

HEALTH LAW COMPLIANCE ISSUES FOR BARIATRIC PHYSICIANS IN FLORIDA

Presented to Florida Society of Bariatric Physicians
by

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I. INTRODUCTION

II. COMPLIANCE ISSUES

A. Practice Formation.

1. **Florida Patient Self Referral Act ("PSRA").** Fla. Stat. Section 456.053. The Florida Patient Self Referral Act is a civil penalty statute that restricts a physician's referral to an entity in which he is an owner or an investor unless an exception is met. This prohibition applies to "designated health services" as defined in the statute and other health care items or services regardless of the payor.
 - a. The PSRA even restricts a physician's referral to his own practice. An exemption exists for referrals of a physician of his patients to his own practice for services provided under the "direct supervision" of the physician. This means that the physician must be onsite and immediately available when their services are rendered. (This is more restrictive than the general law that allows an ARNP to provide services when a physician is not available.)
 - b. **Penalties:** No claim for payment may be presented to an individual or payor for services furnished pursuant to a referral prohibited under this section; civil penalties of \$15,000 per referral violation may be assessed; the physician may be subject to professional discipline.

Option 1: Provide all services through the physician's practice entity.

Option 2: Make the weight loss practice a wholly owned subsidiary. (But 75% of services still need to be provided through the parent entity.)

Option 3: Have a separate entity where 50% is not owned by a family member or a person in a position to refer. Other requirements of this exception must be met as well.

2. **Ownership Disclosures:** (Fla. Stat. § 456.052) Before a physician refers a patient to an entity in which the physician is an investor, the physician must provide the patient with a written disclosure informing the patient of:
 - a. the existence of the investment interest;
 - b. the name and address of each applicable entity in which the referring health care provider is an investor;
 - c. the patient's right to obtain items or services from a provider or supplier of patient's choice, including the location where physician is an investor; and
 - d. the names and addresses of at least two alternate sources of such items or services available to the patient.
3. **Fla. Stat. § 458.357:** It is a third degree felony for MDs to fail to provide this disclosure to the patient if the physician has a 10% or greater investment interest. Exemptions include:
 - a. Publicly held entities;
 - b. A physician's own practice, whether he or she is a sole practitioner or part of a group where the health care good or service is provided solely for the physician's own patients and is provided or performed by the physician or under the physician's supervision.

B. Board of Medicine Rules for the Prescription of Drugs for Obesity.

64B8-9.012 (MDs); 64B15-14.004 (DOs)

Allopathic and Osteopathic medical boards in Florida have issued rules of setting standards for the prescription of obesity drugs.

1. All licensees are expected to abide by the guidelines in the utilization of any drug, synthetic compound, any nutritional supplement, or herbal

treatment, for the purpose of providing medically assisted weight loss. (This does not just set the standard for prescription drugs – it is broader).

2. You cannot prescribe “weight loss enhancers” unless:
 - a. the patient has a BMI (Body Mass Index) of 30 or higher;
 - b. a BMI of 27 or greater with at least one co-morbidity factor; or
 - c. measurable body fat is equal to or greater than 25% of total body weight for men or 30% of total body weight for women.

Risk Management Tip: Medical records for patients should reflect this assessment before a prescription is made.

3. A patient evaluation is required before the prescription. This includes physical and complete history, and any necessary tests.
 - a. A PA or an ARNP can conduct this evaluation;
 - b. However, the physician must personally review the resulting medical records prior to issuing the prescription (higher than typical ARNP standard).
 - c. Note that ARNPs and PAs may also issue prescriptions, but may not prescribe controlled substances.
4. Prescriptions or orders for any drug or synthetic compound to assist with weight loss must be in writing and signed by the prescribing physician.
5. The initial prescription shall not be called into a pharmacy.
6. MD Rule only states: Physicians in Florida are prohibited from prescribing, ordering, dispensing, or administering any weight loss enhancer that is both a serotonergic and anorexic agent unless approved by the FDA specifically for use in weight management. SSRI (selective serotonin re-uptake inhibitors) that have not been approved by the FDA for weight loss may not be prescribed, ordered, dispensed, or administered for such purpose.
7. At the time of delivering the initial prescription or providing the initial supply of such drugs to the patient, the prescribing physician must personally meet the patient and obtain an appropriate written informed consent from the patient.

8. Specific Requirements for Written Consent:
 - a. The consent must state that there is a lack of scientific data regarding the potential danger of long term use of combination weight loss treatments.
 - b. The consent must also state the need for dietary intervention and physical exercise as a part of any weight loss regime.
 - c. A copy of the signed informed consent must be maintained in the patient's personal medical record.
9. Patients must have an in-person re-evaluation every 2-4 weeks of receiving a prescription, order, or dosage. The re-evaluation shall include the elements of an initial evaluation and an assessment of the medical effects of the treatment.
10. Any patient that continues on the drugs shall be re-evaluated every three (3) months.
11. Maintain medical records as you would in any physician's office.
12. You must provide the patient with a legible copy of the Weight Loss Consumers Bill of Rights. MDs must conspicuously post the document.

C. Complementary or Alternative Care: What if I offer the patient a method that is considered alternative therapy?

1. A "complementary or alternative health care treatment is: Any treatment that is designed to provide patients with an effective option to the prevailing or conventional treatment methods associated with the services provided by a health care practitioner.
2. If you offer alternative or complementary care, you must inform the patient:
 - a. of the practitioner's education, experience, and credentials in relation to the complementary or alternative health care treatment option;
 - b. the health care practitioner shall communicate this orally or in writing, but must indicate in the medical record that provider complied with these requirements;
 - c. the provider can recommend any treatment that is in her judgment in the best interests of the patient.

Practice Tip: Put this advice in writing and document the medical record.

D. Weight Loss Practices Act. Fla. Stat. § 501.057 – 501.0581.

1. “Weight-loss Provider” is any person engaged in the business of offering services to consumers to assist them in losing weight and making oral or written statements, advertisements, or other representations, that have the tendency of leading consumers to believe that participation in a weight-loss program will result in weight loss.
2. The Act does not apply to physicians who may give weight-loss advice or provide weight-loss services which is incidental to the performance of their profession and **which is not the primary activity of the person’s practice.**
3. If a physician is primarily operating a weight-loss practice, this Act may apply to physician’s practice.
4. In order to comply with the Act, the physician must:
 - a. Provide to the consumer a written itemized statement of the fixed or estimated cost of the program, including any additional products, services, supplements, examinations, or lab tests that the consumer may have to purchase.
 - b. Disclose the actual or estimated duration of the program.
 - c. Provide a copy of the educational and professional experience of the weight-loss provider’s staff upon request.
5. Distribute Weight-loss Consumer Bill of Rights. Post it in a prominent place. (A copy is part of the handouts)
6. It is an unfair and deceptive practice to violate this Act. This could subject the provider to a civil lawsuit or civil penalties of up to \$5,000 per violation.

E. Advertising.

1. General Rules
 - a. Cannot be false descriptive or misleading.
 - b. Cannot create false expectations.
 - c. Must state the physician’s name and identify physician as MD or DO.

2. **Specific Rules for Advertising Weight-Loss Practices.** Any physician who advertises a practice related to weight loss or whose services are advertised by another person or entity shall be responsible for assuring that such advertising meets the requirements of the Florida Board of Medicine.

Advertisement of weight loss treatment shall be false, deceptive, or misleading if it contains representations that:

- a. promise specific results;
- b. raise unreasonable expectations;
- c. claim rapid, dramatic, incredible or safe weight loss;
- d. state that diet or exercise is not required; or
- e. suggest that weight loss is effortless or magical.

3. **Advertising Board Certification or Medical Specialties.**

- a. A physician may not state that he has received formal recognition as a specialist in any aspect of the practice of medicine unless the physician has in fact received such recognition and such recognizing agency is approved by the Board.
- b. The Board approves the specialty boards of the American Board of Medical Specialties, the American Board of Plastic Surgery, American Board of Pain Medicine, and American Association of Physician Specialists.
- c. You cannot say you are board certified without identifying which board.
- d. A physician may indicate the services offered and state that his practice is limited to one or more types of services.
- e. The American Board of Bariatric Medicine is not approved by the Board of Medicine.

4. **Disclaimer for Free or Discounted Services.** A disclaimer is required for any ads for free or discounted medical service:

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.

F. Is the Injection of Vitamins for Weight Loss the Practice of Medicine?

1. Practice of medicine defined: The diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.
2. A Florida court has opined that the injection of vitamins is a legend drug, allowable only by prescription by a practitioner authorized to issue such prescriptions and, therefore, is not within the scope of practice of chiropractors. *Sullivan v. Department of Health*, 885 So. 2d 873 (Fla. 3rd DCA 2004).
3. Physicians and, to some limited degree, nurse practitioners and physician assistants under a protocol with a physician or physician supervision are the only practitioners who can issue prescriptions for legend drugs.

G. Rules for Dispensing Practitioners.

1. Dispensing is selling medicinal drugs to patients in the office. (Writing a prescription and providing free samples is not dispensing.)
2. You must register as a dispensing practitioner.
 - a. \$100 fee
 - b. Application
 - c. Inspection
 - d. You must advise patient that he/she may fill the prescription in the practice or at a pharmacy.
3. You must comply with Pharmacy Practice Act and all the rules regarding controlled substances if you dispense them.

H. Controlled Substances.

1. If you violate the Controlled Substances Act, you could be prosecuted equal to a drug dealer.
2. You must maintain your controlled substances as securely as they are required to be maintained in a pharmacy.
3. Comply with labeling and recordkeeping requirements.
4. You will be subject to unannounced inspections as a dispensary practitioner.
5. You could be subject to criminal prosecution and professional discipline for failure to comply with the rules.
6. The registered dispensing practitioner stands in the shoes of the pharmacist when dispensing and must personally check each bottle of controlled substances before dispensing. This means the practitioner must check the label, contents, count, and cap.
7. Helpful information for compliance on the website of Florida Society of Bariatric Physicians – www.fsbp.org.