

*** DRAFT - NOT YET FILED ***

4731-11-02

General provisions.

(A) A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code.

(B) A physician shall not utilize a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(C) A physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients. Patient medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.

(D) A physician shall obey all applicable provisions of sections 3719.06, 3719.07, 3719.08 and 3719.13 of the Revised Code, and all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.

(E) Violations of this rule:

(1) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following: "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; and "a departure from, or the failure to conform to, minimal standards of care of similar physicians 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) A violation of paragraph (C) of this rule shall further constitute "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.

4731-11-02 General provisions.

(A) A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code.

(B) Any other provisions of this chapter of the Administrative Code notwithstanding, a physician may utilize the schedule II controlled substance cocaine hydrochloride only as a topical anesthetic in situations in which it is properly indicated.

(C) A physician shall not utilize a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(D) A physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients. Patient medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.

(E) A physician shall obey all applicable provisions of sections [3719.06](#) , [3719.07](#) , [3719.08](#) and [3719.13](#) of the Revised Code, and all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.

(F) 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; and "a departure from, or the failure to conform to, minimal standards of care of similar physicians 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. A violation of paragraph (B) of this rule shall further constitute "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. A violation of paragraph (C) of this rule, if committed purposely, knowingly, or recklessly, as those words are defined in section [2901.22](#) of the Revised Code, shall further constitute "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.

Effective: 09/30/2008

R.C. [119.032](#) review dates: 06/06/2008 and 09/30/2013

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#)

Rule Amplifies: [4731.22](#)

Prior Effective Dates: 11/17/86; 9/1/00

4731-11-03

Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants.

(A) A physician shall not:

- (1) Utilize anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin ("HCG"), or other hormones for the purpose of enhancing athletic ability.
- (2) Utilize the schedule II controlled substance cocaine hydrochloride for a purpose other than one of the following:
 - (a) As a topical anesthetic in situations in which it is properly indicated; or
 - (b) For in-office diagnostic testing for pupillary disorders.
- (3) depression; Utilize a schedule II controlled substance stimulant in any of the following circumstances:
 - (a) For purposes of weight reduction or control;
 - (b) When the physician knows or has reason to believe that a recognized contra-indication to its use exists; or
 - (c) In the treatment of a patient who the physician knows or should know is pregnant.
- (4) {Enter paragraph text here}

(B) Utilizing a schedule II controlled substance stimulant:

- (1) Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician shall perform all of the following:
 - (a) Obtain a thorough history;
 - (b) Perform an appropriate physical examination of the patient; and
 - (c) Rule out the existence of any recognized contra-indications to the use of the controlled substance stimulant to be utilized.
- (2) A physician may utilize a schedule II controlled substance stimulant only for one of the following purposes:
 - (a) The treatment of narcolepsy, idiopathic hypersomnia, and hypersomnias due to medical conditions known to cause excessive sleepiness;

(b) The treatment of abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), and/or related disorders;

(c) The treatment of drug-induced or trauma-induced brain dysfunction;

(d) The differential diagnostic psychiatric evaluation of depression;

(e) The treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as antidepressants;

(f) As adjunctive therapy in the treatment of the following:

(i) Chronic severe pain;

(ii) Closed head injuries;

(iii) Cancer-related fatigue;

(iv) Fatigue experienced during the terminal stages of disease;

(v) Depression experienced during the terminal stages of disease; or

(vi) Intractable pain, as defined in rule 4731-21-01 of the Administrative Code.

(g) {Enter paragraph text here}

(3) Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions, the physician shall perform both of the following:

(a) Reappraise the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use; and

(b) Actively monitor such patient for signs and symptoms of drug abuse and drug dependency.

(4) {Enter paragraph text here}

(C) A violation of any provision of this rule, as determined by the board, shall constitute any or all of 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;
- (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.

4731-11-03 Schedule II controlled substance stimulants.

(A) A physician shall not utilize a schedule II controlled substance stimulant for any purpose except:

(1) The treatment of narcolepsy, idiopathic hypersomnia, and hypersomnias due to medical conditions known to cause excessive sleepiness;

(2) The treatment of abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), and/or related disorders of childhood;

(3) The treatment of drug-induced or trauma-induced brain dysfunction;

(4) The differential diagnostic psychiatric evaluation of depression;

(5) The treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants and MAO inhibitors;

(6) As adjunctive therapy in the treatment of the following:

(a) Chronic severe pain;

(b) Closed head injuries;

(c) Cancer-related fatigue;

(d) Fatigue experienced during the terminal stages of disease;

(e) Depression experienced during the terminal stages of disease; or

(f) Intractable pain, as defined in rule [4731-21-01](#) of the Administrative Code.

(B) A physician shall not utilize a schedule II controlled substance stimulant for purposes of weight reduction or control.

(C) A physician may utilize a schedule II controlled substance stimulant when properly indicated for any purpose listed in paragraph (A) of this rule, provided that all of the following conditions are met:

(1) Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance stimulant to be utilized.

(2) The physician shall not utilize any schedule II controlled substance stimulant when he knows or has reason to believe that a recognized contra-indication to its use exists.

(3) The physician shall not utilize any schedule II controlled substance stimulant in the treatment of a patient who he knows or should know is pregnant.

(4) Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions, the physician shall reappraise the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use. The

physician shall actively monitor such a patient for signs and symptoms of drug abuse and drug dependency.

(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.

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4731-11-04

Controlled substances: Utilization of short term anorexiant 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, behavior modification, 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, behavior modification, 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 anorexiant 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.

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.

Eff 11-17-86; 10-31-98; 6-30-00

Rule promulgated under: RC Chapter 119.

Rule authorized by: RC [4731.05](#)

Rule amplifies: RC [4731.22](#)

[119.032](#) Rule Review Date: 12/16/99, 6/30/05

4731-11-04.1

Controlled substances: Utilization for chronic weight management.

(A) A physician shall determine whether to utilize a controlled substance anorexiant for purposes of chronic weight management as an adjunct to a reduced calorie diet and increased physical activity. The determination shall be made in compliance with the provisions of this rule.

(1) Before initiating treatment utilizing any controlled substance anorexiant, the physician shall complete all of the following requirements:

(a) Obtain a thorough history;

(b) Perform a physical examination of the patient;

(c) Determine the patient's BMI;

(d) Review the patient's attempts to lose weight in the past for indications that the patient has made a substantial good faith effort to lose weight in a regimen for weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without the utilization of controlled substance anorexiant. The review shall include available records from the physician's own prior treatment of the patient, prior treatment provided by another physician, prior participation in a weight-loss program, or prior treatment by a dietitian;

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

(f) Assess and document the patient's freedom from signs of drug or alcohol abuse;

(g) Access OARRS and document in the patient's record the receipt and assessment of the information received; and

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

(2) The physician shall not initiate treatment utilizing a controlled substance 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 or physician assistant relating 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; or

- (c) The physician knows or should know the patient is pregnant.
- (3) The physician shall not initiate treatment utilizing a controlled substance anorexiant if any of the following conditions exist:

 - (a) The patient has an initial BMI of less than thirty, unless the patient has an initial BMI of at least twenty seven with comorbid factors.
 - (b) The review of the patient's attempts to lose weight in the past indicates that the patient has not made a substantial good faith effort to lose weight in a regimen for weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without the utilization of controlled substance anorexiant. The review shall include available records from the physician's own prior treatment of the patient, prior treatment provided by another physician, prior participation in a weight-loss program, or prior treatment by a dietitian.
- (4) The physician shall prescribe the controlled substance anorexiant strictly in accordance with the F.D.A. approved labeling;
- (5) Throughout the course of treatment with any controlled substance anorexiant the physician shall comply with rule 4731-11-11 of the Administrative Code and the physician assistant shall comply with rule 4730-2-10 of the Administrative Code.
- (B) A physician shall provide treatment utilizing a controlled substance anorexiant for weight management in compliance with paragraph (A) of this rule and the following:

 - (1) The physician shall meet face-to-face with the patient for the initial visit and at least every thirty days during the first three months of treatment. If the F.D.A. approved labeling for the controlled substance anorexiant requires induction of treatment at one dose and an increase to a higher dose after a stated period of less than thirty days, the physician may give the patient a prescription for the higher dose at the initial visit and the first thirty day period then starts from the date the prescription for the higher dose may be filled.
 - (2) Following the initial visit and two follow-up visits, the treatment may be continued under one of the following means:

 - (a) The physician may authorize refills for the controlled substance anorexiant up to five times within six months after the initial prescription date;
 - (b) The treatment may be provided by a physician assistant in compliance with this rule, the supervisory plan or policies of the healthcare facility,

and the physician assistant formulary adopted by the board.

(3) When treatment for chronic weight management is provided by a physician assistant, the following requirements apply:

(a) The supervising physician shall personally review the medical records of each patient to whom the physician assistant has prescribed a controlled substance anorexiant following each visit; and

(b) A physician assistant shall not initiate utilization of a different controlled substance anorexiant, but may recommend such change for the supervising physician's initiation.

(4) A physician shall discontinue utilizing any controlled substance anorexiant immediately upon ascertaining or having reason to believe:

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

(b) That the patient is pregnant.

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

(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.

***** DRAFT - NOT YET FILED *****

4731-11-05

~~Use of drugs to enhance athletic ability.~~

- ~~(A) A physician shall not utilize anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of enhancing athletic ability.~~
- ~~(B) A physician shall complete and maintain patient medical records which accurately reflect the utilization of any substance or drug described in this rule. Patient medical records shall indicate the diagnosis and purpose for which the substance or drug is utilized, and any additional information upon which the diagnosis is based.~~
- ~~(C) 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; 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. A violation of paragraph (A) of this rule shall further constitute "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.~~

*** DRAFT - NOT YET FILED ***

4731-11-07

Research utilizing controlled substances.

The provisions of this chapter of the Administrative Code shall not apply to or in any way prohibit research conducted under the auspices of an accredited medical school, or research which meets both of the following conditions:

- (A) The U.S. food and drug administration has approved an investigational new drug ("IND") application for the research or has notified the researchers that the proposed study is exempt from the "IND" regulations; and
- (B) The research is conducted in conformance with the approval granted by either of the following .:
 - (1) An institutional review board of a hospital or medical center accredited by the "Joint Commission," "Healthcare Facilities Accreditation Program" or other accrediting body approved by the board; or
 - (2) An institutional review board accredited by the association for the accreditation of human research protection programs.

4731-11-07 Research utilizing controlled substances.

The provisions of this chapter of the Administrative Code shall not apply to or in any way prohibit research conducted under the auspices of an accredited medical school, or research which meets both of the following conditions:

- (1) The research is conducted in conformance with the approval granted by an institutional review board of a hospital or medical center accredited by the JCAHO or other accrediting body approved by the board; and
- (2) The U.S. food and drug administration has approved an investigational new drug (IND) application for the research or has notified the researchers that the proposed study is exempt from the IND regulations.

R.C. [119.032](#) review dates: 06/06/2008 and 06/06/2013

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#)

Rule Amplifies: [4731.22](#)

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