Ohio State Medical Board of Ohio

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CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Office based treatment of opioid addiction

Rule Number(s): 4730-4-01, 4730-4-03, 4730-4-04, 4731-11-12, 4731-33-01, 4731-33-03, 4731-33-04

Date: August 3, 2018

Rule Type:

- X New
- ☐ Amended
- ☐ 5-Year Review
- X Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

Sections 4730.55 and 4731.056, Ohio Revised Code, require the Medical Board to adopt rules that establish standards and procedures to be followed by physician assistants and physicians in the use of all drugs approved by the FDA for use in medication-assisted treatment, including controlled substances in Schedules III, IV, or V. The required rules must address:

- detoxification,
- relapse prevention,
- patient assessment,
- individual treatment planning,
- counseling and recovery supports,
- diversion control, and
- any other topics selected by the Medical Board after considering best practices in medication assisted treatment.

The Revised Code sections state that the Medical Board may apply the rules to all settings or limit the application of the rules to medication-assisted treatment in the office setting or other practice types and locations.

The rules submitted in this package address the statutorily required components except for detoxification. In the future rule 4730- 4-02 and 473-33-02 will be drafted to set standards and procedure for detoxification. For efficiency, the discussion in this rule uses the proposed physician rules (Chapter 4731- 33) because the physician assistant rules (Chapter 4730-4) are consistent with the physician rules.

The rules provide treatment parameters for prescribers who wish to treat opiate addiction via office-based treatment with controlled substances in schedule III, IV, or V ("OBOT") that have been specifically approved by the U.S. Food and Drug Administration (hereinafter "FDA") or by a non-controlled substance. At this time the only approved controlled substances are buprenorphine products, including the drug with the brand name of Suboxone. The only FDA approved non-controlled substance for treating opioid addiction is Naltrexone, which is sold under the brand name Vivitrol, among others.

The need for regulation is urgent, as there are reports that some prescribers are setting up "pill mills" for specifically approved buprenorphine products, similar to the "pill mills" where prescription opiates such as OxyContin and Vicodin were prescribed for other than legitimate medical purposes (see http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupecan-be-savior-or-menace.html?_r=1&). Recognizing the constellation of factors related to opiate addiction, treatment, and illegal activity, the rules attempt to strike a proper balance between access to opiate addiction treatment and diversion of specifically approved buprenorphine products by setting forth the requirements for treating opiate addiction in a non-institutional setting so that the treatment can be performed in a safe manner for the patient and reduce the risk of unlawful behavior of patients, practitioners, and others.

Current rule 4731-11-12, Ohio Administrative Code, will be rescended.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The rules are authorized by Sections 4730.07, 4730.55, 4731.05, and 4731.056 of the Revised Code.

3. **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.

   The rules do not implement a federal requirement.

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

   Sections 4730.55 and 4731.056 of the Revised Code require the Medical Board to adopt the rules.

5. **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 implement the policy of the State of Ohio to set minimum standards and procedures for the provision of medication-assisted treatment. The policy reflects concerns that some medication-assisted treatment programs have provided such treatment outside of the minimal standards of care.

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

   The success of the rules will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices, and medical facilities regarding the provisions of the rule.

Development of the Regulation

7. **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 initial draft of the rules was completed with significant input from the Ohio Department of Mental Health and Addiction Services ("ODMHAS") and the Ohio Board of Nursing ("Nursing Board"). The physician assistant rules (Chapter 4730-4) were then discussed with the members of the Physician Assistant Policy Committee ("PAPC"), which is composed of three physician assistants, an M.D., a D.O., and a physician member of the Medical Board, at a public meeting held on February 12, 2018. The physician rules (Chapter 4731-33) were discussed by the Medical Board's Policy Committee at a public meeting on February 14, 2018.

On February 21, 2018, the draft rules were sent to interested parties. The parties included, but not limited to: Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Ohio Association of Physician Assistants, Academy of Medicine of Cleveland and Northern Ohio, physicians at Medical Board approved treatment facilities, persons who requested notice of proposed rules applicable to prescribing, and organizations and individuals who have a standing request to receive notice of Medical Board rule activity.

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

Input from the stakeholders significantly affected the draft rules. The proposed rules were circulated twice for comments from interested parties.

1. Thirty-three comments were received in response to the first circulation. The spreadsheet summarizing the comments is attached to this memo.

2. The rules were then revised and sent for comment by all persons who had commented initially. Four comments were received. The spreadsheet summarizing the comments is attached to this memo.

I. Discussion of comments and proposed resulting changes to the draft rules

RULE 4731-33-01 DEFINITIONS:

Paragraph (A): As originally drafted, the definition of "OBOT" did not list the exceptions to the definition. Instead, the exceptions were in rule 4731-33-03. As suggested by the Nursing Board, moving the exceptions to the definition of OBOT adds clarity. Also, wording referencing "alcoholism" was deleted as it is misleading. OBOT is only applicable to treatment for opioid addiction.

Also, at the suggestion of the Nursing Board, a youth services facility was added as an exception.

Paragraphs (C) and (D): Substance use disorder is substituted for alcoholism or drug addiction because it is the term used by professionals in the field.

Paragraph (F): The definition of "qualified behavioral healthcare provider" is amended in paragraph (F)(3) to include marriage and family therapists and in (F)(2) to list out the professionals licensed under Chapter 4758 of the Revised Code, as recommended by the Ohio Council of Behavioral Health & Family Services Providers.

The Ohio Association of Physician Assistants ("OAPA") commented that a physician assistant should be included in "behavioral health care provider," and the rules should reflect that a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist who supervises a

physician assistant may authorize the physician assistant to provide whatever services are within the physician's normal course of practice. However, the professions included as "behavioral health care provider" are those that have formal education focused in behavioral health in order to obtain advanced certification or licensure. The formal education usually requires fulfillment of academic and supervised practice requirements. The original draft of the rules submitted to the PAPC included within the definition a physician assistant who had successfully completed a postgraduate program residency or fellowship program in psychiatry from an accredited program for physician assistants. However, PAPC members stated that those programs no longer exist. The physician assistant's basic medical education is an internal medicine focus. There are not formal education programs through which the physician assistant may complete formal education focused on behavioral health that will result in an advanced degree or certification after examination. Accordingly, the OAPA comment has not resulted in amendment of the language.

Paragraph (G): The definition of "mental health service provider" is deleted because we learned that mental health services are included within behavioral healthcare services.

New paragraph (G): "Community addiction services provider" is added, as recommended by the Ohio Counsel of Behavioral Health & Family Service Providers.

Paragraph (H). "Community mental health services provider" is added, as recommended by the Ohio Counsel of Behavioral Health & Family Service Providers.

Paragraphs (I) and (J) added to define terms for clarification.

II. **RULE 4731-33-03** Office based treatment for opioid addiction

Old paragraph (A): Originally paragraph (A) listed the entities where the rule would not be applicable. However, those exceptions to the rule were moved to the definition of "office based treatment for opioid addition" in rule 4731-33-01.

New paragraph (A): This paragraph now states that the physician must comply with all federal and state laws and regulations. A requirement to complete at least eight hours of Category 1 CME related to substance abuse and addiction every two years has been added, as is in current rule 4731-11-12.

Paragraph (B): In Subparagraph 12, TB testing is no longer required, but screening must be considered.

Basis: ASAM recommends that TB testing "be considered." TIP 63 is silent as to TB testing. Comments received are that TB is rare and expensive so should be at physician's discretion. A physician member of the Medical Board expressed that TB is now on the rise. Dr. Hurst suggests use of "screening" instead of testing. The rule does not require screening, but defers to the physician's judgement after consideration of screening.

There were comments that requiring HIV, Hepatitis B, and Hepatitis C testing is expensive and discourages patient entry into treatment. However, ASAM and Tip 63 recommend they be included in the assessment. The language was not changed.

Paragraph (D): Subparagraph (2), the web link for the ASAM guideline is changed to the general ASAM website.

Paragraph (E): Language is added to clarify that if the physician providing OBOT is a board-certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician may personally provide the behavioral health services for addiction. Added at ODMHAS' suggestion.

- Language is also added to include community mental health services providers and community addiction services providers for purposes of referring and collaborating for the psychosocial treatment. Basis: This reflects the comments by the Ohio Council of Behavioral Health & Family Services Providers that these agencies are important providers of such needed services, especially for patients on Medicaid.

- Subparagraph (2): Some comments were that the list of treatments should not be included. However, they are recommended superior psychosocial treatments by ASAM.

- Subparagraph (3): The word "renegotiation" was changed to "revision," at the suggestion of ODMHAS.

- Subparagraph (5): Two subparagraphs were added. One clarifies when the prescribing physician may provide the behavioral health services. The other requires documentation when the patient is referred to a behavioral health services provider, community addiction services provider, or community mental health services provider.

Paragraph (F): The language is amended to require the physician to offer a prescription for a naloxone kit, instead of providing a kit or a prescription for one. Subparagraph (2) states that if the patient refuses the prescription the physician shall give the patient information on where to obtain a kit without a prescription.

Paragraph (G): This paragraph applies to OBOT using buprenorphine products.

- Subparagraph (1): Wording is added to require that the provision of buprenorphine products be in compliance with the FDA approved REMS. According to the FDA, "[a] Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS." https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm

- Subparagraph (2)(a): Adds “breast-feeding” to the situations in which the buprenorphine mono-product may be prescribed.

- Subparagraph (2)(d): Is added to recognize that the mono-product is used for withdrawal management.

- Subparagraph (2)(e): Is added because numerous comments were received stating that although rare, allergy to naloxone does occur. Commenters indicated that documentation of the allergy should be required.

- Subparagraph (3): Several comments suggested it is not always possible to taper the patient off of other CNS depressants. Language added to reflect information in the 9-20-17 FDA Drug Safety Announcement concerning co-prescribing of buprenorphine and a benzodiazepine, which increases the risks of overdose.

- Subparagraph (4): The language is changed to be less specific as to dosage but instead to require that during the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the FDA approved labeling, except for medically indicated circumstances documented in the medical record.

  Basis: The original language provided a cap of 8mg to start induction, but it was read as not to exceed 8mg during the entire induction period. The changed language reflects TIP 63, which cites the FDA label recommendation of a maximum of 8mg on day 1 and 16 mg on day 2 of induction, and also states that the clinical rationale must be documented when dosing outside of the FDA recommendation.

- Subparagraph (5): The phrase “when using a buprenorphine transmucosal product” is added to clarify that requirements of the paragraph do not prevent the usage of extended-release forms of buprenorphine.

- Subparagraph (5)(b): The phrase “and until the completion of twelve months of treatment” is added to clarify that the patient should only be given a thirty-day prescription for the first twelve months of treatment, as is required by current Rule 4731-11-12.

- Subparagraph (7): Several comments suggested that the cap of twenty-four mgs per day was too low. However, it is not proposed to be changed because TIP 63 says that dosage above 24 mg shows no clinical advantage. ASAM discusses the FDA approval of a dosing limit of 24 mg per day, and does not contradict it or suggest that documentation might cure prescribing of a dosage exceeding 24 mg.

- Subparagraph (9): The language is amended to clarify that the provisions apply to an extended-release, injectable, or implanted buprenorphine product.

III. RULE 4731-33-04 Medication assisted treatment using a non-controlled substance

- The rule requires use of a dosage regime that strictly complies with the FDA labeling.

- Several commenters asked why there are requirements to discourage diversion of Naltrexone when it is not a controlled substance and has no street value. Therefore, the language regarding diversion was deleted. However, the requirement for urine drug screens remains in the proposed rule because urine screens are recommended by ASAM when treatment is by Naltrexone.

9. 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 rule was developed based upon the two published protocols.

- "TIP 63, Treatment Improvement Protocol, Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families," published by the Substance Abuse and Mental Health Services Administration: https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Executive-Summary/SMA18-5063EXSUMM

- "The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," published by the American Society of Addiction Medicine: https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

The rule also benefited from the input of the medical director and other staff of the Ohio Department of Mental Health and Addition Services. ODMHAS certifies community behavioral health agencies that provide behavioral health services and is the lead Ohio agency for addiction services information.

10. 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?

See response to question #8, above.

11. 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 set out the required activities but do not specify the means of performing the required activities.

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

    The Medical Board is the only agency authorized to regulate the prescribing practices of physicians and physician assistants. The Medical Board worked closely with ODMHAS so that the rules do not conflict with that agency's recommendations concerning medication-assisted treatment for opioid addiction.

13. **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 rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations.

Adverse Impact to Business

14. **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;**
       The impacted business community is composed of physicians and physician assistants who provide medication-assisted treatment for opioid addiction.
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
       The adverse impact is the cost of continuing education related to substance abuse and addiction. While the physician or physician assistant is already required to complete continuing education (See Section 4730.14 and 4731.282 of the Ohio Revised Code), the rule requires eight hours to be completed in coursework related to substance abuse and addiction. The eight hours will be counted as part of the overall continuing education hours.

       The physician or physician assistant who chooses to provide medication-assisted treatment for opioid addiction will also incur the cost of the time needed to perform the required assessment, formulation of an appropriate treatment plan for each patient, and documentation of compliance with the activities required by the rule. However, the required activities should not add significantly to the practice costs of a physician or physician assistant who practices within the minimal standards of care.

The U.S. Drug Enforcement Administration (DEA) requires, pursuant to 21 USC § 823(g)(2), that a physician or physician assistant who intends to prescribe certain controlled substance medications for the purposes of maintenance and detoxification of opiate addiction receive a waiver from special registration requirements (waiver). There is no fee associated with applying for the waiver. A physician or physician assistant who intends to prescribe specifically approved buprenorphine products, which are a schedule III, IV, or V controlled substance, must have a current DEA certificate of registration (also known as a DEA number).

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in Sections 4730.252 and 4731.225, Ohio Revised Code

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.

The fee associated with the DEA registration is $731.00 for the initial application and for every three year renewal cycle. In order to qualify for a waiver, the physician or physician assistant must obtain and maintain a certain enumerated specialty certification required by the DEA or eight hours of training approved by certain associations (See http://buprenorphine.samhsa.gov/SMA-167_Increase_Patients.pdf). Some courses may have a fee, but the courses are offered free of charge by Providers of Clinical Support System: https://pcssnow.org/.

Continuing education course options range from a three-day, eight hour course by the American Society of Addiction Medicine for up to $890 (depending on membership status): https://www.asam.org/education/live-online-cme/the-asam-state-of-the-art-2018/registration-rates to "Opioid Use Disorder," a ten-hour course offered by NetCE for $40: https://www.netce.com/courseoverview.php?courseid=1611.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

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

Ohio is experiencing an epidemic of opiate abuse and overdose deaths. Specifically approved buprenorphine products have been used successfully for the maintenance treatment for opioid dependence as part of a treatment plan that includes counseling and psychosocial

support. However, specifically approved buprenorphine products are themselves opioids that are subject to abuse. Concerns have been brought forward by law enforcement, treatment providers, and governmental agencies that office based maintenance treatment with specifically approved buprenorphine products may be contributing to the opiate problem in Ohio. In compliance with Sections 4730.55 and 4731.056 Ohio Revise Code, protection of the public, in general, and persons with opiate addiction, in particular, necessitates that the Medical Board regulate the office based maintenance treatment of persons with opiate addiction in a safe manner, yet at the same time providing greater access to that treatment in Ohio.

Regulatory Flexibility

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

Treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

17. 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?

Due process requires the Medical Board to consistently apply its rules regarding controlled substance prescribing such that all prescriber licensees are equally treated.

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

Medical board staff members are available by telephone and e-mail to answer questions.