4731-11-04 **Controlled substances: Utilization of short term anorexiants for weight reduction.**

(A) A physician shall utilize a schedule III or IV controlled substance short term anorexiant for purposes of weight reduction 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 weight reduction utilizing any schedule III or IV controlled substance short term anorexiant, the physician shall complete all of the following requirements:

(1) The physician shall review the physician's own records of prior treatment or review the records of prior treatment by another treating physician, dietician, 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 caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise, without the utilization of controlled substances, and that the treatment has been ineffective.

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

(a) Obtain a thorough history;

(b) Perform an appropriate physical 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 physician shall not initiate treatment utilizing a controlled substance short term anorexiant 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 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 physician's directions;

(c) The physician 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;

(e) The review of the physician's own records of prior treatment or review of records of prior treatment provided by another physician, dietician, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substances.

(C) A physician may utilize a schedule III or IV controlled substance short term anorexiant, that bears appropriate F.D.A. approved labeling for weight loss, in the treatment of obesity 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 short term anorexiant is prescribed strictly in accordance with the F.D.A. approved labeling. If the F.D.A. approved labeling of the controlled substance short term anorexiant 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.

(3) A physician shall not initiate a course of treatment utilizing a controlled substance short term anorexiant 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 short term anorexiant 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.

(4) After initiating treatment, the physician may elect to switch to a different controlled substance short term anorexiant for weight loss based on sound medical judgment, but the total course of treatment for any short term anorexiant combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.

(5) The physician shall not initiate or shall discontinue utilizing all controlled substance short term anorexiants 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;

(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 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;

(d) That the patient has repeatedly failed to comply with the physician's treatment recommendations; or

(e) That the physician 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) "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;

(2) "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

(3) "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.

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Certification

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