

4731-11-04

Controlled substances for the treatment of obesity.

(A) A prescriber may utilize a schedule III or IV controlled substance for the treatment of obesity only if 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 obesity utilizing any schedule III or IV controlled substance, the prescriber shall complete all of the following requirements:

(1) The prescriber shall review the prescriber's own records of prior treatment or review the records of prior treatment by another treating physician, prescriber, dietitian, or weight-loss program to determine the patient's past efforts to lose weight in a treatment program utilizing a regimen of weight reduction based on nutritional counseling, intensive behavioral therapy, and exercise, without the utilization of controlled substances, and that the treatment has been ineffective

(2) The prescriber shall complete and document the findings of all of the following:

(a) Obtain a thorough history;

(b) Perform an appropriate examination of the patient;

(c) Determine the patient's BMI;

(d) Rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(e) 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.

(f) Access OARRS for the patient's prescription history during the preceding twelve month period and document in the patient's record the receipt and assessment of the report received; and

(g) Develop and record in the patient record a treatment plan that includes, at a minimum, a diet and exercise program for weight loss.

(3) The prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity upon ascertaining or having reason to believe any one or more of the following:

(a) 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 prescriber physician related to the patient's use of drugs or alcohol;

- (b) The patient has consumed or disposed of any controlled substance other than in strict compliance with the treating prescriber's directions;
 - (c) The prescriber knows or should know the patient is pregnant;
 - (d) The patient has a BMI of less than thirty, unless the patient has a BMI of at least twenty seven with comorbid factors, including Type 2 diabetes, cardio vascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, nonalcoholic fatty liver disease, osteoarthritis, insulin resistance, metabolic syndrome, pre-diabetes, or major depression;
 - (e) The patient has any condition that would contraindicate the use of the controlled substance to be utilized;
 - (f) The prescriber shall document in the patient's record the rationale for initiation or re-initiation of treatment utilizing a controlled substance for chronic obesity.
- (C) A prescriber may utilize a schedule III or IV controlled substance that bears appropriate F.D.A. approved labeling for weight loss, in the treatment of obesity as an adjunct, to a lifestyle intervention, such as caloric restriction, provided that:
 - (1) The prescriber shall assess the patient, at a minimum, once in the first three months of utilization of controlled substances 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 prescriber may personally furnish controlled substances for weight reduction or chronic weight management. For any controlled substance that is personally furnished, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for the patient's use in a seventy-two hour period. Dosage unit means any of the following:
 - (a) A single pill, capsule, ampule, or tablet;
 - (b) In the case of a liquid solution, one milliliter;
 - (c) In the case of a cream, lotion or gel, one gram; or

- (d) Any other form of administration available as a single unit.
- (3) The prescriber shall not personally furnish or prescribe additional controlled substances to treat obesity for a patient who has not achieved a weight loss of at least 5% of the patient's initial weight, during the initial three months of treatment using controlled substances to treat obesity.
- (4) The prescriber may personally furnish or prescribe controlled substances to treat obesity when the prescriber observes and records that the patient significantly benefits from the controlled substances and has no serious adverse effects related to the drug regimen. A patient significantly benefits from the controlled substances when weight is reduced or when weight loss is maintained and any existing co-morbidity is reduced.
 - (a) The prescriber shall assess the patient at least once every three months and shall obtain the patient's weight, blood pressure, and heart rate. The findings shall be entered in the patient's record.
 - (b) For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction. The prescriber shall document the patient's weight loss or maintenance in the record.
 - (c) The prescriber shall document the patient's progress with the treatment plan.
 - (d) The prescriber shall access OARRS in accordance with rules 4731-11-11 and 4730-2-10 of the Administrative Code.
- (5) The prescriber shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:
 - (a) That the patient has made any false or misleading statement to the prescriber relating to the patient's use of drugs or alcohol;
 - (b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;
 - (c) That the patient has not responded by achieving less than 5% weight reduction after three months while under treatment with a controlled substance or controlled substances;
 - (d) That the patient has repeatedly failed to comply with the prescriber's treatment recommendations;

(e) That the patient demonstrates any signs that the controlled substance is not safe for or well tolerated by the patient; or

(f) That the prescriber knows or should know the patient is pregnant.

(D) A violation of any provision of this rule, as determined by the board, shall constitute the following:

(1) For a physician:

(a) "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;

(b) "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

(c) "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.

(2) For a physician assistant:

(a) "A departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code;

(b) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4730.25 of the Revised Code; and

(c) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731. of the Revised Code, or the rules adopted by the board," as that clause is used in division (B)(3) of section 4730.25 of the Revised Code.

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