



COMPLIANCE BULLETIN 98-001

TO: ALL OHIO LICENSED PHARMACISTS

DATE: OCTOBER 19, 1998

MEDICAL BOARD - AMENDED CONTROLLED SUBSTANCE WEIGHT REDUCTION RULE
EFFECTIVE OCTOBER 31, 1998

The State Medical Board of Ohio has updated its rules for the use of controlled substances in the treatment of obesity. Many of the questions left unanswered in the original rules have now been addressed. Enclosed is a copy of Ohio Administrative Code Rule 4731-11-04. The following is a breakdown of the major changes and points a pharmacist needs to know and follow when filling prescriptions for these drugs:

1. Rule defines obesity: **A patient must have a BMI of 30 to initiate** the use of controlled substance drugs indicated for weight reduction, or a BMI of 27 with an existing comorbid factor (i.e., diabetes). [Rule 4731-11-04(C)(2)]
2. A physician may prescribe **a thirty-day supply of the controlled substance weight reduction medication** - changed from a fourteen-day supply. [Rule 4731-11-04(C)(5)]
3. Rule defines **"A Few Weeks" as twelve weeks**. Thus, all controlled substance weight reduction medication with an indication of "a few weeks" use in the package insert may only receive prescriptions for a total course of treatment not to exceed twelve weeks. [Rule 4731-11-04(C)(8)]
4. A patient receiving controlled substance medication for the treatment of obesity may restart a program with the use of controlled substance drugs after a **six-month controlled substance weight reduction drug free time period**. [Rule 4731-11-04(D)]
5. If a patient meets all of the conditions listed in Rule 4731-11-04(C)(10), the physician may continue to prescribe a controlled substance drug to **maintain** weight loss. The conditions that must be met are:
 - a. Starting weight of a BMI of 35, morbid obesity;
 - b. An existing comorbid factor (i.e., diabetes), that has not responded to standard treatment but has improved due to weight loss;
 - c. Continued treatment does not violate Rule 4731-11-04(C)(6);
 - d. Drug has an FDA approval for maintenance use;
 - e. Patient has lost at least and continues to **maintain** the loss of five percent or more of their starting weight.

THE ONLY CONTROLLED SUBSTANCE DRUG THAT MAY BE USED FOR MAINTENANCE AT THIS TIME IS MERIDIA SINCE IT IS THE ONLY CONTROLLED SUBSTANCE DRUG THAT CARRIES AN INDICATION FOR MAINTENANCE USE.

A pharmacist is not responsible for documentation of the total weight loss or documentation of the maintenance of weight loss staying under the five percent of total weight loss.

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A PHARMACIST DISPENSING CONTROLLED SUBSTANCE DRUGS FOR WEIGHT CONTROL SHOULD CONSIDER THE FOLLOWING:

- Do not dispense any controlled substance drug for weight reduction beyond twelve weeks at this time, except for *Meridia*.
- Document through prospective drug review that the patient has not exceeded twelve weeks of therapy with a controlled substance, other than *Meridia*, or that it has been six months since the last therapy ended.
- Do not dispense more than a thirty-day supply for any controlled substance drug used for weight reduction. The maximum quantity dispensed is based on the package insert's directions for use.
- The State Medical Board rule does not require a pharmacist to document or ask for the patient's BMI or weight loss since the last prescription.
- However, if the patient personally presents the prescription and obviously does not meet the standards of a BMI of 30, or 27 with comorbid factor, for the first dispensing - DO NOT FILL THE PRESCRIPTION. THIS IS NOT A VALID PRESCRIPTION.

Please review the enclosed rule. If you have questions, please contact the Board of Pharmacy office.



CONTROLLED SUBSTANCES: UTILIZATION FOR WEIGHT REDUCTION
[Medical Board Rule Effective October 31, 1998]

- (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) The appropriate utilization of controlled substances to assist in weight reduction requires continuing interaction between the physician and the patient to assess the patient's dedication to the treatment program, response to treatment, freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects. The physician shall personally meet face-to-face with the patient each time controlled substances are utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.
- (C) A physician may utilize a schedule III or IV controlled substance for purposes of weight reduction in the treatment of obesity only as an adjunct, in accordance with the F.D.A. approved labeling for the product, in a regimen of weight reduction based on caloric restriction, provided that all of the following conditions are met:
- (1) Before initiating treatment utilizing a schedule III or IV controlled substance, the physician determines 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) Before initiating treatment utilizing a schedule III or IV controlled substance, the physician obtains a thorough history, performs a thorough physical examination of the patient, determines that the patient has a BMI of at least thirty, or at least twenty-seven with comorbid factors, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized.
 - (3) The physician shall not utilize any schedule III or IV controlled substance when the physician knows or has reason to believe that a recognized contraindication to its use exists.
 - (4) 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.
 - (5) Except as provided in paragraph (D) of this rule, 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 his 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.
 - (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) Except as provided in paragraph (D) of this rule, the physician shall not resume utilizing a controlled substance following an interruption of treatment of more than seven days unless the F.D.A. approved labeling for the product permits long-term use, or unless 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.
- (8) 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.
- (9) 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.
- (10) The physician may continue to utilize a schedule III or IV controlled substance in the treatment of a patient who has ceased to lose weight during a course of treatment only if all of the following conditions are met:
 - (a) The patient was morbidly obese, having a BMI of at least thirty-five, at the start of treatment;
 - (b) The patient exhibited a comorbid factor, such as uncontrolled diabetes, that did not respond to standard treatment measures but improved or is reasonably expected to improve while under treatment with controlled substances to an extent that significantly reduces risk of mortality;
 - (c) Continued treatment will not violate paragraph (C)(6) of this rule;
 - (d) The F.D.A. approved labeling for the controlled substance being utilized permits maintenance use;
 - (e) The patient lost at least five percent of initial body weight before weight loss stopped and has maintained that weight loss, which determination shall be made by weighing the patient at least every thirtieth day.

If a patient receiving maintenance treatment under this paragraph has maintained weight loss of less than five percent of initial body weight at a required weighing, the physician shall cease utilizing controlled substances to assist the patient's weight loss, and may initiate a new course of treatment utilizing controlled substances only in accordance with paragraph (D) of this rule. If the physician stops maintenance treatment utilizing controlled substances in order to determine whether the patient can maintain weight loss unassisted by controlled substances, the patient's failure to maintain weight loss of at least five percent of initial body weight shall not prohibit reinstatement of treatment using controlled substances.

- (D) Unless prohibited by paragraph (C)(6) of this rule, a physician may initiate a new course of treatment utilizing a controlled substance for purposes of weight reduction if the patient has not received any controlled substance for purposes of weight reduction within the past six months.
- (E) A violation of any provision of this rule, as determined by the board, shall constitute "failure to use reasonable care discrimination in the administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "selling, prescribing, giving away, 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.