

TO BE RESCINDED

4731-11-04

Controlled substances: utilization for weight reduction.

- (A) A physician shall not utilize a schedule III or IV controlled substance for purposes of weight reduction unless it has an F.D.A. approved indication for this purpose and then only in accordance with all of the provisions of this rule.
- (B) Before initiating treatment for weight reduction utilizing any schedule III or IV controlled substance:
- (1) The physician shall determine through review of the physician's own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.
 - (2) The physician shall obtain a thorough history, perform a thorough physical examination of the patient, determine that the patient has a BMI of at least thirty, or at least twenty-seven with comorbid factors, and rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized.
 - (3) The physician shall assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.
- (C) A physician may utilize a schedule III or IV controlled substance, that bears appropriate F.D.A. approved labeling for weight loss or the maintenance of weight loss, in the treatment of obesity only as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:
- (1) The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.
 - (2) The controlled substance is prescribed strictly in accordance with the F.D.A.

approved labeling;

- (a) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for "a few weeks", the total course of treatment using that controlled substance shall not exceed twelve weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule; and
 - (b) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for maintenance of weight loss, that use cannot exceed the time period indicated as effective as reported in the clinical studies' information contained in the F.D.A. approved labeling. That time period includes any interruption in treatment permitted under paragraph (C)(3) of this rule.
- (3) A physician shall not initiate a course of treatment utilizing a controlled substance for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. However, the physician may resume utilizing a controlled substance following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:
- (a) Illness of or injury to the patient justifying a temporary cessation of treatment; or
 - (b) Unavailability of the physician; or
 - (c) Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability; or
 - (d) If the physician utilizes a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" and based on sound medical judgment believes that an interruption of that treatment was medically indicated so long as its use is in accordance with paragraph (C) of this rule.
- (4) After initiating treatment, the physician may elect to switch to a different controlled substance for weight loss based on sound medical judgment, but the total course of treatment for any combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.
- (5) If the patient has continued to lose weight under the short term treatment, the

physician may continue therapy utilizing a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" so long as its use is in accordance with paragraph (C) of this rule.

- (6) The physician shall not initiate or shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:

(a) That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient's use of drugs or alcohol; or

(b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.

- (7) The physician shall not initiate or shall discontinue utilizing all schedule III or IV controlled substances that do not bear F.D.A. Approved labeling which permits long-term use immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days; or

(b) That the patient has repeatedly failed to comply with the physician's treatment recommendations.

- (8) The physician shall not utilize any schedule III or IV controlled substance for purposes of weight reduction in the treatment of a patient the physician knows or should know is pregnant.

- (D) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in DIVISION (B)(2) of section 4731.22 of the Revised Code; "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and "a

departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Effective:

R.C. 119.032 review dates: 06/06/2008

WITHDRAWN ELECTRONICALLY

Certification

11/16/2009

Date

Promulgated Under: 119.03
Statutory Authority: 4731.05
Rule Amplifies: 4731.22
Prior Effective Dates: 11/17/86; 10/31/98; 6/30/00