

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 obtain a thorough history, which includes a detailed history of previous weight loss efforts based on caloric restriction, nutritional counseling, behavior modification and exercise, without the utilization of controlled substances. The physician shall also 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.

(2) 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 and exercise, 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, except when supported by evidence documented in the patient's chart, of uninterrupted weight loss while under treatment utilizing controlled substances, that includes monitoring of the patient's weight, body mass index and waist circumference in compliance with paragraph (C)(1) 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.

- (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 three months.
 - (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, except as provided in paragraph (C)(2)(a) of this section.
 - (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 diverted any controlled substance other than in strict compliance with the treating physician's directions.
 - (7) 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.

Replaces: 4731-11-04

Effective:

R.C. 119.032 review dates:

Certification

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