patient's health care.
2. A health care provider or a health care facility shall, upon request, disclose to each patient who is eligible for Medicare, in advance of treatment, whether the health care provider or the health care facility in which the patient is receiving medical services accepts assignment under Medicare reimbursement as payment in full for medical services and treatment rendered in the health care provider's office or health care facility.
3. A health care provider or a health care facility shall, upon request, furnish a person, prior to provision of medical services, a reasonable estimate of charges for such services. The health care provider or the health care facility shall provide an uninsured person, prior to the provision of a planned nonemergency medical service, a reasonable estimate of charges for such service and information regarding the provider's or facility's discount or charity policies for which the uninsured person may be eligible. Estimates shall, to the extent possible, be written in a language comprehensible to an ordinary layperson. Such reasonable estimate shall not preclude the health care provider or health care facility from exceeding the estimate or making additional charges based on changes in the patient's condition or treatment needs.
4. Each licensed facility not operated by the state shall make available to the public on its Internet website or by other electronic means a description of and a link to the performance outcome and financial data that is published by the agency pursuant to s. 408.05(3)(k). The facility shall place a notice in the reception area that such information is available electronically and the website address. The licensed facility may indicate that the pricing information is based on a compilation of charges for the average patient and that each patient's bill may vary from the average depending upon the severity of illness and individual resources consumed. The licensed facility may also indicate that the price of service is negotiable for eligible patients based upon the patient's ability to pay.
5. A patient has the right to receive a copy of an itemized bill upon request. A patient has a right to be given an explanation of charges upon request.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

(d) Access to health care.—

1. A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.
2. A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide such treatment.
3. A patient has the right to access any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of s. 456.41.

(e) Experimental research.—

In addition to the provisions of s. 766.103, a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research. For any patient, regardless of ability to pay or source of payment for his or her care, participation must be a voluntary matter; and a patient has the right to refuse to participate. The patient's consent or refusal must be documented in the patient's care record.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

(f) Patient's knowledge of rights and responsibilities.—In receiving health care, patients have the right to know what their rights and responsibilities are.

(5) RESPONSIBILITIES OF PATIENTS.—Each patient of a health care provider or health care facility shall respect the health care provider's and health care facility's right to expect behavior on the part of patients which, considering the nature of their illness, is reasonable and responsible. Each patient shall observe the responsibilities described in the following summary.

(6) SUMMARY OF RIGHTS AND RESPONSIBILITIES.—Any health care provider who treats a patient in an office or any health care facility licensed under chapter 395 that provides emergency services and care or outpatient services and care to a patient, or admits and treats a patient, shall adopt and make available to the patient, in writing, a statement of the rights and responsibilities of patients, including the following:



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

SUMMARY OF THE FLORIDA PATIENT'S BILL OF RIGHTS AND RESPONSIBILITIES

Florida law requires that your health care provider or health care facility recognize your rights while you are receiving medical care and that you respect the health care provider's or health care facility's right to expect certain behavior on the part of patients. You may request a copy of the full text of this law from your health care provider or health care facility. A summary of your rights and responsibilities follows:

- A patient has the right to be treated with courtesy and respect, with appreciation of his or her individual dignity, and with protection of his or her need for privacy.
- A patient has the right to a prompt and reasonable response to questions and requests.
- A patient has the right to know who is providing medical services and who is responsible for his or her care.
- A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak English.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

- A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak English.
- A patient has the right to know what rules and regulations apply to his or her conduct.
- A patient has the right to be given by the health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis.
- A patient has the right to refuse any treatment, except as otherwise provided by law.
- A patient has the right to be given, upon request, full information and necessary counseling on the availability of known financial resources for his or her care.
- A patient who is eligible for Medicare has the right to know, upon request and in advance of treatment, whether the health care provider or health care facility accepts the Medicare assignment rate.
- A patient has the right to receive, upon request, prior to treatment, a reasonable estimate of charges for medical care.
- A patient has the right to receive a copy of a reasonably clear and understandable, itemized bill and, upon request, to have the charges explained.
- A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.



Florida's Patient's Bill of Rights and Responsibilities

Section 381.026, Florida Statutes

- A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide treatment.
- A patient has the right to know if medical treatment is for purposes of experimental research and to give his or her consent or refusal to participate in such experimental research.
- A patient has the right to express grievances regarding any violation of his or her rights, as stated in Florida law, through the grievance procedure of the health care provider or health care facility which served him or her and to the appropriate state licensing agency.
- A patient is responsible for providing to the health care provider, to the best of his or her knowledge, accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health.
- A patient is responsible for reporting unexpected changes in his or her condition to the health care provider.
- A patient is responsible for reporting to the health care provider whether he or she comprehends a contemplated course of action and what is expected of him or her.
- A patient is responsible for following the treatment plan recommended by the health care provider.



Florida's Patient's Bill of Rights and Responsibilities Section 381.026, Florida Statutes

- A patient is responsible for keeping appointments and, when he or she is unable to do so for any reason, for notifying the health care provider or health care facility.
- A patient is responsible for his or her actions if he or she refuses treatment or does not follow the health care provider's instructions.
- A patient is responsible for assuring that the financial obligations of his or her health care are fulfilled as promptly as possible.
- A patient is responsible for following health care facility rules and regulations affecting patient care and conduct.



Conclusion

- Questions?

Thanks for coming.



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