

MEMORANDUM

TO: Betty Montgomery, President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Controlled Substance Rules, 4731-11-03, 11-04, 11-04.1

DATE: April 8, 2022

Proposed amendments to Rules 4731-11-03, 11-04, and 11-04.1 were circulated to interested parties. A spreadsheet outlining the comments is attached.

I. Rule 4731-11-03

Three comments were received regarding Rule 4731-11-03, Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants. I reviewed these comments with Dr. Schottenstein because he had recommended the amendments to this rule.

- John Smith, J.D., Government Relations Coordinator had questions regarding the meaning of the term, mental status examination in section (B)(1)(b). Specifically, he questioned whether there was a standard mental status examination for patients that may be prescribed a stimulant and whether comprehensive neuropsych testing was required.

Recommendation: No change. A mental status examination is the psychological equivalent of the physical examination, including the clinician’s observations and impressions of the patient at the time of the interview. Neuropsych testing is not required.

- Lee Reynolds, MD. Of 4KidHelp provided a comment that telehealth should be available for patients with ADD/ADHD being treated with stimulants.

Recommendation: Proposed rules on telehealth as authorized by HB 122 will address this issue.

- Kinsey Jolliff, Principal, Government Relations for The MetroHealth System provided the following recommendations:
 - Add a section requiring a 30-day follow up for the first 90 days and then every 90 days to be consistent with requirements for Schedule III and IV anorexiant since Schedule II drugs have a higher potential for addiction.

Recommendation: No change. The degree of follow-up should be based on clinician judgment.

- Questions why Schedule II stimulants may not be used for weight reduction or control but may be used in paragraph (B)(2)(f) for binge eating disorder.

Recommendation: The language in paragraph (B)(2)(f) is based on FDA approval of Vyvanse for the indication of binge eating disorder. Schedule II stimulants are not used for weight reduction or control due to a perceived increased risk of addiction and diversion when prescribed for that indication.

- Concerned with allowing Schedule II stimulant in (B)(2)(e) for the treatment of chronic pain. Use of stimulants for treatment of chronic pain is outdated.

Recommendation: Stimulants are not recommended for primary treatment of pain but may be helpful for the physical and mental health function in patients who are being treated for pain.

II. Rule 4731-11-04

The majority of the comments received were concerning the proposed amendment to Rule 4731-11-04, OAC, and many of the comments addressed the same rule provisions.

- 4731-11-04(B)(1) Delete “caloric restriction” because it is duplicative with nutritional counseling. (Ohio Health Weight Management, Cleveland Clinic). **Recommend this change.**
- 4731-11-04(B)(3)(d) Dr. Lazarus of the Obesity Medicine Association raised issues that BMI is a population based measurement and should not be strictly enforced with the individual and that the language as drafted does not make allowance for on-label use of medication in children, like Saxenda, with is based on BMI percentile. He recommends adding language to allow for clinical discretion whether the benefits of weight loss treatment for the patient would significantly outweigh any risks of the medication being used or adding language that prescribing should be pursuant to guidance from package inserts. Since we are trying to address restrictions from the package inserts for phentermine, I would not recommend adding language regarding package inserts. **I would like feedback from the Board on adding language to allow for clinical discretion related to BMI.**

Dr. Bruce Barker, Ohio Health Weight Management requested adding the following as comorbid risk factors with the BMI of 27: insulin resistance, metabolic syndrome, prediabetes. **I would like feedback from the Board on adding the three co-morbidities.**

- 4731-11-04(B)(3)(f) Delete language prohibiting initiation of treatment with a controlled substance if the patient was unsuccessful in previous attempts to lose weight. (Obesity Medicine Association, Obesity Action Coalition, Ohio Health Weight Management, Ohio State Medical Association, and Angela Fitch, MD) **Recommend this change.**
- 4731-11-04(C)(1) Delete the requirement for an assessment every thirty days for the first three months of utilization of controlled substances for weight reduction. (Obesity Action Coalition, Academy of Medicine of Cleveland and Northern Ohio, Cleveland Clinic, Angela Fitch, MD, Ohio State Medical Association, and Obesity Society) **Recommend this change, but would like feedback from the Board.**

- 4731-11-04(C)(2) Delete the requirement to limit prescriptions to 30 days. Language regarding personally furnishing needs updated to accurately reflect the language of Section 4729.291 of the Revised Code which places restrictions on the aggregate and individual amounts of controlled substances that can be personally furnished. (Academy of Medicine of Cleveland and Northern Ohio, American Society of Bariatric and Metabolic Surgery, Cleveland Clinic, Angela Fitch, MD, MetroHealth System, The Obesity Society, University Hospitals) **Recommend this change with the following updated language:**

The prescriber shall ~~not personally furnish or prescribe more than a 30-day supply of~~ controlled substances, ~~at one time,~~ for weight reduction or chronic weight management only in accordance with section 4729.291 of the revised code. For any controlled substance that is personally furnished to or for patients, taken as a whole, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and for an individual patient, shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for that patient's use in a seventy-two hour period. Dosage unit means any of the following:

- (a) A single pill, capsule, ampule, or tablet;
- (b) In the case of a liquid solution, one milliliter;
- (c) In the case of a cream, lotion, or gel, one gram; or
- (d) Any other form of administration available as a single unit.

- 4731-11-04(C)(4)(a) Several comments recommended the addition of language that would allow the assessments to be conducted via telemedicine. (Obesity Action Coalition, Academy of Medicine of Cleveland, and Northern Ohio, American Society of Bariatric and Metabolic Surgery, American Society of Bariatric and metabolic Surgery, Cleveland Clinic, Angela Fitch, MD, Ohio State Medical Association, and The Obesity Society). **Rules 4731-11-09 and 4731-37-01 will specifically address telemedicine, but a change is recommended to replace the word, "check" with "obtain" to allow the patient's weight, blood pressure, pulse, heart, and lung assessment to be completed through remote monitoring.**
- 4731-11-04(C)(4)(b) Several comments recommended the elimination of the requirement to continue to lose weight or to maintain a goal weight as these concepts are not consistent with the treatment of obesity as a chronic, progressive disease. (Obesity Medicine Association, Ohio Health Weight Management, Cleveland Clinic, Angela Fitch, MD, and The Obesity Society). **Recommend use of the suggested revised language set forth below:**

For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction ~~continue to lose weight during the active weight reduction treatment or maintain goal weight.~~ The prescriber shall document the patient's weight loss or maintenance in the record.

- 4731-11-04(C)(5)(c) Several comments recommended modification of this language to eliminate the thirty day timeframe and to eliminate weighing the patient at least every thirty days. (Obesity Medicine Association, Academy of medicine of Cleveland and Northern Ohio, Ohio Health Weight Management, Cleveland Clinic, Angela Fitch, MD, The Obesity Society)

Recommend use of the suggested revised language as set forth below:

That the patient has not responded by achieving less than 5% weight reduction after three months ~~failed to lose weight~~ while under treatment with a controlled substance or controlled substances ~~for weight reduction 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;~~

Requested Action: Discuss the rule comments and approve any amendments. Approve filing rules, as amended, with the Common Sense Initiative.