Ohio | Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Controlled Substance Rules

Rule Number(s): 4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-07, 4731-11-11

Date of Submission for CSI Review: 10/5/20

Public Comment Period End Date: 10/19/20

Rule Type/Number of Rules:

New/___ rules

No Change/__2__ rules (FYR? yes___)

Amended/_4_ _ rules (FYR? _yes__)

Rescinded/_ _ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission-

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Rule 4731-11-02 General provisions-No change

   The rule provides general information regarding controlled substance prescribing for physicians.

   Rule 4731-11-03-Utilization of anabolic steroids, schedule II controlled substances-Amend

   The rule outlines the utilization of anabolic steroids and schedule II controlled substances. The rule is proposed to be amended to remove the reference to the rescinded intractable pain rules and to reference chronic pain as defined in Rule 4731-11-01, OAC and to correct a typographical error.

   Rule 4731-11-04 Controlled substances: Utilization of short term anorexiants for weight reduction-Amend

The rules sets forth the requirements for physicians to prescribe short-term anorexiants for weight loss. The rule is proposed to be amended to correct the spelling of dietitian in Section 4731-11-04(B)(1), OAC.

Rule 4731-11-04.1 Controlled substances: utilization for chronic weight management-Amend

The rule sets for the requirements for physicians and physician assistants in the utilization of controlled substances for chronic weight management. The rule is proposed to be amended to remove reference to the discontinued physician assistant formulary in Section 4731-11-04.1(B)(2)(b).

Rule 4731-11-07 Research utilizing controlled substances-No change

The rule outlines the research programs which are not impacted by the rules.

Rule 4731-11-11 Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS)-Amend

The rule sets forth the standards and procedures to be followed by physicians prior to prescribing controlled substances and the red flags of abuse for physicians to monitor when prescribing controlled substances. The rule is proposed to be amended to update the reference to the Pharmacy Board rule for reported drugs in paragraph (A)(5) and to correct a typographical error.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Statutory authority: 4731.295, 4731.281, 4731.05

Amplifying statutes: 4731.281, 4731.296, 4731.295, 4731.294, 4731.293, 4731.292, 4731.291, 4731.282

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
If yes, please briefly explain the source and substance of the federal requirement.

No. Although the Controlled Substance Act establishes the schedule for controlled drugs, the rules are not required by the federal law.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The rules provide specific guidance to physicians in the prescribing of controlled substances, which are prescription drugs which can lead to addiction.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of these regulations will be measured by physicians prescribing controlled substances in accordance with the rules; the rules being written in plain, understandable language; licensee compliance with the rules; and minimal questions from the licensees about the proposed rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

Interested parties that have requested notification of proposed rule changes, including Ohio State Medical Association, Ohio Association of Physician Assistants, Physician Assistant Policy Committee and the Pharmacy Board.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

Comments on Rule 4731-11-02: None

Comments on Rule 4731-11-03: None

Comments on Rule 4731-11-04 and 4731-11-04.1:

- Trace Curry, M.D.Eliminate the 12-week limit:

- Derrick Cetin, D.O.Current rule emphasizes when NOT to use rather than when to use. If patient just 1 day late for filling script, must be off for 6 months, they gain back weight. Should able to use the short acting medications such as phentermine long term to treat obesity as it should be as a chronic disease
- Luke Selby, M.D., Chris Gallagher, Megan Skinner, APRN and Maria Schroff, M.D. Urges the Board to work with both patients and the healthcare community to better understand how Ohio's overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity — in the same fashion that others currently enjoy who struggle with chronic disease such as high cholesterol, heart disease or diabetes.
- Neal Nesbett, M.D.Re-submission of 2013 letter as OSMA position has not changed. Rule is out-dated, particularly 3 months limitation and having see patient every 3 months
- Beth Adamson, OAPA:Comments are applicable to 4731-11-04 and 4731-11-04.1. Supervising physician should be authorize PA to prescribe any drug within physician's normal practice and without requiring physician to review each chart after the PA sees the patient. Recommends use of a more inclusive term such as "practitioner" or "prescriber"
- Donna Leitzel, patient Rule imposes extraordinary restrictions on use of weight loss drugs
- Ross Henchen, M.D., Cheryl Milani, MMS, PA-C, Alana Mercer, MSHS, PA-C:The rules are overly restrictive. Let PAs prescribe weight loss drugs; consider rescinding the rules completely and let physicians use medical judgment.
- Latyonya Fore, NP:Recommends removal of the verbiage "short term anorexiant for purposes of weight reduction" and replacing it with "anti-obesity medication for the purpose of treating overweight and obesity. Allow long-term use of "short-term" drugs. In 4731-11-04.1, allow PAs to prescribe and change medications as do APRNs.
- Barto Burguera M.D., Ph.D.:The rule should allow telemedicine visits for both 4731-11-04 and 4731-11-04.1. For 4731-11-04, drop the 12 weeks maximum, require closer monitoring for 12 weeks, but allow long term use. Should not require discontinuation based on failure to loose weight. Medical Board should designate phentermine to be a chronic weight loss drug. The letter Incudes references to several studies.
- Karen Schultz, CNS:Should amend both 4731-11-04 and 4731-11-04.1 to allow continuous treatment as phentermine is safe.
- Scott W. Butsch, M.D.Obesity is a chronic disease and the rules prevent appropriate treatment.
- Kay Mavko, R.D.Please correct spelling of dietitian. For both 4731-11-04 and 4731-11-04.1, add requirements for "nutritionally adequate calorie restricted diet" , "nutritional counseling and intensive behavioral therapy" and exercise program for weight loss.

- Stan Anderson, M.D. Obesity needs on-going treatment, OARRS should take care of "doctor shopping" concerns, easier to prescribe morphine than Schedule 4 weight loss drug, chronic weight management drugs too expensive for many patients
- Sandra Thornhill, P.A.Should rescind the rule, have a rule for obesity treatment instead. Limits patient's abilty to lose any significant amount of weight. Rule limits PA practice and is contradictive to "new process of prescribing."
- Ethan Lazarus, M.D.Should allow long-term use of phentermine. Ohio physician who treats obesity according to standard of care violates the Ohio rule.
- Steven Schierholt, Executive Director, Board of Pharmacy:Supports continuing the rules are currently written.
- The Board's Physician Assistant Policy Committee recommended two changes to rule 4731-11-04.1:

(1) Remove reference to PA formulary in Rule 4731-11-04.1(B)(2)(b);
(2) Modify requirement for supervising physician to have a discussion with the physician assistant rather than personally reviewing the medical records in paragraph (B)(3)(a) of Rule 4731-11-04.1.

Comments on Rule 4731-11-07: None

Comments on Rule 4731-11-11:

- The Board of Pharmacy recommended changing paragraph (A)(5) to update the rule reference defining "reported drugs".

The Board reviewed the comments at its Policy Committee meetings in September, October and November of 2019. The Board determined to accept the following changes:

4731-11-04: update spelling of dietitian;

4731-11-04.1: remove the reference to the discontinued physician assistant formulary;

4731-11-11: update the Pharmacy Board rule reference in paragraph (A)(5).

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The Medical Board, which includes nine physicians, utilized its medical expertise in developing these rules.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

No alternative regulation was considered other than the amendments discussed above. The Board continues to have concerns regarding the safety of prescribing controlled substance medication and works closely with the Board of Pharmacy on this issue.

13. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The proposed rules are performance based.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Medical Board is the only state agency that licenses physicians.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rule will be posted on the Medical Board's website. Medical Board staff members are available by telephone and e-mail to answer questions.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The business community impacted is composed of physician licensees regulated by the Medical Board.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

The rules require periodic examinations for patients being prescribed controlled substance medications.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

"representative business." Please include the source for your information/estimated impact.

There may be additional time for physicians treating patients with controlled substances for weight loss. However, these rules have been in place for many years, and there are no amendments requiring additional physician time.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Controlled substances pose health and safety risks to patients and it is important to have comprehensive standards for the prescribing of these drugs.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. The regulation is applied equally for all physicians and physician assistants.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Violations of these rules could result in disciplinary action , including fines. Any disciplinary action is imposed pursuant to Chapter 119 and the Medical Board's laws and rules. Due process requires equal application of the laws and rules to all licensees.

20. What resources are available to assist small businesses with compliance of the regulation?

Board staff is available to answer questions regarding the rule. The rules are posted and are available on the Board's website.

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 the rules promulgated thereunder, all prescription issuance rules adopted under Chapter 4729. 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.

4731-11-03 **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) 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, except if the following criteria are met:

(i) After the physician's medical assessment the physician and patient determine that the benefits of treating the patient with a schedule II controlled substance stimulant outweigh the risks, and

(ii) The basis for the determination is documented in the patient record.

(B) Utilizing a schedule II controlled ~~subtance~~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 ~~subtance~~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~~Chronic pain, as defined in rule ~~4731-21-01~~4731-11-01 of the Administrative Code.

(g) The treatment of binge eating disorder.

(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.

(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.

4731-11-04 **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~~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 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~~dietitian, 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.

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, intensive behavioral therapy, and exercise without the utilization of controlled substance anorexiants. 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, intensive behavioral therapy, and exercise without the utilization of controlled substance anorexiants. 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.

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.

4731-11-11 **Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).**

(A) For purposes of this rule:

(1) ~~:~~"Delegate" means an authorized representative who is registered with the Ohio board of pharmacy to obtain an OARRS report on behalf of a physician;

(2) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(3) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(4) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(5) "Reported drugs" means all the drugs listed in rule ~~4729-37-02~~4729:8-2-01 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including controlled substances in schedules II, III, IV, and V.

(B) Standards of care:

(1) The accepted and prevailing minimal standards of care require that when prescribing or personally furnishing a reported drug, a physician shall take into account all of the following:

(a) The potential for abuse of the reported drug;

(b) The possibility that use of the reported drug may lead to dependence;

(c) The possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons; and

(d) The potential existence of an illicit market for the reported drug.

(2) In considering whether a prescription for or the personally furnishing of a reported drug is appropriate for the patient, the physician shall use sound clinical judgment and obtain and review an OARRS report consistent with the provisions of this rule.

(C) A physician shall obtain and review an OARRS report to help determine if it is appropriate to prescribe or personally furnish an opioid analgesic, benzodiazepine, or reported drug to a patient as provided in this paragraph and paragraph (F) of this rule:

(1) A physician shall obtain and review an OARRS report before prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient, unless an exception listed in paragraph (G) of this rule is applicable.

(2) A physician shall obtain and review an OARRS report when a patient's course of treatment with a reported drug other than an opioid analgesic or benzodiazepine has lasted more than ninety days, unless an exception listed in paragraph (G) of this rule is applicable.

(3) A physician shall obtain and review an OARRS report when any of the following red flags pertain to the patient:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Suffering an overdose, intentional or unintentional;

(f) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(g) Having been arrested, convicted, or received diversion or intervention in lieu of conviction for a drug related offense while under the physician's care;

(h) Receiving reported drugs from multiple prescribers, without clinical basis;

(i) Traveling with a group of other patients to the physician's office where all or most of the patients request controlled substance prescriptions;

(j) Traveling an extended distance or from out of state to the physician's office;

(k) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs;

(l) A known history of chemical abuse or dependency;

(m) Appearing impaired or overly sedated during an office visit or exam;

(n) Requesting reported drugs by street name, color, or identifying marks;

(o) Frequently requesting early refills of reported drugs;

(p) Frequently losing prescriptions for reported drugs;

(q) A history of illegal drug use;

(r) Sharing reported drugs with another person; or

(s) Recurring visits to non-coordinated sites of care, such as emergency departments, urgent care facilities, or walk-in clinics to obtain reported drugs.

(D) A physician who decides to utilize an opioid analgesic, benzodiazepine, or other reported drug in any of the circumstances within paragraphs (C)(2) and (C)(3) of this rule, shall take the following steps prior to issuing a prescription for or personally furnishing the opioid analgesic, benzodiazepine, or other reported drug:

(1) Review and document in the patient record the reasons why the physician believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) Review and document in the patient's record the patient's progress toward treatment objectives over the course of treatment;

(3) Review and document in the patient record the functional status of the patient, including activities for daily living, adverse effects, analgesia, and aberrant behavior over the course of treatment;

(4) Consider using a patient treatment agreement including more frequent and periodic reviews of OARRS reports and that may also include more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription or personally furnishing of reported drugs, and consequences for non-compliance with the terms of the agreement. The patient treatment agreement shall be maintained as part of the patient record; and

(5) Consider consulting with or referring the patient to a substance abuse specialist.

(E) Frequency for follow-up OARRS reports:

(1) For a patient whose treatment with an opioid analgesic or benzodiazepine lasts more than ninety days, a physician shall obtain and review and OARRS report for the patient at least every ninety days during the course of treatment, unless an exception listed in paragraph (G) of this rule is applicable.

(2) For a patient who is treated with a reported drug other than an opioid analgesic or benzodiazepine for a period lasting more than ninety days, the physician shall obtain and review and OARRS report for the patient at least annually following the initial OARRS report obtained and reviewed pursuant to paragraph (C)(2) of this rule until the course of treatment utilizing the reported drug has ended, unless an exception in paragraph (G) of this rule is applicable.

(F) When a physician or their delegate requests an OARRS report in compliance with this rule, a physician shall document receipt and review of the OARRS report in the patient record, as follows:

(1) Initial reports requested shall cover at least the twelve months immediately preceding the date of the request:

(2) Subsequent reports requested shall, at a minimum, cover the period from the date of the last report to present;

(3) If the physician practices primarily in a county of this state that adjoins another state, the physician or their delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county; and

(4) If an OARRS report regarding the patient is not available, the physician shall

document in the patient's record the reason that the report is not available and any efforts made in follow-up to obtain the requested information.

(G) A physician shall not be required to review and assess an OARRS report when prescribing or personally furnishing an opioid analgesic, benzodiazepine, or other reported drug under the following circumstances, unless a physician believes or has reason to believe that a patient may be abusing or diverting reported drugs:

(1) The reported drug is prescribed or personally furnished to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill;

(2) The reported drug is prescribed for administration in a hospital, nursing home, or residential care facility;

(3) The reported drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days;

(4) The reported drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer; and

(5) The reported drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery.