Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information:

Kimberly Anderson Kimberly.Anderson@med.ohio.gov;(614) 466-7207

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

Controlled Substance Rules

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

Date of Submission for CSI Review: 9/22/22

Public Comment Period End Date: 10/14/22

Rule Type/Number of Rules:

New/__1_ rules **No Change/____ rules (FYR? ___)**

Amended/___1_ rules (FYR? _y__) **Rescinded/__2__ rules (FYR? _y__)**

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 4731-11-03: Utilization of anabolic steroids, Schedule II controlled substances. The rule outlines the utilization of anabolic steroids and schedule II controlled substances. The rule is proposed to be amended to do the following:

   - Correct a typographical error in paragraph (B);
   - Add the requirement of a mental status examination of the patient to (B)(1)(b);
   - Correct a typographical error in (B)(1)(c);
   - Update the language of attention deficit hyperactivity disorder and delete reference to abnormal behavioral syndrome and hyperkinetic syndrome in (B)(2)(b);
   - Updates the language in (B)(2)(c) regarding certain neurocognitive disorders;

- Deletes the differential diagnostic psychiatric evaluation of depression as a condition for which Schedule II controlled substance could be prescribed in paragraph (B)(2)(d); and
- Updates paragraph (B)(2)(e) reference the definition of chronic pain in Rule 4731-11-01.

Rule 4731-11-04 Controlled Substances: Utilization of short term anorexiants for weight reduction-Rescind/New: The rule sets forth the requirements for physicians to prescribe short-term anorexiants for weight loss.

Rule 4731-11-04.1 Controlled Substances: Utilization for Chronic Weight Management-Rescind

The rule sets forth the requirements for physicians and physician assistants in the utilization of controlled substances for chronic weight management.

A new rule 4731-11-04 is proposed to address controlled substances for the treatment of obesity. The new rule will set forth requirements for the utilization of schedule III or IV controlled substances that are FDA approved for the treatment of obesity.

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.**

   4731-11-03: Authorized by 4731.05, Amplifies 4731.22

   4731-11-04: Authorized by 4731.05; Amplifies 4731.22

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 guidance to physicians in the prescribing of controlled substances for the treatment of specific medical conditions.

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 licensees about the proposed rule requirements.

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.

   The rules were circulated to interested parties, including but not limited to the Ohio State Medical Association, Ohio Association of Physician Assistants, the Pharmacy Board, the Physician Assistant Policy Committee of the State Medical Board, and the Ohio Osteopathic Association, the Ohio Hospital Association and the Academy of Medicine of Cleveland and Northern Ohio. In addition, in November 2020, a virtual meeting was held with Dr. Soin, a member of the State Medical Board and physicians specializing in the treatment of obesity to obtain comments regarding Rules 4731-11-04 and 4731-11-04.1. The State Medical Board made initial draft changes based on the feedback from the virtual meeting, and circulated the draft rules to the interested parties.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?** A spreadsheet outlining the comments received in the most recent circulation is attached.

    The Board fully reviewed the comments received for rule 4731-11-03, as follows:

    - 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.

The Board determined to make 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.

The Board determined to make no change because the 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 anorexiants since Schedule II drugs have a higher potential for addiction.

The Board determined to make no change because 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.

      The Board determined not to make this change because 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.

The Board determined not to make a change here because 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.

The Board fully reviewed the comments and is proposing the following changes to proposed rule 4731-11-04:

- 4731-11-04(B)(1) Delete "caloric restriction" because it is duplicative with nutritional counseling.

- 4731-11-04(B)(3)(d): Add the following as comorbid risk factors with the BMI of 27: insulin resistance, metabolic syndrome, prediabetes.

- 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. **The Board agreed to this change but recommended adding language requiring documentation of the rationale for initiation or re-initiation of treatment with controlled substances.**

- 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.

- 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. **The Board agreed to make 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. **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. **The Board agreed to amend with the following language:**

  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. **The Board agreed to the following revised language:**

  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~~;

The proposed changes to Rule 4731-11-04 were also provided to the Board of Pharmacy and there were no objections.

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. In addition, the Board reviewed journal articles and medical studies provided by the interested parties to make the proposed changes to Rule 4731-11-04.

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?

The Board considered and adopted much of the alternative language suggested by the interested parties.

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 impacted business community is composed of physician and physician assistant 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 requires 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.

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?

The proposed rules will be available on the Board's website. The Board staff is available to answer questions regarding the rules.