

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE PETITION FOR
DECLARATORY STATEMENT OF

JENNIFER FASS, MATTHEW SEAMON,
JENNIFER MCMAHON and MARGARET MESSIHA

FINAL ORDER

THIS CAUSE came before the BOARD OF PHARMACY (hereinafter Board) pursuant to §120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, at a duly-noticed meeting in Gainesville, Florida on December 9, 2009, for the purpose of considering the Petition for Declaratory Statement (attached as Exhibit A) filed by JENNIFER FASS, MATTHEW SEAMON, JENNIFER MCMAHON and MARGARET MESSIHA (hereinafter Petitioners). Having considered the petition, and being otherwise fully advised in the premises, it is hereby

ORDERED that the Petition is dismissed. The Board does not have the authority to issue declaratory statements regarding the medical practice act or the rules promulgated by the Board of Medicine. Petitioners should address their inquiry to the Board of Medicine.

DONE AND ORDERED this 4 day of March, 2010.

BOARD OF PHARMACY

Rebecca Poston
Rebecca Poston, Rph, CPh
Executive Director for
Michele Weizer, PharmD, Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, the parties are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the clerk of the department and by filing a filing fee and one copy of a notice of appeal with the District Court of Appeal within thirty days of the date this Final Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished by U.S. Mail to Petitioner JENNIFER FASS, MATTHEW SEAMON, JENNIFER MCMAHON and MARGARET MESSIHA, Nova Southeastern University, College of Pharmacy, 3200 South University Drive, Ft. Lauderdale FL 33328-2018 and by interoffice mail to Marcella Blocker, Department of Legal Affairs, PL-01 The Capitol, Tallahassee FL 32399, this 8th day of March, 2010.


Deputy Agency Clerk

NOVA SOUTHEASTERN UNIVERSITY
Health Professions Division
College of Pharmacy



BOP/DOC
RECEIVED

2009 OCT -7 PM 3:36

Petition for Declaratory Statement Before the Florida Board of Pharmacy

Nova Southeastern University
Health Professions Division
College of Pharmacy
Drug Information Center
3200 S. University Dr.
Ft. Lauderdale, Fl. 33328
(T) 954-262-3103 (F) 954-262-3170

September 24, 2009

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Angela Barton*
DATE: *10/12/09*

This petition is in reference to the Medical Practice Act 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" and the rule entitled 64B8-9.012 F.A.C.(4)(6) Standards for the Prescription of Obesity Drugs which states the following:

- (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.
- (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."

The Drug Information Center at Nova Southeastern University prides itself on the quality of service it provides to both the healthcare community and consumers. Recently, there have been numerous requests for clarification on the interpretation of this rule. Even though this is considered a Board of Medicine rule, pharmacists have a corresponding responsibility to understand how this relates to pharmacy practice. Although the rule states "initial prescriptions... shall not be called into a pharmacy", there is controversy regarding prescription refills. Does the rule allow for authorization of refills to be written on the initial prescription? Additionally if these requests are permissible, may they be phoned in after the initial written prescription is obtained and on file in the pharmacy? Also, is there a quantity restriction of 30 days on the initial prescription since "patients undergo an in-person re-evaluation within 2 to 4 weeks?" Lastly, may obesity prescriptions be transferred? Thank you for your guidance on this important issue.

Sincerely,

Jennifer Fass
Jennifer Fass, PharmD

Matthew Seamon
Matthew Seamon, PharmD, JD

Jennifer McMahon
Jennifer McMahon, Pharmacy Intern

Margaret Messiha
Margaret Messiha, Pharmacy Intern

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64B8-9.012 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.

Select Year:

The 2009 Florida Statutes

Title XXXII
REGULATION OF PROFESSIONS AND
OCCUPATIONS

Chapter 458
MEDICAL
PRACTICE

[View Entire
Chapter](#)

458.336 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.

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