

## Board of Medicine

### Laws Relating to “Diet Pills”

#### Statute:

**458.336 F. S. Drugs to treat obesity; rules establishing guidelines.**--The Board of Medicine shall adopt rules to establish practice guidelines for physicians to safely prescribe phentermine, fenfluramine, and other drugs used to treat obesity.

*History.--s. 188, ch. 97-264.*

#### Rule:

#### **64B8-9.012 F. A. C. Standards for the Prescription of Obesity Drugs**

The prescription of medication for the purpose of enhancing weight loss should only be performed by physicians qualified by training and experience to treat obesity. All licensees are expected to abide by the following guidelines and standards in the utilization of any drug, any synthetic compound, any nutritional supplement, or herbal treatment, for the purpose of providing medically assisted weight loss.

(1) To justify the use of weight loss enhancers as set forth above, the patient must have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 27 with at least one comorbidity factor, or a measurable body fat content equal to or greater than 25% of total body weight for male patients or 30% of total body weight for women. The prescription of such weight loss enhancers is not generally appropriate for children. Any time such prescriptions are made for children, the prescribing physician must obtain a written informed consent from the parent or legal guardian of the minor patient in addition to complying with the other guidelines and standards set forth in this rule. BMI is calculated by use of the formula  $BMI = kg/m^2$ .

(2) Physicians in Florida are prohibited from prescribing, ordering, dispensing, or administering any weight loss enhancer that is both a serotonergic and anorexic agent unless the drug has been approved by the Food and Drug Administration (FDA) specifically for use in weight loss management. Selective serotonin re-uptake inhibitors (SSRIs) that have not been approved by the FDA for weight loss may not be prescribed, ordered, dispensed, or administered for such purposes.

(3) An initial evaluation of the patient shall be conducted prior to the prescribing, ordering, dispensing, or administering of any drug, synthetic compound, nutritional supplement or herbal treatment and such evaluation shall include an appropriate physical and complete history; appropriate tests related to medical treatment for weight

loss; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care.

(a) The initial evaluation may be delegated to an appropriately educated and trained physician's assistant licensed pursuant to Chapter 458, F.S., or an appropriately educated and trained advanced registered nurse practitioner licensed pursuant to Chapter 464, F.S.

(b) If the initial evaluation required above is delegated to a physician's assistant or to an advanced registered nurse practitioner, then the delegating physician must personally review the resulting medical records prior to the issuance of an initial prescription, order, or dosage.

(4) Prescriptions or orders for any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of assisting in weight loss must be in writing and signed by the prescribing physician. Initial prescriptions or orders of this type shall not be called into a pharmacy by the physician or by an agent of the physician. Even if the physician is registered as a dispensing physician, a hard copy of the written prescription must be maintained in the patient's medical records for each time such weight loss enhancers are prescribed, ordered, dispensed, or administered.

(5) At the time of delivering the initial prescription or providing the initial supply of such drugs to a patient, the prescribing physician must personally meet with the patient and personally obtain an appropriate written informed consent from the patient. Such consent must state that there is a lack of scientific data regarding the potential danger of long term use of combination weight loss treatments, and shall discuss potential benefits versus potential risks of weight loss treatments. The written consent must also clearly state the need for dietary intervention and physical exercise as a part of any weight loss regimen. A copy of the signed informed consent shall be included in the patient's permanent medical record.

(6) Each physician who is prescribing, ordering, or providing weight loss enhancers to patients must assure that such patients undergo an in-person re-evaluation within 2 to 4 weeks of receiving a prescription, order, or dosage. The re-evaluation shall include the elements of the initial evaluation and an assessment of the medical effects of the treatment being provided. Any patient that continues on a drug, synthetic compound, nutritional supplement or herbal treatment assisted weight loss program shall be re-evaluated at least once every 3 months.

(7) Each physician who prescribes, orders, dispenses, or administers any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of assisting a patient in weight loss shall maintain medical records in compliance with Rule 64B8-9.003, F.A.C., and must also reflect compliance with all requirements of this rule.

(8) Each physician who prescribes, orders, dispenses, or administers weight loss enhancers for the purpose of providing medically assisted weight loss shall provide to

each patient a legible copy of the Weight-Loss Consumer Bill of Rights as set forth in Sections 501.0575(1)(a) through (e)3., F.S. The physician shall also conspicuously post said document in those rooms wherein patients are evaluated for weight loss treatment.

(9) Any physician who advertises practice relating 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 Rule 64B8-11.001, F.A.C. In addition advertising of weight loss treatment shall be considered 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 or suggest that diets or exercise are not required; or
- (e) Suggest that weight loss is effortless or magical.

*Specific Authority 458.336 FS. Law Implemented 458.336 FS. History--New 12-4-97, Amended 2-17-98.*

This law is administered and enforced by the Dept of Agriculture and Consumer Services.

**<sup>1</sup>501.0583 F. S. Selling, delivering, bartering, furnishing, or giving weight-loss pills to persons under age 18; penalties; defense.--**

(1) As used in this section, the term "weight-loss pill" means a pill that is available without a prescription, the marketing, advertising, or packaging of which indicates that its primary purpose is for facilitating or causing weight loss. The term includes a pill that contains at least one of the following ingredients: *ephedra* species, ephedrine alkaloid containing dietary supplements, or *Sida cordifolia*. However, the term does not include a pill containing one or more of such ingredients which is marketed or intended for a primary purpose other than weight loss.

(2) It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, a weight-loss pill to a person under 18 years of age. However, it is a defense to a charge of violating this subsection if the buyer or recipient of the weight-loss pill displayed to the person alleged to have committed the violation a driver's license or identification card issued by this state or another state, a passport, or a United States armed services identification card that indicated that the buyer or recipient was 18 years of age or older and the appearance of the buyer or recipient was such that a prudent person would reasonably believe that the buyer or recipient was not under 18 years of age.

(3) A first violation of subsection (2) or this subsection is punishable by a fine of \$100. A second violation of subsection (2) or this subsection is punishable by a fine of \$250. A third violation of subsection (2) or this subsection is punishable by a fine of \$500. A fourth or subsequent violation of subsection (2) or this subsection is punishable by a fine as determined by the Department of Agriculture and Consumer Services, not to exceed \$1,000.

(4) The Department of Agriculture and Consumer Services is authorized to adopt rules to implement this section.

**History.**--s. 1, ch. 2003-24.

**<sup>1</sup>Note.**--Effective July 1, 2004.