Common Sense Initiative

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Business Impact Analysis

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

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

Opioid Treatment Rules for Physicians and Physician Assistants

Rule Number(s): 4731-33-01, 4731-33-02, 4731-33-03, 4731-33-04, 4730-4-01, 4730-4-02, 4730-4-03, 4730-4-04

Date of Submission for CSI Review: 4/4/24

Public Comment Period End Date: 4/19/24

Rule Type/Number of Rules:

New/8 rules
No Change/____ rules (FYR? ___)
Amended/____ rules (FYR? ___)
Rescinded/8 rules (FYR?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.

Sections 4730.55 and 4731.056 of the Revised Code require the State Medical Board of Ohio to adopt rules that establish standards and procedures to be followed by physicians and physician assistants in the use of all drugs approved by the FDA for use in medication-assisted treatment. The rules are required to address withdrawal management, relapse prevention, patient assessment, individual treatment planning, counseling and recovery supports, diversion control and other topics selected by the board after considering best practices in medication-assisted treatment.

The rules are proposed to be amended more than 50%, so they are proposed as Rescind/New rules, as set forth below:

Physicians:

4731-33-01 Definitions-Proposed New Rule

4731-33-01 Definitions-Proposed to Rescind

4731-33-02 Standards and Procedures for Withdrawal Management for Substance Use Disorder-Proposed New Rule

4731-33-02 Standards and Procedures for Withdrawal Management for Drug or Alcohol Addiction-Proposed to Rescind

4731-33-03 Office-Based Opioid Treatment-Proposed New Rule

4731-33-03 Office-Based Treatment for Opioid Addiction-Proposed to Rescind

4731-33-04 Medication-Assisted Treatment Using Naltrexone-Proposed New Rule

4731-33-04 Medication-Assisted Treatment Using Naltrexone-Proposed to Rescind

Physician Assistants:

4730-4-01 Definitions-Proposed New Rule

4730-4-01 Definitions-Proposed to Rescind

4730-4-02 Standards and Procedures for Withdrawal Management For Substance Use Disorder-Proposed New Rule

4730-4-02 Standards and Procedures for Withdrawal Management For Substance Use Disorder-Proposed to Rescind

4730-4-03 Office-Based Opioid Treatment-Proposed New Rule

4730-4-03 Office-Based Treatment for Opioid Addiction-Proposed to Rescind

4730-4-04 Medication-Assisted Treatment Using Naltrexone-Proposed New Rule

4730-4-04 Medication-Assisted Treatment Using Naltrexone-Proposed to Rescind

The draft rules make the following changes:

- Eliminates any requirements for DATA 2000 waiver for prescribing buprenorphine in line with the federal changes;
- Updates terminology;
- Updates the options for obtaining naloxone, including directing prescribers and patients to www.naloxone.ohio.gov;
- Clarifies that office based opioid treatment may be initiated prior to completion of the full assessment and lab testing;
- Updates the protocols for treatment;
- Amends the behavioral health treatment section to clarify that if psychosocial interventions are not available or if the patient declines to participate, the prescriber shall continue to treat the patient with buprenorphine so long as the patient adheres to other treatment requirements; and
- Allows dosage to exceed 24 mg of buprenorphine daily dose if the prescriber is board certified addiction specialist or addiction psychologist or a consultation has been obtained from a specialist recommending the higher dose. The dosage may not exceed 32 mg per day;
- Allows for the use of methadone for the alleviation of withdrawal symptoms as permitted by 21 C.F.R. 1306.07(b);
- Simplifies and consolidates the documentation requirements for healthcare providers; and
- Eliminates many of the specific steps for patient assessments, with a general requirement for assessments to gather sufficient information and data to justify the use of the treatment interventions.

The proposed rules retain the requirement for 8 hours of CME related to substance use disorder and addiction every two years for physicians and physician assistants providing office-based opioid treatment.

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.**

   4730-4-01: Authorized by 4730.07, 4730.55; Amplifies:4730.55, 4730.56

   4730-4-02: Authorized by 4730.07, 4730.55; Amplifies: 4730.55, 4730.56

   4731-4-03: Authorized by 4730.07, 4730.55; Amplifies: 4730.20, 4730.55, 4730.56

   4731-4-04: Authorized by 4730.07, 4730.55; Amplifies: 4730.55, 4730.56

   4731-33-01: Authorized by 4731.05, 4731.056; Amplifies: 4731.056, 4731.83

   4731-33-02: Authorized by 4731.05, 4731.056; Amplifies: 4731.056, 4731.83

   4731-33-03: Authorized by 4731.05, 4731.056; Amplifies: 4731.056, 4731.83

   4731-33-04: Authorized by 4731.05, 4731.056; Amplifies 4731.056, 4731.83

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.

   The rules do not implement a federal requirement. The rules reflect changes in federal law, and eliminate any requirements for the DATA 2000 waiver for prescribing buprenorphine.

5. **If the regulation implements a federal requirement, but 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)?**

   Sections 4730.55 and 4731.056 of the Revised Code require the State Medical Board of Ohio to adopt these rules. The rules implement the policy of the State of Ohio to set minimum standards for the provision of treatment of substance use disorders with medication.

7. **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 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.

Since May 2023 through the present, the State Medical Board has regularly met with representatives of Mental Health and Addiction Services, Ohio Department of Health, Ohio Department of Medicaid, Ohio Pharmacy Board, Ohio Nursing Board and other state agencies to discuss issues related to opioid treatment for patients with substance use disorders. In June 2023, the State Medical Board held three virtual meetings with interested parties to solicit comments related to these rules. The meeting attendees included representatives from the Ohio Medical Association, Ohio Hospital Association, Ohio Society of Addiction Medicine, Ohio Psychiatric Physicians Association, Ohio Osteopathic Association, Academy of Medicine of Cleveland & Northern Ohio, physicians practicing addiction medicine, entities treating patients with substance use disorder, and representatives from state agencies.

The rules were drafted and provided to the State Medical Board at its regularly scheduled meeting in September 2023. The Board approved the circulation of rules to interested parties and the rules were sent out for comment from September 15, 2023 through October 6, 2023.

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

The Board received comments from eighteen individuals and entities. A spreadsheet summarizing the comments and copies of the comments received are attached.

After review of the comments received, the rules were revised and reviewed with representatives of the Mental Health and Addiction Services, Ohio Department of Health, Ohio Department of Medicaid, Ohio Pharmacy Board, Ohio Nursing Board and other state agencies.

The rules were changed based on input from the commenters, as follows:

- Updating terminology related to substance use disorder and medications for opioid use disorder or “MOUD”;

- Updating options for obtaining naloxone and eliminating references to naloxone "kit";
- Clarifying that treatment may be initiated prior to completion of the full assessment and lab testing;
- Updating the treatment protocols;
- Allowing for the use of methadone for the alleviation of withdrawal symptoms as permitted by 21 CFR 1306.07(b);
- Simplifying and consolidating the documentation requirements for healthcare providers; and
- Eliminating many of the specific steps for patient assessments.

The revised rules were reviewed by the State Medical Board at its meeting on March 13, 2024 and approved for filing with the Common Sense Initiative.

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?

Rules 4730-4-02 and 4731-33-02, related to ambulatory withdrawal were developed based upon three published protocols:

"ASAM Criteria, Fourth Edition" by the American Society of Addiction Medicine, and available at www.asam.org

"TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the Substance Abuse and Mental Health Services Administration and available at https://store.samhsa.gov

"Clinical Practice Guideline on Alcohol Withdrawal Management by the American Society of Addiction Medicine and available at https://www.asam.org/quality-care/clinical-guidelines/alcohol-withdrawal-management-guideline.

Rules 4730-4-03 and 4731-33-03, related to office based opioid treatment, were developed based on two published protocols:

"TIP 63 Medications for Opioid Use Disorder (2021)" published by the Substance Abuse and Mental Health Services Administration and available at https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

"The ASAM National Practice Guideline for the treatment of Opioid Use Disorder: 2020 Focused Update, " available at https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

The Board also received significant input from the medical director and other staff of the Ohio Department of Mental Health and Addiction Services.

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? ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

As listed in paragraphs 9 and 10, the State Medical Board has considered alternative language and has made significant changes to the existing rules. Sections 4730.55 and 4731.056 of the Revised Code require the State Medical Board to promulgate rules for physician assistants and physicians on the use of medications for treatment of substance use disorder.

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

The State Medical Board is the agency authorized to regulate the prescribing practices of physicians and physician assistants. The Board staff worked closely with other state agencies, including the Ohio Department of Mental Health and Addiction Services, to ensure that the proposed rules are consistent with and not duplicative of other existing regulations.

14. 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 website of the State Medical Board of Ohio and information concerning the rules will be included in informational materials provided to licensees through on-line newsletters. Medical Board staff members are available by telephone and e-mail to answer questions.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

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

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

a. The impacted business community includes physicians and physician assistants treating patients with substance use disorder with medication.

b. The adverse impact includes possible formal disciplinary action and civil penalties up to $20,000 for violation of the rules. In addition, the rules require that physicians and

physician assistants providing office-based opioid treatment must complete at least eight hours of continuing medical education relating to substance use disorder and addiction every two years.

The cost for CME course options vary. ASAM State of the Art Course in Addiction Medicine is a two-day in-person event offering up to 20 AMA PRA Category 1 Credits at a cost of up to $1,090 depending on membership status. https://stateoftheart.asam.org/aaStatic.asp?SFP=WkZBUEtGTEtAMTgyMzlAUmVnaXN0cmF0aW9uICYgUmF0ZXM

The AMA provides information for CME courses for prescribing to treat substance use disorder that meet the DEA one-time eight hour training requirements and many of the courses are available at no cost. https://edhub.ama-assn.org/course/302

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

Many of the proposed changes are intended to reduce the regulatory burden on the impacted business community, including the following:

- Elimination of the documentation requirement for doses of buprenorphine exceeding sixteen milligrams per day;
- Allowing dosage to exceed 24 mg of buprenorphine daily dose up to 32 mg daily dose if the prescriber is board certified addiction specialist or addiction psychologist or a consultation has been obtained from a specialist recommending the higher dose.
- Simplifying and consolidating the documentation requirements for healthcare providers;
- Eliminating many of the specific steps for patient assessments, with a general requirement for assessments to gather sufficient information and data to justify the use of the treatment interventions;
- Amending the behavioral health treatment section to clarify that if psychosocial interventions are not available or if the patient declines to participate, the prescriber shall continue to treat the patient with buprenorphine so long as the patient adheres to other treatment requirements; and
- Clarifying that office based opioid treatment may be initiated prior to completion of the full assessment and lab testing.

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

The State Medical Board is required by Sections 4730.55 and 4731.056 of the Revised Code to have rules that address substance use disorder treatment with medication and include withdrawal management, relapse prevention, patient assessment, individual treatment planning, counseling and recovery supports, diversion control, and other topics selected by the Board.

Regulatory Flexibility

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

The public safety requirements for patients require consistency in their application to all State Medical Board licensees undertaking this treatment and are not amenable to exemptions or alternative means of compliance for small business.

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?

Due process requires the State Medical Board to consistently apply its rules such that all prescriber licensees are fairly treated.

20. 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.

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy, in a private office or public sector clinic that is not otherwise regulated by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid use disorder. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) Addiction specialist physician" means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine ("ABPM");

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology ("ABPN");

(3) Subspecialty board certification in addiction medicine by the American osteopathic association ("AOA"); or

(4) Certification by the American board of addiction medicine ("ABAM")

(D) "Medications for Opioid Use Disorder or "MOUD" refers to all medications approved by the United States food and drug administration for the treatment of opioid use disorder.

(E) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress, as determined by application of the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."

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

(G) For purposes of the rules in this chapter:

(1) "Qualified behavioral healthcare provider" means the following healthcare providers practicing within the scope of the professional license:

(a) Addiction medicine specialist physician or board certified psychiatrist, licensed under Chapter 4731 of the Revised Code;

(b) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732 of the Revised Code;

(c) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758 of the Revised Code;

(d) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757 of the Revised Code;

(e) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

(f) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; and

(g) Advanced practice registered nurse, licensed under Chapter 4723 of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730 of the Revised Code who practices under a

supervision agreement with a board certified addiction psychiatrist, board certified addiction medicine specialist, or psychiatrist who is licensed as a physician under Chapter 4731 of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and rules.

(H) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(J) "Induction phase" means the phase of MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) “Stabilization phase” means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) “Maintenance phase" means the ongoing period of time when the patient’s medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of medical withdrawal management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory withdrawal management does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. OBOT includes treatment with all controlled substance medications approved by the United Stated food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) "Medication-assisted treatment" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

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

(F) For purposes of the rules in Chapter 4730-4 of the Administrative Code:

(1) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of the professional license:

(a) Board certified addictionologist, board certified psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(b) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;

(c) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;

(d) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

(e) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center;

(f) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code;

(g) Advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addictionologist, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in cmpliance with Ohio and federal laws and

rules.

(G) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(H) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(I) "Induction phase" means the phase of opioid treatment during which maintenance medication dosage levels are adjusted until a patient attains stabilization.

(J) "Stabilization phase" means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.

(K) "Withdrawal management" or "detoxification" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse. Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of drug addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory detoxification does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised

Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

4730-4-02 Standards and procedures for withdrawal management for substance use disorder.

(A) In order to provide ambulatory withdrawal management, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with the following requirements:

(1) The physician assistant shall hold a valid prescriber number;

(2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement;

(3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing; and

(4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory withdrawal management for any substance use disorder the physician assistant shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician assistant shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(E) Ambulatory withdrawal management for opioid use disorder.

(1) The physician assistant shall provide ambulatory withdrawal management only when the following conditions are met:

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management; and

(b) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-WM or II-WM level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include a review of the patient’s prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall complete as soon as possible following initiation of treatment.

(5) The physician assistant shall inform the patient about the following before treatment for opioid withdrawal is initiated:

(a) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in MOUD treatment;

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician assistant shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate

an individualized treatment plan based on the needs of the specific patient.

(7) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraph (D) of rule 4730-4-03 of the Administrative Code.

(8) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician assistant shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a higher level of care, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.

(9) The physician assistant shall comply with the following requirements for the use of medication:

(a) The physician assistant may treat the patient's withdrawal symptoms with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American society of addiction medicine's "National Practice Guideline" (https://www.asam.org/), which is available from the medical board's website at https://med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product), unless contraindicated, in which case buprenorphine mono-product may be utilized.

(b) The physician assistant shall not use anesthetic agents to treat the patient's withdrawal symptoms.

(c) The physician assistant shall comply with the following:

(i) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is effective in suppressing withdrawal symptoms and is well tolerated by the patient.

(b) The dosage level shall be consistent with the currently accepted standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not prescribe nor dispense more than one week of unsupervised or take-home medications for the patient.

(10) The physician assistant shall offer the patient a prescription for an overdose reversal drug, directly provide them with the overdose reversal drug, or direct the patient to an easily accessible source to obtain the overdose reversal drug, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(a) The physician assistant shall ensure that the patient, and if possible, those residing with the patient receives instruction on the drug's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician assistant shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(c) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain the overdose reversal drug without a prescription.

(11) The physician assistant shall take steps to reduce the risk of medication diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician assistant who provides ambulatory withdrawal management for benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/. (Search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory withdrawal management for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician assistant shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment;.

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

(d) The safe storage and disposal of prescribed medications.

(5) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that medication dosage can be adjusted if needed.

(a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for the use of licit and/or illicit drugs.

(b) The physician assistant shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher

level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(G) The physician assistant who provides ambulatory withdrawal management for withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and “Clinical Practice Guideline on Alcohol Withdrawal Management by the American society of addiction medicine available from the American society of addiction medicine website at the following link:http://www.asam.org/quality-care/clinical-guidelines/alcohol-withdrawal-management-guideline.

(1) The physician assistant shall provide ambulatory withdrawal from alcohol with medication management only when patient has sufficient social, medical, and psychiatric stability and when they do not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that the dosage can be adjusted if needed:

(a) The physician assistant shall require the patient to undergo toxicological screenings in order to assess for the presence of alcohol metabolites, licit or illicit drugs;

(b) The physician assistant shall consider revising the treatment plan or referring a patient who has a positive toxicological screening test to a higher level of care; and

(c) The physician assistant shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

4730-4-02 **Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) In order to provide ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with all of the following requirements:

(1) The physician assistant shall hold a valid prescriber number.

(2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement.

(3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing, including holding a DATA 2000 waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility.

(4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, for any substance use disorder the physician assistant shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

(1) Both orally and in writing, give the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an opioid treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using Naltrexone or who holds the DATA 2000 waiver to provide office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the

date of the referral shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory detoxification for opioid addiction.

(1) The physician assistant shall provide ambulatory detoxification only when all of the following conditions are met:

(a) A positive and helpful support network is available to the patient.

(b) The patient has a high likelihood of treatment adherence and retention in treatment.

(c) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a mood-altering drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, third edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory detoxification, the physician assistant shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid addiction and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) Prior to providing ambulatory detoxification, the physician assistant shall conduct a biomedical and psychosocial evaluation of the patient, to include the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually transmitted diseases in patients with known risk factors.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall document the reason in the medical record.

(5) The physician assistant shall request and document review of an OARRS report on the patient.

(6) The physician assistant shall inform the patient about the following before the patient is undergoing withdrawal from opioids:

(a) The detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse following detoxification without entry into medication-assisted treatment;

(c) The high risk of overdose and death when there is a relapse following detoxification;

(d) The safe storage and disposal of the medications.

(7) The physician assistant shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a treatment plan based on the needs of the specific patient.

(8) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4730-4-03 of the Administrative Code.

(9) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician assistant shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.

(10) The physician assistant shall comply with the following requirements for the use of medication:

(a) The physician assistant may treat the patient's withdrawal symptoms by use of any of the following drugs as determined to be most appropriate

for the patient.

(i) A drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American society of addiction medicine's "National Practice Guideline" (https://www.asam.org/), which is available from the medical board's website at https://med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record

(b) The physician assistant shall not use any of the following drugs to treat the patient's withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician assistant shall comply with the following:

(i) The physician assistant shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone. Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization

during withdrawal management.

(a) The dosage level shall be that which is well tolerated by the patient.

(b) The dosage level shall be consistent with the minimal standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not allow more than one week of unsupervised or take-home medications for the patient.

(11) The physician assistant shall offer the patient a prescription for a naloxone kit.

(a) The physician assistant shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(c) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(12) The physician assistant shall take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(E) The physician assistant who provides ambulatory detoxification with medication management for withdrawal from benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/. (Search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to

the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory detoxification, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

(4) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

(5) During the ambulatory detoxification, the physician assistant shall regularly assess the patient during the course of treatment so that dosage can be adjusted if needed.

(a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

(b) The physician assistant shall document consideration of referring the patient who has a positive urine and/or toxicology screening to a higher level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(F) The physician assistant who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available from the medical board's website at:

https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory detoxification, the physician assistant shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.

(4) During the course of ambulatory detoxification, the physician assistant shall assess the patient regularly:

(a) The physician assistant shall adjust the dosage as medically appropriate;

(b) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician assistant shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(5) If the patient agrees to enter alcohol treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be

documented in the patient record.

(6) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

4730-4-03 **Office-based opioid treatment.**

(A) A physician assistant who provides office-based opioid treatment(“OBOT”) shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license;

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise;

(5) The physician assistant who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination, and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall complete as soon as possible following initiation of treatment; and

(6) The physician assistant shall provide accurate, objective, and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician assistant who provides OBOT shall establish a treatment plan that includes the following:

(1) The physician assistant's rationale for selection of the specific drug to be used in the treatment based upon discussion of all MOUDs and non-medication options with the patient;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant;

(6) Documentation regarding psychosocial intervention, pursuant to paragraph (D)

of this rule; and

(7) The treatment plan shall be revised if the patient does not show improvement with the original plan.

(C) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update", available from the website of the American society of addiction medicine at: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

(D) The physician assistant shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;

(2) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;

(3) Ensure that psychosocial interventions are person-centered and tailored to the patient's insight, motivation, and stage of recovery;

(4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient's treatment and recovery;

(5) If the psychosocial interventions are not available or if the patient declines to participate, the physician assistant shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;

(6) Psychosocial treatment or intervention includes the following:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management and motivational incentives;

(d) Motivational interviewing;

(e) Behavioral couples counseling;

(f) Twelve-step facilitation; and

(g) Other therapies based on the patient's individual needs;

(7) When necessary, the physician assistant may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4730-4-01 of the Administrative Code; and

(8) The physician assistant may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician assistant determines such intervention would benefit the patient.

(E) The physician assistant who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with the overdose reversal drug, or direct the patient to an easily accessible source to obtain overdose reversal drugs, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(1) The physician assistant shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the overdose reversal drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(2) The physician assistant shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain overdose reversal drugs without a prescription.

(F) In addition to paragraphs (A) to (E) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with the following requirements:

(1) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www,accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products

for use in OBOT.

(2) The physician assistant may prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue the drug. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall also consider these options and consider consultation for another healthcare provider. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.

(5) During the maintenance phase, the physician assistant shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving.

(a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product,

unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.

(6) The physician assistant shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, conducting random pill counts, and checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the physician assistant obtains a consultation from a addiction specialist physician recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance within the scope of their professional license.

4730-4-03 **Office-based treatment for opioid addiction.**

(A) A physician assistant who provides OBOT shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license; and

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise.

(B) The physician assistant who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprenhensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and the pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall document the reasons in the medical record.

(C) The physician assistant who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician assistant's rationale for selection of the specific drug to be used in the medication-assisted treatment;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov/.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American society of addiction medicine in 2015, available from the website of the American society of addiction medicine at: https://www.asam.org/.

(E) The physician assistant shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4730-4-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

(1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

(2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management/motivational incentives;

(d) Motivational interviewing; or

(e) Behavioral couples counseling.

(3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.

(4) When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4730-4-01 of the Administrative Code, the physician assistant shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program. If the patient is required to participate in a twelve step program, the physician

assistant shall require the patient to provide documentation of on-going participation in the program.

(5) If the physician assistant refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health servics provider, the physician assistant shall document the referral and the physician assistant's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician assistant who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician assistant shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(2) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(G) In addition to paragraphs (A) to (F) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with all of the following requirements:

(1) The provision shall be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician assistant shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration;

(d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication included in the patient record; or

(e) When the patient has an allergy to or intolerance of a buprenorphine/naloxone combination product, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documentation included in the patient record.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall taper the other drug to discontinuation, if it is safe to do so. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document progress with achieving the tapering plan.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.

(5) During the stabilization phase, when using any oral formulation of buprenorphine, the physician assistant shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

(a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product containing naloxone.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(6) The physician assistant shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician assistant shall also require urine drug screens, serum medication levels, or oral fluid drug testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(7) When using any oral formulation of buprenorphine, the physician assistant shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance with the scope of their professional license.

4730-4-04 Medication-assisted treatment using naltrexone.

(A) In addition to the requirements in paragraphs (A) to (E) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with the following requirements:

(1) Before initiating naltrexone, the physician assistant shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The physician assistant shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician assistant shall use oral naltrexone only for treatment of patients who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician assistant shall conduct random pill counts and require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid or alcohol dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have difficulties with treatment adherence.

(2) The dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) The physician assistant shall incorporate relapse prevention strategies into

counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

4730-4-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements in paragraphs (A) to (F) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

(1) Prior to treating a patient with naltrexone, the physician assistant shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician assistant shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

(2) The physician assistant shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician assistant shall require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

(2) The injection dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall incorporate relapse prevention strategies into

counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy in a private office or public sector clinic that is not otherwise regulated by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid use disorder. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) “Addiction specialist physician” means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine (“ABPM”);

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology (“ABPN”);

(3) Subspecialty board certification in addiction medicine by the American osteopathic association (“AOA”); or

(4) Certification by the American board of addiction medicine (“ABAM”)

(D) “Medications for Opioid Use Disorder” or “MOUD” refers to all medications approved by the United States food and drug administration for the treatment of opioid use disorder.

(E) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress as determined by application of the diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."

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

(G) For purposes of the rules in this chapter:

(1) "Qualified behavioral healthcare provider" means the following healthcare providers practicing within the scope of the professional license:

(a) Addiction medicine specialist physician, or board-certified psychiatrist, licensed under Chapter 4731 of the Revised Code;

(b) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732 of the Revised Code;

(c) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758 of the Revised Code;

(d) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757 of the Revised Code;

(e) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center.

(f) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; and

(g) An advanced practice registered nurse, licensed under Chapter 4723 of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730 of the Revised Code who practices under a

supervision agreement with a board-certified addiction psychiatrist, board certified addiction medicine specialist, or psychiatrist who is licensed as a physician under Chapter 4731 of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and rules.

(H) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Community mental health services provider," has the same meaning as in section 5119.01 of the Revised Code.

(J) "Induction phase," means the phase of MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) “Stabilization phase” means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) “Maintenance phase," means the ongoing period of time when the patient’s medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance or evidence that supports the expectation that such a syndrome would develop without the provision of medical withdrawal management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory withdrawal management does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) "Medication-assisted treatment" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

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

(F) For purposes of the rules in Chapter 4731-33 of the Administrative Code:

(1) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of the professional license:

(a) Board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(b) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;

(c) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;

(d) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center.

(e) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center;

(f) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code; or

(g) An advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addictionologist, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and

rules.

(G) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(H) "Community mental health services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Induction phase," means the phase of opioid treatment during which maintenance medication dosage levels are adjusted until a patient attains stabilization.

(J) "Stabilization phase," means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.

(K) "Withdrawal management" or "detoxification" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse. Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management or detoxification occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance or evidence that supports the expectation that such a syndrome would develop without the provision of detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory detoxification does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised

Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

4731-33-02 **Standards and procedures for withdrawal management for substance use disorder.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state laws and rules applicable to prescribing.

(B) Prior to providing ambulatory withdrawal management for any substance use disorder the physician shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) When providing withdrawal management for opioid use disorder the physician may use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(E) Ambulatory withdrawal management for opioid use disorder.

(1) The physician shall provide ambulatory withdrawal management only when the following conditions are met:

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management.; and

(b) There is little risk of medication diversion.

(2) The physician shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-WM or II-WM level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory withdrawal management, the physician shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include

a review of the patient's prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician complete as soon as possible following initiation of treatment.

(5) The physician shall inform the patient about the following before treatment for opioid withdrawal is initiated:

(a) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in MOUD treatment;

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate an individualized treatment plan based on the needs of the specific patient.

(7) For persons projected to be involved in withdrawal management for six months or less, the physician shall offer the patient counseling as described in paragraph (D) of rule 4731-33-03 of the Administrative Code.

(8) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a higher level of care.

(9) The physician shall comply with the following requirements for the use of medication:

(a) The physician may treat the patient's withdrawal symptoms with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American Society of Addiction Medicine's National Practice Guideline (https://www.asam.org/), which is available on the Medical Board's website at: https://www.med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product), unless contraindicated, in which case buprenorphine mono-product may be utilized.

(b) The physician shall not use anesthetic agents to treat the patient's withdrawal symptoms:

(c) The physician shall comply with the following:

(i) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is effective in suppressing withdrawal symptoms and is well tolerated by the patient.

(b) The dosage level shall be consistent with the currently accepted standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician shall not prescribe nor dispense more than one week of unsupervised or take-home medications for the patient.

(10) The physician shall offer the patient a prescription for an overdose reversal drug, directly provide them with the overdose reversal drug, or direct the patient to an easily accessible source to obtain the overdose reversal drug,

such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(a) The physician shall ensure that the patient, and if possible, those residing with the patient receives instruction on the drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(b) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(c) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain the overdose reversal drug without a prescription.

(11) The physician shall take steps to reduce the risk of medication diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician who provides ambulatory withdrawal management for benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory withdrawal management for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall perform an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory withdrawal management, the physician shall conduct a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment.;

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

(d) The safe storage and disposal of prescribed medications.

(5) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that medication dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for the use of licit and/or illicit drugs.

(b) The physician shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher level of care.

(c) The physician shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

(G) The physician who provides ambulatory withdrawal management for withdrawal from alcohol shall comply with paragraphs (A), (B), and (C) of this rule and "Clinical Practice Guideline on Alcohol Withdrawal Management by the American society of addiction medicine available from the American society of addiction medicine website at the following link: https://www.asam.org/quality-care/clinical-guidelines/alcohol- withdrawal-management-guideline.

(1) The physician shall provide ambulatory withdrawal from alcohol with medication management only when patient has sufficient social, medical, and psychiatric stability and when they do not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall

perform an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory withdrawal management, the physician shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that the dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo toxicological screenings in order to assess for the presence of alcohol metabolites, licit or illicit drugs;

(b) The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening test to a higher level of care; and

(c) The physician shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

4731-33-02 **Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state laws and rules applicable to prescribing, including holding a "DATA 2000" waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4731-33-01 of the Administrative Code, for any substance use disorder the physician shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

(1) Both orally and in writing, give the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician determines that such treatment is clinically appropriate, the physician shall refer the patient to an opioid treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using Naltrexone or who holds the DATA 2000 waiver to provide office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder the physician may use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory detoxification for opioid addiction.

(1) The physician shall provide ambulatory detoxification only when all of the following conditions are met:

(a) A positive and helpful support network is available to the patient.

(b) The patient has a high likelihood of treatment adherence and retention in treatment.

(c) There is little risk of medication diversion.

(2) The physician shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a mood-altering drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, third edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory detoxification, the physician shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid addiction and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) Prior to providing ambulatory detoxification, the physician shall conduct a biomedical and psychosocial evaluation of the patient, to include the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall document the reason in the medical record.

(5) The physician shall request and document review of an OARRS report on the patient.

(6) The physician shall inform the patient about the following before the patient is undergoing withdrawal from opioids:

(a) The detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse following detoxification without entry into medication-assisted treatment;

(c) The high risk of overdose and death when there is a relapse following

detoxification;

(d) The safe storage and disposal of the medications.

(7) The physician shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a treatment plan based on the needs of the specific patient.

(8) For persons projected to be involved in withdrawal management for six months or less, the physician shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4731-33-03 of the Administrative Code.

(9) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record.

(10) The physician shall comply with the following requirements for the use of medication:

(a) The physician may treat the patient's withdrawal symptoms by use of any of the following drugs as determined to be most appropriate for the patient.

(i) A drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms.

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American Society of Addiction Medicine’s National Practice Guideline (https://www.asam.org/), which is available on the Medical Board’s website at: https://www.med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record.

(b) The physician shall not use any of the following drugs to treat the patient’s withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician shall comply with the following:

(i) The physician shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone. Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is well tolerated by the patient.

(b) The dosage level shall be consistent with the minimal standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician shall not allow more than one week of unsupervised or take-home medications for the patient.

(11) The physician shall offer the patient a prescription for a naloxone kit.

(a) The physician shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(c) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain a kit without a prescription.

(12) The physician shall take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(E) The physician who provides ambulatory detoxification with medication management for withdrawal from benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board’s website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

(4) The physician shall instruct the patient not to drive or operate dangerous machinery during treatment.

(5) During the ambulatory detoxification, the physician shall regularly assess the patient during the course of treatment so that dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

(b) The physician shall document consideration of referring the patient who has a positive urine and/or toxicology screening to a higher level of care.

(c) The physician shall take steps to reduce the chances of diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(F) The physician who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory detoxification, the physician shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.

(4) During the course of ambulatory detoxification, the physician shall assess the

patient regularly:

(a) The physician shall adjust the dosage as medically appropriate;

(b) The physician shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(5) If the patient agrees to enter alcohol treatment and the physician determines that such treatment is clinically appropriate, the physician shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(6) The physician shall instruct the patient not to drive or operate dangerous machinery during treatment.

4731-33-03 **Office-based opioid treatment.**

(A) A physician who provides office-based opioid treatment (“OBOT”) shall comply with the following requirements:

(1) Before initiating OBOT, the physician shall comply with section 3719.064 of the Revised Code;

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license;

(4) The physician who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician shall complete as soon as possible following initiation of treatment; and

(5) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician who provides OBOT shall establish a treatment plan that includes the following:

(1) The physician's rationale for selection of the specific drug to be used in the treatment based upon discussion of all MOUDs and non-medication options with the patient;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician;

(6) Documentation regarding psychosocial interventions, pursuant to paragraph (D) of this rule; and

(7) The treatment plan shall be revised if the patient does not show improvement

with the original plan.

(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 “Medications for Opioid Use Disorder” (2021) available from the https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

(2) “ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

(D) The physician shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;

(2) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;.

(3) Ensure that psychosocial interventions are person-centered and tailored to the patient’s insight, motivation, and stage of recovery;

(4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient’s treatment and recovery;

(5) If the psychosocial interventions are not available or if the patient declines to participate, the physician shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;

(6) Psychosocial treatment or intervention includes the following:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management and motivational incentives;

(d) Motivational interviewing;

(e) Behavioral couples counseling;

(f) Twelve-step facilitation; and

(g) Other therapies based on the patient's individual needs;

(7) When necessary, the physician may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4731-33-01 of the Administrative Code; and

(8) The physician may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician determines such intervention would benefit the patient.

(E) The physician who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with the overdose reversal drug, or direct the patient to an easily accessible source to obtain overdose reversal drugs, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(1) The physician shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the overdose reversal drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(2) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(3) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain overdose reversal drugs without a prescription.

(F) In addition to paragraphs (A) to (E) of this rule, the physician who provides OBOT using buprenorphine products shall comply with the following requirements:

(1) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician may prescribe buprenorphine without naloxone (buprenorphine

mono-product) only in the following situation:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

(a) The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue the drug. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall also consider these options and consider consultation with another healthcare provider. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. The physician shall see the patient at least once a week during this phase.

(5) During the maintenance phase, the physician shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving.

(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than

a thirty-day supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.

(6) The physician shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, conducting random pill counts, checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the prescriber is an addiction specialist physician, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

(b) The physician shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician shall document in the patient record the rationale for the use of the extended-release buprenorphine product

(d) The physician who orders or prescribes an extended-release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care professional acting in accordance within the scope of their professional license.

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

(A) A physician who provides OBOT shall comply with all of the following requirements:

(1) Before initiating OBOT, the physician shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication; and

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license.

(B) The physician who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician shall document the reasons in the medical record.

(C) The physician who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician's rationale for selection of the specific drug to be used in the medication-assisted treatment;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American society of

addiction medicine in 2015, available from the website of the American society of addiction medicine at https://www.asam.org/.

(E) Except if the physician providing OBOT is a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4731-33-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

(1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

(2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management/motivational incentives;

(d) Motivational interviewing; or

(e) Behavioral couples counseling.

(3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.

(4) When clinically appropriate and if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4731-33-01 of the Administrative Code, the physician shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program or appropriate self-help recovery program. If the patient is required to participate in a twelve step program or self-help recovery program, the physician shall require the patient to provide documentation of on-going participation in the program.

(5) Additional requirements related to the provider of behavioral health services:

(a) If the physician providing OBOT is a board certified addictionologist, psychiatrist, or board certified psychiatrist, the physician may personally provide behavioral health services for addiction.

(b) If the physician refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician shall document the referral and the physician's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(2) The physician shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(3) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain a kit without a prescription.

(G) In addition to paragraphs (A) to (F) of this rule, the physician who provides OBOT using buprenorphine products shall comply with all of the following requirements:

(1) The provision shall be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the

evidence for the decision to use buprenorphine mono-product in the medical record:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration;

(d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record; or

(e) When the patient has an allergy to or intolerance of a buprenorphine/naloxone combination product, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documenation included in the patient record.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

(a) The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall taper the other drug to discontinuation, if it is safe to do so. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document progress with achieving the tapering plan.

(4) During the induction phase the physician shall not prescribe a dosage that exceeds the recommendaton in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. The physician shall see the patient at least once a week during this phase.

(5) During the stabilization phase, when using any oral formulation of buprenorphine, the physician shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(6) The physician shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician shall require urine drug screens, serum medication levels, or oral fluid testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(7) When using any oral formulation of buprenorphine, the physician shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(9) The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

(b) The physician shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician shall document in the patient record the rationale for the

use of the extended-release buprenorphine product.

(d) The physician who orders or prescribes an extended-release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care professional acting in accordance with the scope of the professional license.

4731-33-04 Medication-assisted treatment using naltrexone.

(A) In addition to the requirements of paragraphs (A) to (E) of rule 4731-33-03 of the Administrative Code, the physician using naltrexone to treat opioid use disorder shall comply with the following requirements:

(1) Before initiating naltrexone, the physician shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The physician shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician shall use oral naltrexone only for treatment of patients who are highly motivated.

(a) The dosage regime shall strictly comply with the food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician shall conduct random pill counts and require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(B) The physician may treat a patient with extended-release naltrexone for opioid or alcohol dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician should consider treatment with extended-release naltrexone for patients who have difficulties with treatment adherence.

(2) The dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider,

as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) to (F) of rule 4731-33-03 of the Administrative Code, the physician using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

(1) Prior to treating a patient with naltrexone the physician shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

(2) The physician shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician shall require urine drug screens,serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualifed behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(B) The physician may treat a patient with extended-release naltrexone for opioid dependence or for co-occuring opioid and alcohol use disorders.

(1) The physician should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

(2) The injections dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider,

as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

Support		
The Academy of Medicine of Cleveland & Northern Ohio (AMCNO)	**4731-33-03: (E)** Support Board's removal of behavior health treatment requirement. The orignial requirement had potential to decrease access to care and cause delays in care. **4731-33-03: (G)(7): Dosage Limits:** Support board's change to allow for prescribing of 32 mg per day of buprenorphine if a prescriber is a board certified addiction specialist or addiction psychiatrist. Believe clincially this change is appropriate and allows precriber to adjust the dosage when appropriate.	
Ohio Board of Nursing	**4731-33-01(L):** is "abuse" there intentionally or should a different term be used?; **4731-33-01(M)(3)**: addiction instead of addition.; **4731-33-02(B)(1**): should something like "…and the communication shall be documented in the patient's medical record" be added?; **4731-33-02(E)(2)**: should cite be to 33-02(D)(4) not (B)(4)?; **4731-33-03(E)(2)**: word choice question: "denied" in place of "declined"?;	Is it intentional when "urine and/or other" is kept versus the times when "urine and/or other is deleted? It seems "urine and/or other" is included within toxicological so it is not needed (except for any time when a urine test itself is specifically required). Compare 33-02(D)(9) and 33-02(E)(5)(a),(b), and (c), for example.; Also in 33-02(E)(5)(a) and/or 33-02(D)(9), should alcohol metabolities be added? Compare 33-02(F)(4)(a). "...to assess for the presence of alcohol metabolites, licit, or illicit drugs." Or is "presence of alcohol metabolites" intentionally only referenced in 33-02(F)(4)(a)?; Should "kit" be removed throughout, in case a newly approved overdose reversal drug is not a kit
Dr. Nishit Mehta - Summa Health	Question regarding whether rules apply to free standing emergency departments	
Healthy State Alliance	Support the Board in efforts to modernize office-based OUD treatment; Support the prescibing of sunlingual buprenorphine mono-product without limitations, concerens about injection misuse and diversion of mono-formulated buprenorphine were misguided; Strongly support the Board eliminating the requirement that patients adhere to psychosocial treatment to continue buprenorphine. While counseling services have value, they do not redue the risk of dying from an overdose, this approaching ensures medication won't be witheld based on these factors.	
onefifteen	Appreciate the Board's efforts to update the rules by relaxing the requirements for psychosocial interventions,recognizing that higher doses of buprenorphine are sometimes medically indicated, and revising its language to use terminology consistent with the DSM5-TR.	
Ohio Society of Addiction Medicine	Proposal represents an improvement over the previous iteration; Appreciate the Board proposing to revise a strict cap on more than 24mg buprenorphine per day, OHSAM feels the language is still too restrictive.	
The Ohio Institute for SUD Excellence	Appreciate the Board's efforts to update these rules by relaxing the requirements for psychosocial interventions, recognizing that the evolving climate of the opioid epidemic, higher doses of buprenorphine are often medically indicated, and revising its language to use terminology consistent with the evolving science.	
Ohio Association for the Treatment of Opioid Dependence	Make positive changes, including streamling and clarifying requirements, updating certain terms and definitions, recognizing peer supporters and case management, and emphasizing a harm-reduction or patient-centered approach to medication-assisted-treatment; OATOD encourages OBOT practitioners to consult, collaborate and refer patients in need of a higher level of care to community MH/SUD providers for psychosocial services and more intensive MAT services if needed - amended paragraphs (E) of rules 4731-33-03 and 4730-4-03 laregly appear to reflect this practice. OATAD recommends that both rules continue to require physicians and PAs to document the referral of psychosocial services to patients. This should help keep OBOT practitioners aware of such resources in their communities.	

Recommend Changes		
The Academy of Cleveland & Northern Ohio (AMCNO)	**4731-33-03: (A)(3): CME Requirements**: Disagee with the Board's inclusion of 8 hours of "Category 1" CME relating to substance abuse and addition every 2 years to prescribe buprenorphine. This would barriers in place for potential prescribers, as Ohio would be 1 of 2 states (Kentucky) with CME requirements to prescribe buprenorphine.	
MetroHealth	**4731-33-03: Office-Based Treatment for Addiction; 4731-33-04: Medicaiton-Assisted Treatment Using Naltrexone; 4730-4-03 (PA): Office-Based Treatment for Addiction; 4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone:** Recommend removing these regulations for OBOT treatment using naltrexone and buprenorphine (MOUD). Removing Ohio's additional outpatient addiction treatment regulations is a vital step towards combating the opioid crisis. Removing the crucial because: 1) Buprenorphine and Naltrexone are safe, effective and save lives. 2) Extra state regulations create prescribing barriers for providers. 3) Removing regulations will increase the number of PCPs willing to prescribe MOUD and expand treatment access across our state, particularly rural areas. If the rules must stay in place, PCPs with less than 100 MOUD patients should be exempted.	
	Recommend removing state's beuprenorphine regulations and deferring to the standard federal regulations on buprenorphine prescribing. OH regulations attempt to codify medical practices in state law that are not evidence based. Much of what it attempts to regulate falls into the "art of medicine, such as specificed frequency of mandatory visits and urine drug testing. Currently, there is no evidence to suggest the appropriate frequency of visits or how to best monitor a patient with toxicology because the need should be based on unique patient factors. If the state medical board is highly concerned about "pill mills", then I recommend that the state regulations NOT apply to physicians who prescibe OBOT to fewer than 100 patients.	**4731-33-01(C)** : MAT is no longer the recommended term replace with MAUD or MAUD; **(J and K):** Induction and maintenance definitions are inaccurate, Induction is a medical phase of MOUD, during which the dosage levels are adjusted until a patient is no longer in physiological opoid withdrawl. Recommend replacing the defintions for maintenance as "the phase in which a person has been sustained on a steady dose of buprenorphine; **(L)** Replace "substance abuse" with the correct teriminology "substance use disorder"; **4731-33-02: (B)(1)** Remove documentation requirement as it is unnecessarliy burdensome to the clincian; **(B)(2)**Remove requirement for confirmation of acceptance and documentation, in busy PCP the burden is impractical and would; **(D)(1)(a)** allow a clinician to utilize their medical judgement without adding the word social would make this clause less likely to be misinterpreted; **(D)(1)(b)** "The patient has a high likelihood of treatment adherence and retention in treatment", concerned this statement will be used against patient populations that is highly stigmatized and could predispose physicians to implicit bias.; **(D)(1)(c)** "There is little risk of medication diversion", Recommend removal, we should not preemptively decide if a patient is at risk of mediciation diversion before offering treatment.; **(4)(D)(g-k)**: Recommend that a statement be included that a patient can defer the lab tests listed, as they have the right to autonomy to defer lab test such as HIV, hep B, hep C, and a pregnancy test,; **(4)(e)** Recommend amending to "Appropriate physicial examination, which can be conducted in-person or via telehealth.; **(10)(a)(i) and (10)(b)**: There is a DEA exception to using methadone for 3 days to manage opioid withdrawl outside of OTPS. The working here would make it illegal to use this rule.

UC Health - Dr. Carolyn Chan		**4731-33-03 Office Based Buprenophine: (C) (3-7):** "The physician who provided OBOT shall establish and document a treatment plan that includes written, informed consent", recommend removing the requirement for written informed consent, and a signed treatment agreement, this is a documenting burden.; **(D):** Recommend removing TIPS and ASMA protocols, the listed documents are outdated and do not include newer standards of care for buprenorphine inductions; **(3)(e):** "coordinate care with the prescriber for the other drug" working should be changed to add "attempt to coordinate", recommend this clause only apply for chronic medications rather than acute wording should be changed to "If the patient is receiving the medication for a chronic condition and attempt to coordinate care with the prescriber for the other drug"; **(4)** Recommend changing wording to "The physician shall determine when to see the patient based on medical necessity, clinic capacity, and patient preference" from "The physician shall see the patient at least once a week during induction" There is no evidence to suggest that this frequency in necessary, though it may be appropriate for some patients; (**5)(a) and (b**)Change during first 90 days of treatment "physician shall prescribe no more than a 2 week supply of buprenorphine" to "prescribe an appropriate duration of supply based on their clinical OUD stability, medical necessity, and clinic capacity" no evidence a 2 week supply will decrease diversion or overdose risk; **(6)** There is no evidence to suggest requiring UDT decreases diversion and may be a burden of costs to patients, recommend changing language to "The physician shall take steps to reduce the risk chances of buprenorphine diversion, which may include any of the following strategies: by using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, and checking checks of OARRS. The physician shall use any combination of urine drug testing screens, serum medication levels, or oral fluid testing to monitor adherence to the medication. The frequency of this ordering will be based on their medical necessity for treatment and clinical judgment. At minimum, they will use urine drug testing at least twice per year, once in each half of the year." If a patient has ESRD on hemodialysis and is unable to provide a urine drug test, then the physician shall use their judgment and document on how they are monitoring medication adherence.; **(7)** Recommend rewriting clause based on updated evidence supporting 24mg as the standard of care in the era of fentanyl; **(9)(a-d):** Feds have extended-release buprenorphine requirements for REMS, recommend removing clause to decrease doc burden" **MAT treatment using naltrexone: (2)(a-d)** Recommend removing clause, Oral nalrexone is not evidence based for treatment of OUD, it is not approved by FDA for treatment for OUD.
Dr. Dennis Helmuth	**4731-33-03:** The requirement of quarterly urine tests does not always serve a legitimate medical purpose. I have patients maintained on Suboxone where this is not necessary. It's unnecessarily stigmatizing. We're trying to save lives here. Leave the doctor some discretion	
Dr. Seth Sigler, DO, Obstetrics and Gynecology, Addiction Medicine Fellow Summa Health	**4731-4-02:** Issue with obtaining a urine pregnancy test for every patient of childbearing age. Negative urine pregnancy test does not exclude that a woman is not pregnant, miss very early pregnancies. Universal pregnancy testing leads to another charge for the patient that may be unnecessary if the physician can be reasonably certain they are not pregnant	
Dr. Nishit Mehta - Summa Health	**4730-4-02(B)(1):** Should specify it's for opioid use disorder. Otherwise the provision providing information about all medicaitons approved will become burdensome.; **4730-4-02 (D)(4):** Requiring testing for HIV, Hep B, and Hep C will make clinicians less likely to initiate treatment, the requirement will become onerous for emergency providers	
Healthy State Alliance	Support relaxing the prohibition against prescribing an oral dose of buprenorphine greater than 24mgs per day. However, disagree with requiring an addiction specialist consultation to exceed this limt. Because of workforce challenges rural and urban areas do not have available board-certified addiction specialists on hand. Recommend raising the cap to 32mgs, which is the FDA approved limit, and reomove the additional requirements; Remove gabapentin from the list of medications that should not be co-prescribed with buprenorphine, 62% of OUD patients suffer from chronic pain and uncontrolled pain is a major cause of relapse.	
AMERSA	Agreed with Dr. Chan from UC Health; AMERSA is advocating for increasing access to medications for persons with opioid use disorder, ensuring that treatments are evidence-based, and utlizing acceptable, non-stigmatizing, and person-centered language in scientific and public-facing documents	

Dr. Michael E. Martin - Scioto County Health Commissioner	Increase in overdose deaths in Scioto County is in part due to onerous regulations by SMBO. SMBO has criminalized failure to follow the rules. The rules need to be removed in light of the X waiver removal and the Xiulu Ruan vs. United States Supreme Court decision. Reasons why they need removed: Buprenorphine and Naltrexone are safe and effective for OUD, harms associated with diversion are minimal and telehealth flexiblity has not resulted in increased buprenorphine overdose; Removing state regulations allows prescribers to work without unnecessary documentation and will increase the number of prescribers; Current regulations perpetutate the stigma associated with addiction treatment, normalizing accessiblity of buprenorphine can help reduce stigma and foster a more empathetic and supportive community for those in recovery; New rules should allow for increased flexibility in treatment
onefifteen	Believe that there are opportunities to further enable access to evidence-based SUD treatment, including modifying the language to allow for physician's judgment to determine the best course of treatment based on their patients' unique, personalized needs.; As we consider the future of SUD treatment in Ohio, we encourage the Board to consider broader changes to the regulatory code that would make treatment of substance use disorders more similar to treatment of other high-risk, chronic medical and behavioral health conditions, where circumscribed state regulations focus on public health concerns (e.g. communicable disease reporting), and the practice of medicine falls largely under the purview of the physician to adhere to evidence-based best practices and the authority of federal agencies (e.g. DEA). We appreciate the steps that the Ohio State Medical Board took in 2021 to align Ohio's telemedicine rules with those of federal agencies. To remove Ohio's buprenorphine-specific state regulations would align our regulations with forty other states across the U.S. Ultimately, we all share in our desire to reduce the impact of the opioid crisis on Ohioans, who continue to die from accidental overdose at staggering rates.
Ohio Society of Addiction Medicine	**4731-33-02(D)(1)(b):** Remove language stating treatment should only be initiated if there is "high likelihood of treatment adherence and retention in treatment". Feels the language is subjective and stigmatizing for vulnerable, low-income and unhoused populations; **4731-33-03(G)(6)**: Replace the numerical requirements with language clarifying the utility of drug testing and recommending practitioners use it as a tool to address patient compliance, rather than explicitly defining a minimum number of tests per quarter; **4731-33-03(G)(7) Daily dosage guideline for buprenorphine:** Appreciate the Board proposing to revise a strict cap on more than 24mgs of buprenorphine per day, OHSAM feels that the language is still too restrictive to meet the treatment challenges posed by HPSO's. Some patients benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24mg per day). OHSAM is concerned that the Board did not consider whether there are enough ASPs to meet demand of patients in Ohio who may need treatement beyond 24mgs due to HPSOs.

Ohio Institute for SUD Excellence	Current rules compound stigma in both access to appropriate treatment for patients and by creating an arbitrary barrier of entry into the behavioral health workforce by dictating and/or limiting provider deference; Inclusion of harm reduction into any addiction language updates, a harm reduction lens would remove all stigmatizing langugae while prioritizing all patients receiving suboxone, short or long term, based on patient-centered care planning. Dosing ranges would be removed as would counseling requirements; Broaden language when incorporating national practice guidance in rules. Suggests the Board use language such as "the most current version" of guidance from "federal regulatory entities" or "national societies" to prevent confusion and unnecessary revisions of the outdated regulations.; Supports the langugae that state MOUD dosage amount for withdrawal management should be "effective in suppressing withdrawal symptoms" and is "consistent with currently accepted standards of care".
Dr. Roma Amin	Current proposed rules would provide a significant documentation burden for primary care physicians and risk decreasing access for patients, especially in underserved areas
University of Cincinnati Health Addiction Sciences	Same comments as Dr. Chan from UC Health
Ohio Psychiatric Physicians Association	Understand concerns with diverson and misuse of buprenorphine but, must balance those concersn with concerns about adding language to the rules that would restrict access to patients whose lives can be saved with the use of the medication. Studies have found that only 22% of individuals suffering from opioid use disorder receive treatment. Current rules deter many physicians from prescribing buprenorphine to their patients. Restrictions on MAT can lead to prolonged suffering for those with SUD as well as create barriers to treatment.
Dr. Michael Binder	Strongly supports removing the physician and physician assistant regulations from office-based addiciton treatment and medication-assisted treatment using naltrexone. Removing X-waiver was a start, removing outpatient addiction treatment regulations on buprenorphine and naltrexone in Ohio is a vital step towards combating the opioid crisis. FDA already regulated prescribing these mesdication and most state do not have addition buprenorphine regulations. Further regulations make prescribing a life-saving medication much more burdensome.
Janet Baker	Expresses concern that rules are decreasing access to Vivitrol and requiring extra steps for patients.

October 5, 2023

Kimberly Anderson, Chief Legal Officer
Ohio State Medical Board
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Sent via Email to Medical Board at: Kimberly.Anderson@med.ohio.gov

RE: Proposed Rules 4731-33: 01-04

Dear Ms. Anderson,

Thank you for the opportunity to comment on Rules 4731-33: 01-04—Office Based Treatment for Opioid Addiction.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region's professional medical association and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing over 6,700 physicians and medical students from all the contiguous counties in Northern Ohio. We are proud to be the stewards of Cleveland's medical community of the past, present, and future.

The mission of the AMCNO is to support physicians in being strong advocates for all patients and to promote the practice of the highest quality of medicine. With that in mind, we offer the following comments.

4731-33-03: Section (A)(3): Continuing Medical Education Requirements

We respectfully disagree with the Board's inclusion of 8 hours of "Category 1," continuing medical education relating to substance abuse and addiction every two years to prescribe buprenorphine. This requirement puts Ohio in a category outside other states, who do not have such requirements, leading to a potential access issue for our patients. From our research on this topic, we have found only one other state, Kentucky, with a CME requirement to prescribe buprenorphine. The more barriers in place to potential prescribers, the less likely those prescribers are to offer this treatment to patients. With the current shortage of addiction specialists in Ohio, and an opioid epidemic that continues to surge, we ask the board to reconsider this requirement.

4731-33-03: Section (E): Behavioral Health Treatment Requirement

We support the board's removal of the behavioral health treatment requirement, and the change to instead require an assessment of each patient's psychosocial treatment needs in addition to medication. While well-intentioned, the original requirement forcing a physician to work with a behavioral health provider for all patients had the potential to decrease access to care and cause significant delays in care to patients.

4731-33-03: Section (G)(7): Dosage Limits

We support the board's change to allow for the prescribing of 32 mg per day of buprenorphine if a prescriber is a board-certified addiction specialist or addiction psychiatrist, or a consultation has been obtained from such a specialist recommending the higher dose. We believe clinically this change is appropriate and allows for a prescriber to adjust the dosage of medicine when and where appropriate.

Thank you again for the opportunity to comment and for your continued efforts to advocate in the best interest of Ohio's physicians.

Sincerely,

Jen Johns, MPH
AMCNO Executive Director

6111 Oak Tree Blvd., Ste 150
Cleveland, Ohio 44131

Tel: 216.520.1000
Fax: 216.520.0999

academyofmed@amcno.org
www.amcno.org

MetroHealth

CASE WESTERN RESERVE UNIVERSITY
School of Medicine

Date October 4, 2023

Regarding Rule Proposed Amendment

4731-33-93: Office-Based Treatment for Addiction

4731-33-04: Medication-Assisted Treatment Using Naltrexone

4730-4-03 (PA): Office-Based Treatment for Addiction

4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone

Dear State Medical Board of Ohio,

My name is Christina Antenucci MD. I am a physician working in Cleveland at MetroHealth Medical Center. I am both a Family Medicine doctor and an Addiction Medicine specialist. I am writing because the over-regulation of addiction treatment makes it harder for our patients to access life-saving medications.

I have reviewed the proposed amendment to the rules listed above, and strongly support removing these regulations for office-based addiction treatment using naltrexone and buprenorphine (MOUD). The federal government removed the DATA-waiver and now allows any individual with a DEA number to prescribe buprenorphine for opioid use disorder (OUD). Removing Ohio's additional outpatient addiction treatment regulations is a vital step towards combating the opioid crisis.

As the Assistant Program Director of Medication Assisted Treatment at our hospital, I spend a great deal of time training and supporting our primary care physicians (PCPs) in MOUD prescribing. I teach them evidence-based addiction care, and I also teaching them how to adhere to these regulations. I see how these rules create fear, confusion and hesitance. They discourage busy PCPs from prescribing MOUD.

It is crucial we remove these rules because:

1. Buprenorphine and Naltrexone are safe, effective and save lives.
2. Extra state regulations create prescribing barriers for healthcare providers.
3. Removing regulations will increase the number of PCPs willing to prescribe MOUD and expand treatment access across our state, particularly in rural areas.

Several years ago, I saw a patient, "Janet", who had OUD for years. She had seen many physicians, but had never been offered MOUD. She didn't even know it existed. With the help of Buprenorphine and counseling, Janet went from a life of being unemployed, sexually trafficked and homeless to having an apartment, working in a culinary training program and graduating from drug court. Her life was transformed. I often wonder if she would have received MOUD sooner if we made it easier for the PCPs of Ohio to do the right thing - and provide evidence-based addiction care (MOUD).

2500 MetroHealth Drive, Cleveland, OH 44109

If these rules must remain in place, then we need PCPs with less than 100 MOUD patients to be exempted. We know that MOUD in primary care has better outcomes than MOUD in specialty programs (eg. better treatment retention and less illicit opioid use). And many communities have more access to PCPs than addiction specialists. So let's make it possible for our PCPs to provide MOUD access and save lives.

I also strongly recommend the board increase the flexibility of all the listed procedures in these regulations. There should be opportunity for the physician to use their clinical judgment and adjust the care plan based on an individual patient's needs (eg. visit frequency, toxicology testing, script supply and method of buprenorphine induction). In order to engage and retain patients in treatment, we need flexible care that is based on a patient's medical stability and social circumstance and the provider's clinical judgement.

I appreciate your consideration of my comments. Feel free to reach out to me with any additional questions.

Sincerely

Dr. Christina Antenucci

Assistant Program Director of Medication Assisted Treatment

Associate Program Director, Addiction Medicine Fellowship

MetroHealth Medical Center

2500 MetroHealth Drive

Cleveland OH 44109

cantenucci@metrohealth.org

Reference:

Korowynk et al. Opioid Use Disorder in Primary Care: PEER umbrella systematic review of systematic reviews. Canada Family Physician. 2019 May; 65 (5): 321-330.

From: Dipasquale, Anita
To: Anderson, Kimberly
Cc: Eschbacher, Lisa
Subject: Re: Rules
Date: Thursday, October 5, 2023 9:53:40 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png

Hi Kim,

I will send an invitation for 1.

Thanks,

Anita

Thank you,
Anita A. DiPasquale, JD
ADVISORY ATTORNEY
EDUCATION, PRACTICE, & LICENSURE
OHIO BOARD OF NURSING
17 S. High Street, Suite 660
Columbus, Ohio 43215
Phone: 614-466-9546
ADiPasquale@nursing.ohio.gov
www.nursing.ohio.gov
Customer Service: 614-466-3947
How was your experience with the Ohio Board of Nursing?

From: "Anderson, Kimberly" <Kimberly.Anderson@med.ohio.gov>
Date: Thursday, October 5, 2023 at 8:56 AM
To: Anita Dipasquale <ADiPasquale@nursing.ohio.gov>

Cc: "Eschbacher, Lisa" <leschbacher@nursing.ohio.gov>
Subject: RE: Rules

Anita-

I can be available for a Teams call anytime today. Let me know when you have availability. Thanks.

Kim

Kimberly C. Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
O: (614) 466-7207
C: (614) 230-9077
Kimberly.Anderson@med.ohio.gov
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From: Dipasquale, Anita <ADiPasquale@nursing.ohio.gov>
Sent: Wednesday, October 4, 2023 5:33 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Cc: Eschbacher, Lisa <leschbacher@nursing.ohio.gov>
Subject: Rules

Hello Kim,

We appreciate having had the opportunity to review proposed changes to Chapters 4730 and 4733, OAC. I have a few questions about the SMBO draft rules particularly as we begin drafting possible changes to OBN's Chapter 4723-9, OAC, consistent with Section 4723.51(C), ORC. My questions are below. If you are available for a

quick call, that would be much appreciated and may be easier than proceeding via email.

•33-01(L), is “abuse” there intentionally or should a different term be used?

•33-01(M)(3), addiction instead of addition.

•33-02(B)(1), should something like “…and the communication shall be documented in the patient’s medical record” be added?

•33-02(E)(3), should cite be to 33-02(D)(4) not (B)(4)?

•Rule 33-03(E)(2), word choice question: “denied” in place of “declined”?

•Is it intentional when “urine and/or other” is kept versus the times when “urine and/or other” is deleted? It seems “urine and/or other” is included within toxicological so it is not needed (except for any time when a urine test itself is specifically required). Compare 33-02(D)(9) and 33-02(E)(5)(a),(b), and (c), for example.

•Also in 33-02(E)(5)(a) and/or 33-02(D)(9), should alcohol metabolites be added? Compare 33-02(F)(4)(a), “…to assess for the presence of alcohol metabolites, licit, or illicit drugs.” Or is “presence of alcohol metabolites” intentionally only referenced in 33-02(F)(4)(a)?

•Should “kit” be removed throughout, in case a newly approved overdose reversal drug is not a kit.

Thank you in advance for your time and consideration,
Anita

Thank you,
Anita A. DiPasquale, JD
Advisory Attorney
Education, Practice, & Licensure
OHIO BOARD OF NURSING
17 S. High Street, Suite 660
Columbus, Ohio 43215
www.nursing.ohio.gov
Customer Service: 614-466-3947
How was your experience with the Ohio Board of Nursing?
Customer Service Survey

Department of Health hotline at 1-833-4-ASK-ODH.

This message and any response to it may constitute a public record and thus may be publicly available to anyone who requests it.

Dr. Sherry Johnson
President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Attn: Regarding Rule Proposed Amendment

4731-33-93: Office-Based Treatment for Addiction

4731-33-04: Medication-Assisted Treatment Using Naltrexone

4730-4-03 (PA): Office-Based Treatment for Addiction

4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone

Dear President Johnson:

10/5/2023

My name is Carolyn Chan, MD, MHS, I am a board-certified internist and addiction medicine physician. I completed my addiction medicine fellowship in 2021 at Yale Program in Addiction Medicine and internal medicine residency at CWRU/UH Hospitals in Cleveland. I spent a few years practicing as a hospitalist at MetroHealth in Cleveland, the safety net hospital for the city. Now I practice at the University of Cincinnati Medical Center and provide primary care and addiction treatment in outpatient and inpatient settings. I co-host the Curbsiders Addiction Medicine Podcast (Curbsiders.com/addiction), providing clinicians with education and CME on addiction medicine topics. I am writing regarding the proposed revisions for outpatient addiction treatment, which is the clinical care I provide. I would like to provide individual comments from a primary care provider and an addiction treatment expert.

As of 2021, there are an estimated 2.5 million individuals with opioid use disorder (OUD), yet only 22% of them received any medications for OUD (Jones et al., 2023). Buprenorphine is extremely safe, and compared to individuals not receiving treatment, buprenorphine reduces mortality by 38% (Larochelle et al., 2018). The fourth wave of the opioid overdose crisis started in 2015, driven by the introduction of fentanyl and other high-potency synthetic opioids (HPSO) into the U.S. This change in drug supply has caused opioid overdoses to skyrocket. According to Ohio's most recent CDC data, our state ranks 8th regarding the highest drug overdose death rate (CDC, 2021). We must expand access to evidence-based medications for OUD (MOUD).

These proposed rules for outpatient buprenorphine treatment had the intent to decrease the risk of diversion and misuse of the medication. Since they were conceived, further research exists to characterize this risk and the impact of regulations. We must balance the need for broadly accessible, low-barrier treatment for OUD with MOUD against the risk of diversion and misuse and let the evidence guide us in determining how to make this medication safe and accessible to those who need it. **Overall, we strongly support the removal of all the existing OH Outpatient Addiction Treatment Regulations.**

To use the rules to help avoid clinics that prescribe large amounts of buprenorphine with inadequate medical treatment, the rules could be limited and apply to only clinicians who care for more than 100 patients on buprenorphine. I recommend that the state rules not apply to physicians who prescribe office-based opioid treatment (OBOT) to fewer than 100 patients**.** This would exempt primary care physicians who provide some OBOT as part of their practice from being overly concerned about "messing up" a regulation that would push them not to provide this life-saving evidence-based treatment. Numerous outpatient providers have informed me that they do not provide buprenorphine due to the concern about OH's legislative requirements to provide this medication. I do not believe this is the regulation's intent, but it is an unfortunate outcome.

NIDA has created an excellent summary of this risk of diversion vs. treatment with buprenorphine which can be reviewed here (NIDA, 2021): To summarize some of the evidence, a US survey among individuals with OUD found that diverted buprenorphine was utilized for therapeutic purposes with 97% of respondents reporting using it to prevent cravings, and 90% using it to prevent withdrawal (Schuman-Olivier et al., 2010). Not surprisingly, illicit use of buprenorphine decreased as individuals had greater access to treatment, supporting the need to expand treatment access urgently (Schuman-Olivier et al., 2010). Even among the minority of individuals (likely 8-25%) who use buprenorphine for non-therapeutic purposes, their use for this purpose rapidly decreases over time, likely because of the unique pharmacology of the medication, which quickly blunts the rewarding effects over time (Cicero et al., 2007; Schuman-Olivier et al., 2010). In addition, a recent study demonstrated that overdose deaths involving buprenorphine did **NOT** proportionally increase with the new flexibility in buprenorphine prescribing that was put in place during the COVID-19 pandemic (Tanz et al., 2023). This further supports that removing these regulations will unlikely impact buprenorphine overdose deaths. This evidence points in one direction: the medical board should remove these regulations. Currently, only ten states have buprenorphine regulations in place, and despite our regulations, our overdose deaths remain one of the highest in the country (Andraka-Christou et al., 2022). We must remove these regulatory barriers to outpatient providers.

Overall, the current regulations are outdated and prevent access to care by overburdening outpatient providers. Evidence supports that increased regulatory flexibility did not increase buprenorphine overdose deaths. Forty states do not regulate buprenorphine, and evidence supports that it is used for therapeutic purposes even if diversion occurs. In fact, by removing these regulations, we are likely to see a decrease in buprenorphine diversion as treatment access would be expanded.

We need to remove unnecessary barriers to treatment with buprenorphine for OUD urgently. Evidence supports that buprenorphine is a safe, effective medication. While diversion may occur, the harms are minimal compared to the risk of outpatient providers opting out of providing this life-saving medication due to regulation burdens. Physicians can provide safe treatment to patients with OUD without these regulations, as demonstrated by the federal decision to remove the X-wavier and the fact that most states do not have these additional regulations. We need flexibility in tailoring care to individual patients' needs; these regulations do not allow that. We do not regulate other chronic diseases, and the existence of these regulations contributes to the stigma our patients face daily.

Thank you for your time and consideration of my commentary. Should the board keep the rules in place, I have provided specific commentary to improve the proposed rules based on the most recent evidence in addiction treatment. Feel free to contact me at ChanCL@UCmail.edu with any questions

Sincerely,
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Assistant Professor of Medicine
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General Comments

I recommend removing our state's buprenorphine regulations and deferring to the standard federal regulations on buprenorphine prescribing. These OH regulations attempt to codify medical practices in state law and concern me as these proposed regulations are not evidence-based (see specific comments for citations on buprenorphine dose caps). Much of what it attempts to regulate falls into the "art" of medicine, such as specified frequency of mandatory visits and urine drug testing. Currently, there is no evidence to suggest the appropriate frequency of visits or how to best monitor a patient with toxicology because the need should be based on unique patient factors. Requirements such as these could place patients at risk of not having their medication should they miss an appointment and create barriers, particularly for individuals who work night shifts and lack reliable transportation or childcare. The current and proposed revisions of the rules unnecessarily place individuals at risk of overdose and death.

If the state medical board is highly concerned about "pill mills," then I recommend that the state regulations NOT apply to physicians who prescribe OBOT to fewer than 100 patients. This would exempt primary care physicians who provide some OBOT as part of their practice from being overly concerned about "messing up" a regulation that would push them not to provide this life-saving evidence-based treatment.

Documentation Burden

We know that the EMR documentation burden contributes to physician burnout and could decrease the number of providers willing to prescribe OBOT due to this burden. In my commentary below, I have suggested areas where the documentation burden could be lessened. It is reasonable to request documentation on key areas, such as the reason for using a buprenorphine mono-product over a combination product. Still, several documentation requirements are unnecessary and their removal could decrease the burden on physicians.

4731-33-01: Specific Commentary

Definitions

1. (C) The term **medication-assisted treatment (MAT)** is no longer recommended.

Comment: It is considered inaccurate as it could imply that pharmacotherapy is inferior to psychosocial pathways. Instead, the current accepted terminology is medications for opioid use disorder (MOUD) and medications for alcohol use disorder (MAUD). Please see the following editorial from the American Society of Addiction Medicine (ASAM) Journal of Addiction Medicine for more information (Saitz et al., 2021). I recommend replacing MAT with either MOUD or MAUD, depending on the context throughout the document.

2. (J and K) The definitions of the **induction** and **maintenance** phases are clinically inaccurate.

Comment: Induction is the medical phase of MOUD, during which the dosage levels are adjusted until a patient is no longer in physiological opioid withdrawal. I recommend replacing the definition for maintenance as "the phase in which a person has been sustained on a steady dose of buprenorphine."

3. (L) I recommend **removing the word "substance abuse**" and replacing it with substance use disorder, which is the correct terminology.

Comment: Substance abuse is considered outdated and stigmatizing terminology (Saitz et al., 2021). I recommend this for all appearances of substance abuse throughout the document.

4731-33-02: Standards and procedures for withdrawal management for substance use disorder

1. **B1**: "The patient shall be provided information about all medications approved… and **shall be documented** in the patient record".

Comment: I recommend removing the documentation requirement as this is unnecessarily burdensome on the clinician. If a patient has high blood pressure, I do not document all the medications discussed; it is implied as part of a routine visit when starting any medication for a chronic disease.

2. **B2:** "and **confirmation of acceptance** of the referral by the program, physician, physician assistant or advanced practice registered nurse shall be documented in the patient record."

Comment: I recommend removing the requirement for confirmation of acceptance and documentation. In a busy primary care practice, the burden of confirmation of acceptance is impractical. Confirmation of referral acceptance is not required for any other primary care referral. This rule would deter primary care providers from referring/offering OBOT as this is currently not a standard of care for any other chronic condition.

3. **D1a: "**The patient has adequate **social**, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management."

Comment: I am concerned that this statement would deter individuals from providing low-barrier buprenorphine to patients who are homeless or individuals in shelters, as their social situation could be interpreted as inadequate. OBOT has been successfully implemented for individuals who were homeless and had comparable outcomes to those who were housed regarding treatment failure, return to use, and treatment utilization (Alford et al., 2007). In

general, allowing a clinician to utilize their medical judgment without adding the word social would make this clause less likely to be misinterpreted.

4. **D1b**: "The patient has a **high likelihood of treatment adherence and retention in treatment**; and…"

Comment: I am concerned that this statement will be used against a patient population that is highly stigmatized and could predispose physicians to implicit bias and I recommend it be removed. There is already a significant disparity in who receives buprenorphine, with black patients with a lower odds of receiving buprenorphine (OR of 0.23) compared to white patients (Lagisetty et al., 2019). If a patient requests treatment, it is not upon the physician to "judge" whether they are likely to adhere; their presence and request should be enough. This rule could result in implicit bias preventing certain groups from accessing treatment. In my experience, you can never "judge a book by its cover," it is not appropriate to guess if someone has a high likelihood of treatment adherence. In my clinical experience with this, I have often been wrong in which patients I think will continue treatment. I am gravely concerned that this phrase could be used, or interpreted to deny at risk-populations OBOT.

5. **D1c**- "There is **little risk of medication diversion**".

Comment: I recommend removing this statement; we should not preemptively decide if a patient is at risk of medication diversion before offering treatment. For example, an individual who is homeless could be perceived as being at risk of medication diversion, yet studies support that this population can be effectively treated with OBOT (Alford et al., 2007). If a patient IS diverting medication, that is a different clinical scenario, but again, these statements make me concerned about clinicians refusing to provide a lifesaving medication based on biases. I am gravely concerned someone will use this phrase to deny at-risk populations OBOT.

6. **4.** "**Prior to providing** ambulatory withdrawal management detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient, to include the following…"

Comment: While this list is not unreasonable if a patient presents in severe opioid withdrawal in my office, it may not be possible to obtain a very detailed history due to discomfort. I do note clause (4m), and recommend moving the "If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall document the reason in the medical record" to the top of the document. Hence, it is less likely to be misinterpreted as a requirement PRIOR to receiving MOUD.

7. **4Dg-k**: "Prior to providing ambulatory withdrawal management detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient, to include the following:… including HIV, hep B, hep C, pregnancy test

Comment: I recommend that a statement be included that a patient can defer the laboratory tests listed, as they have the right to autonomy to defer lab tests such as HIV, hep B, hep C, and a pregnancy test.

8. **4e:** "**Appropriate physical examination**".

Comment: I recommend that it be amended to "Appropriate physical examination, which can be conducted in-person or via telehealth," which was a change from the COVID-19 pandemic, which at this time is still allowed and is a safe and effective way to provide OBOT treatment. Telehealth OBOT expansion during the pandemic was associated with individuals staying in treatment longer and decreasing their risk of overdose (Jones et al., 2022; Krawczyk et al., 2023).

9. **10ai and 10b:** "The physician shall not use any of the following drugs to treat the patient's withdrawal symptoms: "**Methadone**" A medication drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms.

Comment: There is a DEA exception to using methadone for three days to manage opioid withdrawal outside of OTPs called the "3-day rule". The wording here would make it illegal to use this rule. This clause should be removed, and deferred to federal regulations. Since OTPs do not always have 7-day-a-week availability, the intent of this rule is to let providers, in very certain and limited circumstances, provide and dispense methadone for up to 3 days. Please see the federal registrar rule here: https://www.federalregister.gov/documents/2023/08/08/2023-16892/dispensing-of-narcotic-drugs-to-relieve-acute-withdrawal-symptoms-of-opioid-use-disorder . The provider must be separately registered with the DEA to provide this care, and there are many regulatory burdens around this already in place. For example, on the use of this rule, there are low-barrier clinics that assess patients. After assessment and discussion with the patient, methadone instead of buprenorphine may be the recommended clinical option. Depending on local access, they refer to an OTP, and it may take a few days for that patient to get an appointment to start methadone. Instead of leaving the patient in withdrawal, they can provide up to 3 days of methadone to relieve their symptoms. This should be allowed and is allowable via federal law. In a recent study of a clinic using this model, 87% of patients who received methadone under this three-day rule were successfully linked to an OTP (Taylor et al., 2022)! Another example of the use of the 3 day rule can be found here: https://medicine.yale.edu/news-article/addiction-medicine-team-dispenses-first-three-day-supply-of-methadone-at-yale/

4731-33-03 OFFICE BASED BUPRENOPHINE

1. **C3-7:** The physician who provides OBOT shall establish and document a treatment plan that includes all the following: … "Written, informed consent)

Comment: I recommend removing the requirement for written informed consent, and a signed treatment agreement. I do not have patients sign a written consent for insulin. If an individual physician elects to do this, this is not unreasonable, but I believe adds an unnecessary document burden and does not improve care. In addition, the removal of this rule will assist with the decrease in the documentation burden.

2. **D: "**The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following: **TIP-63 and ASAM 2020 protocols**

Comment: I recommend removing this clause as the TIPS and ASAM documents listed are outdated, and do not include newer standards of care for buprenorphine inductions. Low-dose and high-dose inductions are considered reasonable treatment plans to offer as a standard of care, and neither document discusses those options**. Please see the most recent ASAM clinical considerations in the era of fentanyl that describe both induction options (Weimer et al., 2023)**. Due to fentanyl, it has increased the risk of individuals experiencing buprenorphine-precipitated withdrawal as fentanyl is lipophilic. Heavy fentanyl use results in the storage of fentanyl in adipose tissues, making a standard induction challenging for many patients. Furthermore, the high potency requires higher doses of buprenorphine to manage opioid withdrawal. A recent study supported that high-dose buprenorphine is safe and effective (Herring et al., 2021).

3. **3e:** "The physician shall verify the diagnosis for which the patient is receiving the other drug and **coordinate care with the prescriber for the other drug**, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue taper the…".

Comment: I recommend that this wording be addended to "**attempt to coordinate."** In my practice, I have called numerous other provider offices, often with no response when trying to coordinate. I support that a good faith effort

should be made to coordinate, but if another physician's office is unresponsive **buprenorphine should NOT** be withheld due to an inability to speak to another provider, as their risk of an opioid overdose without buprenorphine outweighs any risk of co-prescribing. In fact, individuals on chronic benzodiazepines who are on buprenorphine are more likely to be retained in treatment (Park et al., 2020).

In addition, I recommend this **clause apply only for chronic medications** rather than acute. For patients, for example, who have an ACUTE medication need, e.g. oxycodone for a few more days after surgery, or a one-time dose of a benzodiazepine due to a flying phobia, physicians should not be burdened with coordination for these low-risk scenarios. Maintaining the wording that physicians must still counsel patients on the increased risk of overdose while on these medications is reasonable.

I recommend that the words be changed to "**If the patient is receiving the medication for a chronic condition**, the physician shall verify the diagnosis for which the patient is receiving the other drug and **attempt to coordinate care with the prescriber for the other drug.**"

4. **4:** "During the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. **The physician shall see the patient at least once a week during this phase.**"

Comment: I recommend removing the requirement to be seen at least once a week during the induction phase. There is no evidence to suggest that this frequency is necessary, though it may be appropriate for some patients. A physician and patient best determine the visit frequency. In the outpatient clinical setting, scheduling frequent patient visits can be very challenging. Visit frequency should be based on medical necessity, clinic capacity, and patient preference. In my practice, several patients work night shifts and can only come in every two – three weeks to prevent them from losing their jobs. I believe this is reasonable, and physicians should have the flexibility to determine the visit frequency. I recommend changing the wording to "**The physician shall determine when to see the patient based on medical necessity, clinic capacity, and patient preference."**

5. **5a:** "During the first ninety days of treatment, the physician shall **prescribe no more than a two-week supply** of the buprenorphine product containing naloxone, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants."

Comment: There is no evidence to suggest that only providing a 2-week supply will decrease diversion or overdose risk. While this may be clinically appropriate for OUD treatment, a physician should individualize the supply duration based on the patient's needs. In my experience, I have many patients who stabilize earlier than 90 days and have real-world concerns of losing their employment due to frequent missing of work or lack of transportation/childcare, as well as challenges fitting in visits this frequently due to clinic capacity. I recommend that this clause be removed or added to the following: "During the first ninety days of treatment, the physician shall **prescribe an appropriate duration of supply** of buprenorphine product containing naloxone based on their **clinical OUD stability, medical necessity, and clinic capacity,** unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants

6. **5b:** "Starting with the **ninety-first day** of treatment and until the completion of twelve months of treatment, the physician shall **prescribe no more than a thirty-day supply of** the buprenorphine product containing naloxone, unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implant."

Comment: See rationale in comment 13. I recommend that physicians should use their clinical judgment and rewrite as follows: "During the first ninety days of treatment, the physician shall **prescribe an appropriate duration of supply** of buprenorphine product containing naloxone based on their **clinical OUD stability, medical necessity, and clinic capacity,** unless utilizing a formulation with a duration of action exceeding two weeks, such as injections

or implants." When I practiced in Connecticut, I had a patient who traveled out of the country and requested 40 days of the medication within the first 90 days of treatment. In this clinical scenario, this was medically appropriate as the patient was stable in their OUD. It was reasonable to prescribe for 40 days rather than deny the medication and have the person leave treatment entirely and experience withdrawal. The physician should determine the duration of the prescription on several factors that I listed in the revision.

7. **6**: "The physician shall take steps to reduce the risk chances of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, and checking checks of OARRS. The physician **shall require urine drug testing screens**, serum medication levels, or oral fluid testing at **least twice per quarter for the first year of treatment and at least once per quarter thereafter.**"

Comment: There is no evidence to suggest that required urine drug testing (UDT) decreases diversion. In addition, there can be a burden of costs to patients when ordering this test, and they should be ordered if clinically necessary. A physician should determine the optimal frequency for UDT testing rather than a state regulation. This can stop patients from coming to OBOT clinic due to cost concerns around UDT.

I recommend that this be revised to: "The physician shall take steps to reduce the risk chances of buprenorphine diversion, **which may include any of the following strategies**: by using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, and checking checks of OARRS. The physician **shall use any combination of urine drug testing screens**, **serum medication levels, or oral fluid testing to monitor adherence to the medication. The frequency of this ordering will be based on their medical necessity for treatment and clinical judgment. At minimum, they will use urine drug testing at least twice per year, once in each half of the year.**" **If a patient has ESRD on hemodialysis and is unable to provide a urine drug test, then the physician shall use their judgment and document on how they are monitoring medication adherence.** For my patients who cannot provide a UDT due to a medical condition, and if saliva testing is not covered by insurance, physicians should be able to document other modalities, such as checking OARRS, and random pill counts to monitor adherence. Saliva testing is expensive, not always accessible in many clinics, and not always covered by insurance.

8. **7:** "When using any oral formulation of buprenorphine, the physician **shall document** in the medical record the rationale for prescribed **doses exceeding sixteen milligrams** of buprenorphine per day. The physician shall **not prescribe a dosage exceeding twenty-four milligrams** of buprenorphine per day, unless the prescriber is a board-certified addiction specialist or addiction psychiatrist, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day."

Comment: In the era of high-potency synthetic opioids (HPSO) such as fentanyl, 24 mg of buprenorphine daily is the most effective dose for retaining patients in treatment. A recent study compared buprenorphine retention in treatment in patients with 16 vs 24 mg dose (Chambers et al., 2023). Patients on the 24 mg dose were statistically more likely to remain in treatment than those on the 24 mg dose (Chambers et al., 2023). The ASAM clinical considerations for buprenorphine in the era of HPSO acknowledge that individuals who use fentanyl have more challenges stabilizing their OUD on buprenorphine and likely need a higher dose of 24 – 32 mg of buprenorphine (Weimer et al., 2023). A recent review on buprenorphine dose limits supports evidence for dose-dependent benefits up to at least 32mg/day (Grande et al., 2023). The challenge with the original 16mg dose suggestion of a cap is that those studies were done before the fentanyl era. Fentanyl has changed the game in managing OUD, and all the recent evidence supports the use of 24-32 mg to stabilize patients with OUD and fentanyl use.

I recommend rewriting this clause based on the updated evidence supporting 24mg as the standard of care in the era of fentanyl: "When using any oral formulation of buprenorphine, the physician shall **not prescribe a dosage exceeding twenty-four milligrams** of buprenorphine per day, unless the prescriber is a board-certified addiction specialist or addiction psychiatrist, or a consultation has been obtained from such a specialist recommending the

higher dose.". No additional documentation should be required for individuals who are on up to 24mg. It is reasonable for an addiction provider to be involved if patients need more than 24 mg a day dose is being considered, as well as generally a 32 mg cap for maintenance.

9. **9a-d:** "The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

Comment: Due to the already existing federal regulations on extended-release buprenorphine requiring Risk Evaluation and Mitigation Strategy (REMS), I recommend removing this clause to decrease the documentation burden. REMS have appropriate high standards, and since this medication must be administered in person due to this clause, there is zero risk of patient diversion. Evidence suggests ER buprenorphine is superior to SL buprenorphine for overdose prevention, and since it is injectable, there are no concerns about medication adherence (Lee et al., 2023).

Medication-assisted treatment using naltrexone

1. **2a-d:** "The physician shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated."

Comment: Oral naltrexone is not evidence-based for the treatment of OUD, I recommend removing this clause entirely as it is not approved by the FDA for the treatment for OUD. Should a patient defer all other evidence-based treatments for OUD (bup, methadone, IM naltrexone), and request PO naltrexone, it is not unreasonable to provide this medication. It cannot be misused, is very safe, and requires nearly no monitoring to be medically safe for an individual. Since PO naltrexone is not considered a standard of care in OUD, I do not feel the medical board needs a separate rule on this topic. Even IM naltrexone is not considered a standard of care, though it is reasonable to use for OUD based on patient preference. A reanalysis of the XBOT trial found that IM naltrexone did not decrease overdose deaths, and is often considered "third-line" treatment after buprenorphine and methadone(Ajazi et al., 2008). To decrease the documentation burden and rules on standards, I think this rule can be removed as both IM and PO naltrexone are not considered standards of care for OUD, though clinicians can still use it as they see fit in clinical cases.

Thank you for reviewing and considering my individual specific comments. Please see the additional letter of support from the Association of Multidisciplinary Education and Research in Substance use and Addiction (AMERSA) on this commentary.

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From: Contact
To: Anderson, Kimberly
Subject: FW: New submission for Contact Us.
Date: Monday, September 25, 2023 4:03:59 PM

From: noreply@das.ohio.gov <noreply@das.ohio.gov>
Sent: Monday, September 25, 2023 3:56 PM
To: Contact <Contact@med.ohio.gov>
Subject: New submission for Contact Us.

There is a new submission for Contact Us.

Subject	State Medical Board Of Ohio
Name	Dennis Helmuth, MD
Email	denhel2@gmail.com
Message	Re: Rule 4731-33-03. Comment. The requirement of quarterly urine tests does not always serve a legitimate medical purpose. I have patients maintained on Suboxone where this is not necessary. It's unnecessarily stigmatizing. We're trying to save lives here. Leave the doctor some discretion.

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From: Sigler, Seth
To: Anderson, Kimberly
Subject: Public Comment for Medication-Assited Treatment Rules for Physicians/PAs
Date: Wednesday, September 27, 2023 12:35:39 PM

Good Afternoon,

I wanted to make a comment regarding rule 473-4-02 of the Standards and Procedures for Withdrawal Managment for Substance Use Disorder. Specifically regarding Section D subsection 4 "the physician shall conduct and document including the following: (g) pregnancy test for women of childbearing age and ability. "

I take issue with obtaining a urine pregnancy test for every patient of childbearing age and ability for two reasons.

1. As an OBGYN a single negative urine pregnancy test does not in isolation exclude that a woman is not pregnant as these will miss very early pregnancies. Instead we should utilize the CDC guidelines for How To Be Reasonably Certain a Woman Is Not Pregnant - US SPR | CDC . If one of these criteria is not met, then a urine pregnancy test should be performed with the caveat that it does not completely exclude very early pregnancy.

> How To Be Reasonably Certain a Woman Is Not Pregnant - US SPR | CDC
>
> How To Be Reasonably Certain that a Woman Is Not Pregnant
>
> www.cdc.gov

2) universal pregnancy testing leads to another charge for the patient that may be unnecessary if the Physician can be reasonably certain they are not pregnant by the above questionnaire.

Please let me know if you have any questions or need further clarification.

Warmest Regards,

Seth Sigler, DO
Obstetrics and Gynecology

Addiction Medicine Fellow

Summa Health
525 East Market Street, Med 2 | Akron, OH 44309
p 740-475-9146 f 330-375-4067
siglers@summahealth.org

From:	Reardon, Jill
To:	Anderson, Kimberly
Subject:	Draft rules comment from PAPC member
Date:	Tuesday, September 12, 2023 8:44:16 AM
Attachments:	image001.png image001.png Memo and Attachments-Rules-PAPC-September 2023.pdf

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From: Nishit Mehta <mehtan1@outlook.com>
Sent: Tuesday, September 12, 2023 3:26 AM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: Draft rules comment

Jill are you able to clarify or maybe Kim Anderson can regarding OBOT/MAT draft 4730-4-01:
Currently some of our sites are free standing emergency departments part of Summa health system and we offer MAT including administration of Suboxone, addiction consultation ; do free standing emergency departments fall under 4730-4-01 (A) (2) and are considered a hospital thus the draft rules of this section won't apply .

Some Comments on 4730-4-02 (B)(1)
It should specify it's for opioid use disorder.
Otherwise the Provision on providing information about ALL medications approved will become burdensome. The way it's currently reading it can include treatment of withdrawal management from alcohol. There are numerous benzodiazepines and barbiturates that can be used for treatment of alcohol withdrawal and multiple chapters of text books can be written about this subject matter. Specifying in the corresponding physician rules as well.

4730-4-02 (D)(4)
When we made this protocol at our wmer facilities we had excluded testing for HIV, hepatitis B and hepatitis c as having these conditions doesn't preclude a patient from getting MAT. I think having these requirements will be make clinicians less likely to initiate treatment. knowing the way most emergency providers work in general we don't order tests for identification of chronic illnesses. So a requirement like this will become onerous.

Nishit Mehta M.D.
quality director
Emergency departments
Summa Health

On Sep 7, 2023, at 3:12 PM, Jill.Reardon@med.ohio.gov wrote:

Good afternoon,
Attached please find rules that Kim Anderson, SMBO Chief Legal Counsel will be discussing at tomorrow's meeting.

Jill

Jill Phalen Reardon
Deputy Director of External Affairs
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
c: 614 551 9957
Jill.Reardon@med.ohio.gov
w: med.ohio.gov

Healthy State Alliance

THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER

BON SECOURS MERCY HEALTH

October 6, 2023

Stephanie Loucka, Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: Proposed Medication-Assisted Treatment Rules (OAC 4731-33-01, 4731-33-02, 4731-22-03, 4731-33-04)

Dear Director Loucka,

On behalf of the Healthy State Alliance, we appreciate the opportunity to comment on the State Medical Board of Ohio's proposed medication-assisted treatment rules. Only 11% of the 2.5 million Americans with OUD received any medication in 2020.[1]

Background on the Healthy State Alliance

The Healthy State Alliance is a strategic initiative between The Ohio State University Wexner Medical Center, one of the nation's preeminent academic health centers, and Bon Secours Mercy Health, a Catholic health ministry serving Ohio and other states. Collectively, we are investing resources and providing tangible solutions to tackle Ohio's most critical health needs. The alliance is committed to transforming the health of the communities we serve, while making health care more affordable and accessible for all.

Office-based treatment for opioid addiction (4731-33-03)

We appreciate the Board's recognition of the importance of increasing access to office-based treatment for opioid use disorder (OUD) with buprenorphine. Buprenorphine is safe, effective, and is one of only two treatments for OUD known to reduce patients' risk of dying from accidental overdose.[2] Health State Alliance researchers have found opioid overdose is a growing cause of death among some of our state's most vulnerable populations including pregnant women, new mothers, and adolescents.[3–7] Therefore, we enthusiastically support the Board in their current efforts to modernize office-based OUD treatment.

In particular, we support the sentiment of relaxing the prohibition against prescribing an oral dose of buprenorphine greater than twenty-four milligrams per day. However, we disagree with requiring an addiction specialist consultation to exceed this limit. We know the Board is aware of the workforce challenges in the health care sector in general, and particularly in specialties related to behavioral health and addiction. The Healthy State Alliance serves both urban and rural areas of Ohio, including many where behavioral health resources are scarce. Requiring the prescriber to be a board-certified addiction

specialist or addiction psychiatrist is so limiting as to make the exception almost meaningless in a real-world setting. We recommend the Board consider raising the cap to thirty-two milligrams, which is the FDA approved limit, and remove the additional requirements.

We also support the prescribing of sublingual buprenorphine mono-product without limitations. We believe the decision to prescribe a mono-product or a buprenorphine/naloxone combination product is a clinical one based on a variety of factors specific to the patient. Current scientific evidence suggests that many of the historical concerns about injection misuse and diversion of mono-formulated buprenorphine were misguided. For example, large real-world studies have shown rates of misuse of these medications do not meaningfully differ and that the ratio of buprenorphine to naloxone in buprenorphine/naloxone is unlikely to deter such misuse. Instead of protecting the public, restricting access to mono-formulated buprenorphine has hindered providers in fighting the overdose crisis. As we stated above, buprenorphine is one of only two treatments that reduce the risk of overdose death.

Additionally, we strongly support the Board in eliminating the requirement that patients adhere to psychosocial treatment to continue buprenorphine. We would like to reiterate that while psychosocial treatments like counseling services have value, they do not reduce the risk of dying from overdose. Therefore, the current regulation makes a life-saving treatment (buprenorphine) contingent on participation in non-life-saving treatment (counseling). Under the proposed rule, the physician will be required to consider the psychosocial needs of the patient, including offering interventions or referrals, but can continue to provide treatment even if those interventions are not available or if the patient declines to participate. This approach is evidence-based and ensures medication won't be withheld from patients in need based on these factors.

Our team of physicians, scientists, and pharmacists have also noticed that gabapentin has been added to the list of medications that should not be co-prescribed with buprenorphine. We strongly disagree with this change. As many as 62% of patients with OUD also suffer from chronic pain.[8,9] Uncontrolled pain is a major cause of relapse and has been linked to increased risk of overdose and death by suicide among patients with OUD.[10–12] For example, patients with uncontrolled chronic pain and OUD are 3 to 5 times more likely to relapse and die by suicide at a rate that is 3-fold higher than those with OUD alone.[13] While gabapentinoids do have misuse potential, best evidence suggests they do not increase the risk of fatal outcomes among OUD patients.[14] Therefore, the risk-benefit ratio strongly favors the use of adjunctive non-opioid analgesics like gabapentin among patients with co-morbid OUD and chronic pain.

Thank you for your consideration of our comments.

Sincerely,

W. Carson Felkel II, M.D., FAPA
Addiction Co-Lead, Healthy State Alliance
Medical Director for Behavioral Health
Bon Secours Mercy Health System

O. Trent Hall, D.O.
Addiction Co-Lead, Healthy State Alliance
Assistant Professor, Addiction Medicine
Department of Psychiatry & Behavioral Health
The Ohio State University Wexner Medical Center

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AMERSA

Interdisciplinary Leaders in Substance Use Education, Research, Care and Policy

October 4, 2023

Carolyn Chan, MD, MHS
Internal Medicine/Addiction Medicine
Assistant Professor of Medicine
University of Cincinnati College of Medicine

Dear Dr. Chan,

Thank you for your advocacy for persons with opioid use disorder who can benefit from buprenorphine treatment and for the treatment providers in Ohio. Your response to the State Medical Board of Ohio has been reviewed by the Directors of AMERSA who support and commend you for your commentary on the proposed rules for outpatient buprenorphine treatment.

As a member of AMERSA, you are keenly aware that our professional organization advocates for (1) increasing access to medications for persons with opioid use disorder, (2) ensuring that treatments are evidence-based, and (3) utilizing acceptable, non-stigmatizing, and person-centered language in scientific and public-facing documents. Clinicians, educators, and researchers who are members of AMERSA contributed to the body of evidence related to buprenorphine, called for the removal of the x-waiver, and were among the first to address the need to change language that contributes to the stigma experienced by persons with substance use and substance use disorders.

In your commentary, you clearly identified the need for, and importance of removing unnecessary barriers to treatment for a population and minimizing burdens on the health care providers who provide evidence-based treatment. In 2023, treatment of persons with opioid use disorder took a step forward with the passage of H.R. 2617: Consolidated Appropriations Act of 2023. Section 1262 of that legislation addressed the removal of the x-waiver. Section 1263 specified training requirements for **all** prescribers of controlled medications which includes buprenorphine. The Consolidated Appropriations Act underscores the critical need for the nation's prescribers to collectively address this major public health crisis.

We look forward to hearing from you about the finalized ruling.

In solidarity,

Phone (401) 615-4047
www.amersa.org

Deborah S. Finnell, PhD, RN, CARN-AP, FAAN
President

Consolidated Appropriations Act of 2023. (2023). P.L. 117-328. Retrieved from https://www.policymed.com/wp-content/uploads/2023/01/CME-DEA-Omnibus-Bill-2023-Clean-Version-Requiring-Prescribers-of-Controlled-Substances-to-Complete-Training.pdf

From: Martin, Dr. Michael E.
To: Anderson, Kimberly
Cc: michael.martin; Melissa Spears
Subject: New regulations 4731-33-93 Office Based Treatment for addiction (OBOT)
Date: Tuesday, October 3, 2023 10:42:57 AM

Dear State Medical Board of Ohio,

My name is Dr. Michael E. Martin , M.D. and I am a practicing physician in Portsmouth Ohio as well as the Scioto County Health Commissioner. The regulation of addiction treatment affects my patients , my practice and the health of the citizens of Scioto County. Scioto County continues to suffer from overdose deaths due to fentanyl at an extremely high rate. The Ohio Department of Health reports the "Average Age- Adjusted Rate of Unintentional Drug Overdose Deaths in Ohio from 2017- 2021", Scioto County ranked first with 106.2 deaths per 100,000 population. This rate is due in part to the onerous regulations promulgated by the Ohio Medical Borad rules on treatment of Opioid Use Disorder. I know of several colleagues wanted to help but after reading the regulations on Office Based Opioid Treatment, they demurred. The Medical Board has criminalized failure to follow their rules . These regulations have directly impaired care for this deadly disease. In light of recent developments with the X waiver and the Supreme Court Ruan decision (Xiulu Ruan vs United States), **these rules need removed.**

It is critical we remove these rules for the following reasons:

1.**Buprenorphine and Naltrexone are safe and effective for OUD**: These evidence-based medications are safe and effective to treat OUD. In many studies the harms associated with diversion have been minimal, with most individuals using diverted buprenorphine for therapeutic purposes. Recent flexibility through telehealth as a result of the Covid pandemic did not result in an increase in buprenorphine overdose.
2. **Empowerment of Health care providers** : Removing onerous state regulations allows providers to prescribe buprenorphine without unnecessary documentation and will increase the number of individuals prescribing buprenorphine. I personally know of several Nurse Practioners who wish to treat in their offices but are afraid to due to regulations, fear of losing their licenses and lack of collaborating physicians.
3. **Stigma Reduction**." Current regulations perpetuate the stigma associated with addiction treatment. Removing these barriers sends a strong message that addiction is a medical condition deserving the same compassion and treatment as any other medical disease. Normalizing the accessibility of buprenorphine can help reduce the stigma surrounding medication treatment of OUD, encouraging more individuals to seek help without fear of judgement or discrimination. This shift can significantly impact public

perception and attitudes towards addiction, fostering a more empathetic and supportive community for those in recovery.

4. **Flexibility**: Any new rules should allow for increased flexibility in treatment. Unlike other diseases, I am Board bound to prescribe and limit prescriptions . Recently I had a patient who I treated for Opioid Use Disorder for many years. He was unable , due to work , to come to my office for a urine drug test within 90days. I told him the Ohio Medical Board Rules prevent me from writing his medication on day 100. He has hopefully found treatment elsewhere. What other disease process should this occur? Should I stop insulin if patient doesn't get a Hemoglobin A1C every 90 days? There must be and opportunity for the physician to adjust the care plan based on the clinical scenario.

Thank you for your consideration

Sincerely,

Dr. Michael E. Martin , M.D.
Scioto County Health Commissioner
Scioto County Health Department
612 6th St. Portsmouth Ohio
740-821-4145

Oct 5, 2023

To the State Medical Board of Ohio:

Thank you for the opportunity to provide comments to the proposed rule amendments that govern the treatment of opioid and other substance use disorders within Ohio. It is imperative that we continue to expand access to high-quality treatment for opioid and other substance use disorders. Ohioans continue to be impacted by the opioid crisis, with recent data indicating that Ohio has the seventh highest overdose death rate in the country (CDC, 2021). Ohio is also one of just 10 states that places additional regulatory restrictions on the prescription of buprenorphine (Andraka-Christou et al., 2022), an FDA-approved medication critical to stemming the tide of overdose deaths.

In order to increase access to evidence-based, lifesaving interventions for individuals who need it most, **we urge the State Medical Board to reconsider the need for such a proscriptive approach to the treatment of opioid and other substance use disorders. If these regulations must remain within the Ohio Administrative Code, then we urge the Board to reconsider the language of the rules in order to align with national practice guidelines and to allow physician and physician assistants to use their clinical judgment in difficult cases.** OneFifteen is a non-profit organization that provides treatment for substance use disorders in Dayton, and we have served over 7,000 individuals in the past four years. In our community, we know reputable physicians who choose not to prescribe buprenorphine because they perceive Ohio's OBOT rules to be complicated and difficult to implement. Even more alarming, we know of treatment centers who terminate access to services for patients, despite the judgment that it would be in the best interest of the patient to continue treatment.

An overly regulated OBOT environment will have the effect of limiting access to OUD treatment and will slow our state's progress in addressing the opioid crisis. While we understand that the desire to regulate OUD treatment occurs against the backdrop of physicians' role in the origins of the opioid epidemic, there is a relevant physiologic difference between opioids prescribed for pain control (such as oxycodone, hydrocodone, and morphine) and the partial-agonist buprenorphine used in OUD treatment. Buprenorphine has a "ceiling" or plateau effect of opioid stimulation, such that increasing doses will not result in an ever-increasing opioid effect, making it a much safer medication with lower (though not zero) abuse potential. Indeed, a recent survey among individuals with OUD found that diverted buprenorphine was taken not recreationally, but rather for self-treatment: 97% of respondents reported using it to prevent cravings and 90% to prevent withdrawal (Schuman-Olivier et al., 2010). Buprenorphine has been shown to reduce mortality from OUD by 38% (Larochelle et al., 2018). Furthermore, the COVID-19 pandemic provided a natural experiment to evaluate what would happen when buprenorphine regulations are relaxed, and no increase in overdose rates was observed (Lee et al., 2023).

Progress is being made at the national level, both in Congress and in the Administration, to secure access to evidence based treatment for OUD. In January 2023, the X-waiver requirement for buprenorphine prescribing was removed, thus enabling any individual with a DEA license to prescribe this medication. In June 2023, the DEA instituted a requirement for eight hours of mandatory training in substance use disorders in order to attain

a license. The DEA recently hosted a listening with stakeholders, including physician groups, to understand the impacts of restrictive teleprescribing regulations on access to SUD care. The net effect of these federal changes is to improve the recognition of and expand access to evidence-based interventions.

Ohio's proposed rule amendments signify, on the whole, a step forward since the rules were last revised in 2019, but they remain inadequate and restrictive particularly in light of such significant progress being made at the federal level. Below we articulate specific concerns about the proposed language and considerations for how it can be updated.

We appreciate that the Board is adopting a more focused harm-reduction approach, and would encourage greater room for physician judgment.

We commend the Board for revising the rules regarding psychosocial interventions, as described in 4731-33-03 (E), in particular the statement that "OBOT should not be declined or discontinued even if the patient is unable or unwilling to engage in psychosocial interventions." This is an important step forward. Medication treatment *is* treatment, and individuals can benefit from access to medication even if they decline other interventions.

We also appreciate that the Board has increased the maximum daily dose of buprenorphine from 24 to 32 mg per day. In this section, we would suggest an additional revision regarding dosage targets. Section 4731-33-03 (G)(7) states "the physician shall document in the medication record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day," suggesting that a dose of up to 16 mg per day is an acceptable dose, whereas higher doses are unusual and require special consideration. While this had been generally true when heroin predominated the opioid supply, the introduction of fentanyl has changed this. There have been a number of recent studies showing that doses of 24 mg (and up to 32 mg) per day may be required to reduce cravings and increase retention in care (e.g., Chambers et al 2023, Weimer et al., 2023, Grande et al 2023). We recommend that the Board revises this limit to state that rationale should be documented for doses exceeding 24 mg per day. Also within 4731-33-03 (G)(7), we suggest the phrase "oral formulation of buprenorphine" be replaced with the phrase "sublingual formulation of buprenorphine" to be consistent with administration recommendations of buprenorphine, which has reduced bioavailability when administered orally.

Many of the recommendations described within these rules are consistent with sound clinical practice, but encoding these practices as *rules* rather than *guidelines* prohibits use of clinical judgment. The proposed amendments would benefit from a rewording of the language, for example by changing the verbs "shall" to "may" or to otherwise indicate that the physician should make a good-faith effort to adhere to these rules, but may use their clinical judgment under extenuating circumstances. Some specific examples include:

(1) It is reasonable for patients early in their treatment to receive no more than a two-week supply of buprenorphine (4731-33-03 (G)(5)), but there are instances where it is reasonable to give a longer prescription (e.g., patient travel, physician travel, holiday scheduling, or transitioning into a maintenance

phase before completion of a full 90 days).

(2) Rules 4731-33-02 (D)(4) and 4731-33-03 (B)(1) list several required elements of an initial assessment, including a history and physical exam, drug testing, a review of OARRS results, and laboratory tests. There are instances when it is not possible to complete elements (a) through (l). Comprehensive physical exams cannot be completed over telemedicine. Sometimes patients refuse to have their labs drawn, even when they have been ordered by the physician. We appreciate inclusion of clause (m) in Section 4731-33-02 (D)(4), which states, "If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall document the reason in the medical record," and we suggest that this same clause should also apply to 4731-33-03 (B)(1). Preferably, rather than making this a documentation requirement, the language would be modified to allow physician judgment for how to proceed when a part of the assessment cannot be completed.

(3) According to 4731-33-02 (D)(1)(a), the physician shall only provide ambulatory withdrawal management when "the patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management" and "the patient has a high likelihood of treatment adherence and retention in treatment." This is not a harm-reduction approach to care and would restrict life-saving medications from individuals who could benefit from treatment. For example, suppose an individual who is unhoused and has a history of non-adherence to treatment presents to a clinical setting ready to start buprenorphine for treatment of OUD. The physician may recommend a referral into an inpatient setting, but if the patient declines, then it becomes the physician's responsibility to recommend the next best course of action for that individual. In many cases, from a harm-reduction perspective, ambulatory withdrawal management would be recommended as the next best option, but the language of this provision suggests that the physician may be in violation of this rule if ambulatory withdrawal management is offered. This puts physicians in an unnecessary bind between adherence to the state rules and acting to reduce risk of harm to their patient.

The term "medication-assisted treatment" should be removed from these rules.

We appreciate that the Board has taken steps to improve the language used within these rules. Use of the terms "addiction" and "dependence" have been updated to be consistent with the less stigmatizing DSM5-TR terminology, "substance use disorder." The Board appropriately introduced the term "Medications for opioid use disorder (MOUD)" and has replaced the term "detoxification" with "withdrawal management." We appreciate these steps to modernize the language within the regulations. Of note, in section 4731-33-01(L), the term "substance abuse treatment" should be replaced with "substance use disorder treatment."

Additional steps could be taken to further update this language. The term "medication-assisted treatment (MAT)" has been virtually eradicated from medical literature and the lexicon of substance use treatment providers. The term is no longer used due to its conveyance that treatment with medication itself is not treatment – that the "real" treatment is psychosocial and medication is relegated to the role of "assisting" this treatment – yet this term is used ten times in the proposed amendments. Extensive research over the past 20 years is clear that medication for OUD itself *is* treatment, and its use improves clinical outcomes and reduces

mortality (Larochelle et al, 2018). We would encourage the Board to remove use of the term "MAT" throughout these rules, and instead to use the term MOUD where indicated. Where a broader term is needed, "pharmacotherapy for substance use disorders" or "pharmacotherapy" could be substituted.

These rules place undo documentation burden on the physician.

Physicians document their patient care encounters, usually within an EHR, for a variety of reasons: record keeping, communication to other team members, billing, justification for insurance, medicolegal protection, and to jog their own memory at the next visit. To our knowledge, there is no other area of medicine where extensive requirements are also written into law. Across 4731-33-02, 4731-33-03, and 4731-33-04, there are twenty-two references to items that the physician must document in the patient record, sometimes with multiple items within a single reference (e.g., items (a)-(l) under 4731-33-02 (D)(4) and 4731-33-03 (B)(1)). Some of these documentation requirements align with standard practice, such as documenting patient examinations. Others place undo documentation burden on the physician. For example, 4731-33-02 (B)(2) and 4731-33-02 (F)(5) state that when a treatment program referral is made, "confirmation of the referral by the program, physician, physician assistant or advanced practice nurse shall be documented in the patient record"; this confirmation is not usually documented as a routine part of clinical care, and the acknowledgment of the referral, if made, is often not done temporaneously with the physician's documentation. Section 4731-33-02 (B)(1) indicates that a physician must offer all FDA-approved medication to an individual undergoing ambulatory withdrawal management, and must document this discussion in the chart. In clinical practice, it is common for a physician to discuss various treatment options with a patient before selecting a specific course of treatment, and then to document the treatment course that was selected, but treatment options that were not selected are not always documented.

While each individual documentation requirement itself seems like a small additional step, and many will be done as a part of routine care, the net effect of having so many documentation requirements encoded into law is that physicians become reluctant to treat OUD in office settings due to concerns about their ability to adhere to these rules.

The phase of care descriptions (Definitions (J)-(M)) are inaccurate and require further clarification.

The definition of "maintenance phase" in this rule (K) is written as "the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable state free of the symptoms of substance use disorder." This definition conflates a number of treatment phases. In a care delivery setting, the phases of care are observed in the following order:

1. "Withdrawal management": The definition within 4731-33-01 (L) is appropriate, with the exception that withdrawal management does not typically include management of substance intoxication. We suggest removal of the reference to intoxication within this definition.
    a. "Ambulatory withdrawal management" (4731-33-01 (M)) includes a description of the setting where withdrawal management may occur. The definition here is appropriate.

b. “Induction phase” (4731-33-01 (J)) refers to the process of starting an individual on an FDA-approved medication for SUD. The definition in the proposed amendment is “the phase of medication assisted treatment during which maintenance dosage levels are adjusted until a patient attains stabilization” describes the two phases of induction (starting the medication) and stabilization (adjusting the dose).

2. “Stabilization phase”: This term has been removed from the proposed rule. The stabilization phase is usually considered the period of time following the induction phase, when medication doses are adjusted to target a reduction in SUD symptoms such as cravings.
3. “Maintenance phase”: This term is used to describe the ongoing period from the time when an individual’s medication dose has reached a therapeutic level, allowing the individual to focus on other recovery activities (repairing relationships, gaining stability in their employment and finances, etc.).

In summary, we appreciate the Board’s efforts to update these rules by relaxing the requirements for psychosocial interventions, recognizing that higher doses of buprenorphine are sometimes medically indicated, and revising its language to use terminology consistent with the DSM5-TR. We believe that there are opportunities to further enable access to evidence-based SUD treatment, including modifying the language to allow for physician’s judgment to determine the best course of treatment based on their patients’ unique, personalized needs. We hope that the Board takes these recommendations into consideration.

As we consider the future of SUD treatment in Ohio, we encourage the Board to consider broader changes to the regulatory code that would make treatment of substance use disorders more similar to treatment of other high-risk, chronic medical and behavioral health conditions, where circumscribed state regulations focus on public health concerns (e.g. communicable disease reporting), and the practice of medicine falls largely under the purview of the physician to adhere to evidence-based best practices and the authority of federal agencies (e.g. DEA). We appreciate the steps that the Ohio State Medical Board took in 2021 to align Ohio’s telemedicine rules with those of federal agencies. To remove Ohio’s buprenorphine-specific state regulations would align our regulations with forty other states across the U.S. Ultimately, we all share in our desire to reduce the impact of the opioid crisis on Ohioans, who continue to die from accidental overdose at staggering rates. Our team remains available to support the Board and other officials through this rulemaking process, and other regulatory considerations. We appreciate your continued commitment to Ohioans and physicians across the state.

Sincerely,

Natalie Lester, MD, MPH, MBA
Chief Medical Officer, Chief Strategy Officer
OneFifteen

Martha Taylor, MSN
President and Chief Executive Officer
OneFifteen

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Ohio Society of Addiction Medicine

A Chapter of American Society of Addiction Medicine

October 6, 2023

Ms. Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 E Broad St
3rd Floor
Columbus, OH 43215

Re: OHSAM's Comments on the Proposed Changes to Medical Board's OH Physician Rules Relating to Buprenorphine Treatment

Dear Ms. Anderson,

On behalf of the Ohio Society of Addiction Medicine (OHSAM), the medical specialty society representing physicians and clinicians in Ohio who specialize in the prevention and treatment of addiction, thank you for the opportunity to comment on this important proposal. We greatly appreciate your continued efforts to ensure that the practice of medicine is safe for the patients of Ohio. Today, we write to comment on the Board's proposed changes to the Physician Rules Chapter 4731-33 regarding the provision of buprenorphine treatment in our state. **In sum, while we feel that this proposal represents an improvement over the previous iteration, we urge revisions in areas such as the numerically defined frequency of urine drug screenings and continued limitations around prescribing higher dose buprenorphine in the era of high potency synthetic opioids (HPSO's).** Absent a discussion about a full-scale revision/retraction of these rules, OHSAM supports a prompt review of the highlighted provisions in support of further expanding access to evidence-based treatment for opioid use disorder (OUD) at this time of great need.

First, we want to highlight the language in §4731-33-02(D)(1) (b) of the withdrawal management section of the proposal. The language states that treatment should only initiate treatment if there is 'high likelihood of treatment adherence and retention in treatment.' While OHSAM agrees that treatment adherence and retention are important goals, we feel that this language is subjective and stigmatizing. Further, we fear that in worst cases it could be used as a justification to deny withdrawal management services from vulnerable populations, such as low-income persons and the unhoused. Ultimately, we want to ensure that treatment for OUD is as accessible as possible, regardless of a person's station in life. **As such, we urge you to remove this line from the final version of these rules.**

Section 4731-33-03 sets the rules for practitioners operating in office-based treatment for opioid addiction (OBOT). Specifically, in §4731-33-03(G)(6), the proposal stipulates that practitioners must require at least two drug tests per quarter during the first year of treatment then one per quarter afterwards. Drug tests, including urine drug screenings, are a useful tool to evaluate patient compliance with a treatment plan. However, OHSAM opposes placing numerical

requirements on clinicians and instead urges an approach of maximizing clinical discretion. Indeed, ASAM's 2020 National Practice Guideline acknowledges that limited research supports an exact frequency of drug screenings for patients receiving treatment for OUD. Instead, it states that frequency should be determined by a number of individual factors, including the stability of the patient, the type of treatment, and the treatment setting.[1] The guideline also states that urine drug screenings are more likely necessary during the beginning stages of treatment. Additionally, the guideline notes federal laws requiring opioid treatment programs (OTPs) to conduct 8 drug screens per year at a minimum. However, given the inconclusive nature of research supporting an ideal frequency of drug tests and the importance of clinical flexibility in this area, we urge you to consider removing numerical defined requirements for a minimum amount of drug tests in OBOT settings. **We encourage replacing these numerical requirements with language clarifying the utility of drug testing and recommending practitioners use it as a tool to address patient compliance, rather than explicitly defining a minimum number of tests per quarter.**

Additionally, we seek revision to §4731-33-03(G)(7) of the OBOT rules, relating to daily dosage guidelines for buprenorphine. While we appreciate the Board proposing to revise a strict cap on more than 24mg of buprenorphine per day, OHSAM feels that the language is still too restrictive to meet the treatment challenges posed by HPSO's. ASAM recently released updated clinical considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids (HPSOs).[2] These clinical considerations account for the increased prevalence of HPSO's--like fentanyl-- in the drug supply. Crucially, the clinical considerations reference high quality studies showing improved treatment retention, reduced opioid use, and lack of adverse events at 16-32 mg doses of buprenorphine. The clinical considerations conclude that some patients may benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24 mg per day).

However, this proposed rule does not grant all practitioners the same ability to treat patients with higher dosages of buprenorphine if necessary. Instead, this rule would only allow clinicians with board certification in addiction medicine/psychiatry to prescribe dosages above 24mg/day. While OHSAM recognizes the value of addiction specialist physicians (ASPs)[3] who are uniquely trained and qualified to treat addiction and similarly appreciates the Board's recognition, OHSAM is concerned that the Board did not consider whether there are enough ASPs to meet the demand of patients in Ohio who may need treatment with buprenorphine beyond 24mg due to HPSOs. **Before the Board finalizes a requirement to mandate that only ASPs be permitted to prescribe buprenorphine beyond 24mg or require a consultation with an ASP in the case of non-ASPs, OHSAM encourages the Board to consider whether this mandate would jeopardize access to treatment due to limited numbers of board-certified addiction medicine/psychiatrist clinicians.**

Relatedly, OHSAM encourages the Board to define board-certified addiction medicine specialists/addiction psychiatrists in line with ASAM's Recognition and Role of Addiction Specialist Physicians in Health Care in the United States policy statement.[4]

OHSAM greatly appreciates the opportunity to comment on this important proposal. We commend the Board for its willingness to change and improve. We hope that you will consider our suggestions and look forward to working collaboratively to produce rules that ensure expanded access to treatment for OUD. Please do not hesitate to contact me at tvp@cwru.edu

or Dr. Krisanna Deppen at krisanna.deppen@ohiohealth.com if our organization can assist you any further.

Sincerely,

Theodore V. Parran, MD, FACP, FASAM
President, Ohio Society of Addiction Medicine

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[4] **Ibid.**

October 6, 2023

TO THE STATE MEDICAL BOARD OF OHIO REVISIONS TO REGULATIONS

CONCERNING WITHDRAWAL MANAGEMENT FOR SUBSTANCE USE DISORDER

AND OFFICE-BASED TREATMENT OF OPIOID ADDICTION

OAC 4731-33-01

OAC 4731-33-02

OAC 4731-33-03

OAC 4731-33-04

Thank you for the opportunity to comment publicly we appreciate the Board's efforts to update these rules by relaxing the requirements for psychosocial interventions, recognizing that in the evolving climate of the opioid epidemic, higher doses of buprenorphine are often medically indicated, and revising its language to use terminology consistent with the evolving science. We believe that there are opportunities for further improvement, for example by modifying the language to allow room for physician judgment to proceed with treatment when circumstances prevent full adherence to the extensive requirements described in these rules. We hope that the Board takes these recommendations into consideration.

The Ohio Institute for SUD Excellence (OISE) is a provider-driven non-profit organization whose members are SUD providers who are committed to transparently reporting outcomes, evidence-based practice, and defining a standard of care in addiction treatment. Our members are eager to support this opportunity to, if not remove entirely, update the language and rules to align with current and future progress in addiction treatment while removing the stigma inherent to the current language and the very existence of the rules.

Current rules compound stigma in both access to appropriate treatment for patients and by creating an arbitrary barrier of entry into the behavioral health workforce by dictating and/or limiting provider deference. By regulating providers in this way, we unintentionally increase the trepidation of medical providers to embrace, incorporate, and pursue the practice of addiction medicine. This is in direct contrast with the federal landscape which seeks to expand capacity and access to care. This is further negatively compounded as we struggle to change the tide of Ohio's behavioral health workforce shortage.

OISE further advocates for the inclusion of harm reduction into any addiction language updates. Harm Reduction is an evidence-based approach that is critical to engaging with people who use drugs by approaching patients with a values-neutral mindset that allows us to equip them with lifesaving tools, mitigate public health infections, and set a course for empowering them to drive toward positive change. For example, a harm reduction lens would remove all stigmatizing language while prioritizing all patients receiving suboxone, short or long term, based on patient-centered care planning. Dosing ranges would be removed as would counseling requirements.

Current rules run opposite to the tenets of Harm Reduction. While harm reduction has gained traction as a formal evidence-based movement built around protecting the dignity and humanity of individuals experiencing substance use disorders, its principles are not novel to practicing physicians. Harm reduction seeks to reduce the hazard and harm associated with substance use; much in the way treating diabetes and hypertension seeks to reduce the morbidity and mortality associated with those disorders. Physicians treating chronic diseases do not insist upon a perfect or complete treatment plan before instituting or continuing treatment. They instead work with the patient to describe evidence-based treatments and jointly construct a treatment plan.

OISE also encourages using broader language when incorporating national practice guidance in the rules. As you are aware, the regulations reference the third edition of the American Society of Addiction Medicine (ASAM) criteria and other published national practice guidelines. In other sections, specific Training Improvement Protocols (TIPs) from the Substance Abuse and Mental Health Services Administration (SAMHSA) are referenced as patient treatment guidance. Considering recent updates and a rapidly evolving best practice environment, OISE suggests the Board use language such as "the most current version" of guidance from "federal regulatory entities" or "national societies" to prevent confusion and unnecessary revisions of the regulations.

As a final note, OISE is cognizant of the necessity to provide general dosing protocols for controlled substances. However, they should ensure the physician has sufficient discretion when determining exact amounts for individual patients. OISE fully supports the language that states a MOUD dosage amount for withdrawal management should be "effective in suppressing withdrawal symptoms" and is "consistent with currently accepted standards of care." This type of discretionary language allows physicians to effectively treat patients by alleviating the fear of noncompliance with strict limitations.

Yours in good health,

Ms. Tia Marcel Moretti

Ms. Tia Marcel Moretti, LSW, OCPC

Founder/CEO

Ohio Institute for SUD Excellence

From: Roma Amin
To: Anderson, Kimberly
Subject: MAT Rules for Physicians
Date: Wednesday, September 27, 2023 7:51:49 PM

To whom this may concern:

My name is Roma Amin. I am a family medicine physician in Columbus, Ohio. I prescribe medication-assisted therapy as a part of my primary care. The current proposed rules would provide a significant documentation burden for primary care physicians and risk decreasing access for patients, especially in underserved areas - but also for more privileged patients who also face significant stigma in accessing care for their substance use. I would respectfully ask the committee to reconsider the documentation burden. Having increased barriers to MAT perpetuates the stigma of substance use, which we know is a health condition - similar to diabetes, hypertension, depression, etc. The care of substance use is a crucial part of primary care. Primary care physicians provide a significant amount of the substance use care across the state, and it is integral that we continue to put our efforts towards increasing access to self and life saving medications - and supporting the clinicians who are providing this care.

Respectfully submitted,
Roma Amin

UC Health

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513-585-6000
www.uchealth.com

October 6, 2023

Dr. Sherry Johnson
President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Re: Regarding Rule Proposed Amendment

4731-33-93: Office-Based Treatment for Addiction

4731-33-04: Medication-Assisted Treatment Using Naltrexone

4730-4-03 (PA): Office-Based Treatment for Addiction

4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone

Dear President Johnson:

The University of Cincinnati Health Addiction Sciences utilizes state-of the art evidence-based treatment for substance use disorder. We provide a wide variety of clinical services such as an opioid treatment program, outpatient addiction treatment. In addition, our researchers are nationally recognized experts in the field of designing, leading and performing clinical trials for the development of substance use disorder treatment. We have been part of the National Institute on Drug Abuse Clinical Trials Network (NIDA) since 1997. We have reviewed the proposed rule amendment on outpatient office-based addiction treatment and would like to provide some comments based on our program's expertise.

As of 2021, there are an estimated 2.5 million individuals with opioid use disorder (OUD), yet only 22% of them received any medications for OUD (Jones et al., 2023). Buprenorphine is extremely safe, and compared to individuals not receiving treatment, buprenorphine reduces mortality by 38% (Larochelle et al., 2018). The fourth wave of the opioid overdose crisis started in 2015, driven by the introduction of fentanyl and other high-potency synthetic opioids (HPSO) into the U.S. This change in drug supply has caused opioid overdoses to skyrocket. According to Ohio's most recent CDC data, our state ranks 8th regarding the highest drug overdose death rate (CDC, 2021). It is urgent that we expand access to evidence-based medications for OUD (MOUD).

These proposed rules for outpatient buprenorphine treatment had the intent to decrease the risk of diversion, misuse of the medication and serve as clinician education to increase confidence in quality of care. New research exists to characterize this risk and the impact of regulations. We must balance the need for broadly accessible, low-barrier treatment for OUD with MOUD against the risk of diversion and misuse and let the evidence guide us in determining how to make this medication safe and accessible to those who need it. **Overall, we strongly support the removal of all the existing OH Outpatient Addiction Treatment Regulations.**

NIDA has created an excellent summary of this risk of diversion vs. treatment with buprenorphine which can be reviewed here (NIDA, 2021): To summarize some of the evidence, a US survey among individuals with OUD found that diverted buprenorphine was utilized for therapeutic purposes with 97% of respondents reporting using it to prevent cravings and 90% using it to prevent withdrawal (Schuman-Olivier et al., 2010). Not surprisingly, illicit use of buprenorphine decreased as individuals had greater access to treatment, supporting the need to expand treatment access urgently (Schuman-Olivier et al., 2010). Even among the minority of individuals (likely 8-25%) who use buprenorphine for non-therapeutic purposes, their use for this purpose rapidly decreases over time, likely because of the unique pharmacology of the medication which quickly blunts the rewarding effects over time (Cicero et al., 2007; Schuman-Olivier et al., 2010). In addition, a recent study demonstrated that overdose deaths involving buprenorphine did **NOT** proportionally increase with the new flexibility in buprenorphine prescribing that was put in place during the COVID-19 pandemic (Tanz et al., 2023). This further supports that removing these regulations will not increase buprenorphine overdose deaths. This evidence points in one direction: the medical board should remove these regulations. Currently, only ten states have buprenorphine regulations in place and despite our current rules, our overdose deaths remain one of the highest in the country (Andraka-Christou et al., 2022). We must remove these regulatory barriers to outpatient providers.

Preventing diversion is important; if the goal is to minimize high-volume clinics that prescribe large amounts of buprenorphine with inadequate medical treatment, the rules could be limited to clinicians that care for more than 100 patients on buprenorphine. We recommend that the state rules not apply to physicians who prescribe office-based opioid treatment (OBOT) to fewer than 100 patients. This would exempt primary care physicians who provide OBOT as part of their general practice – currently many of these physicans are fearful violating the complicated regulations and therefore avoid providing this life-saving evidence-based treatment.

If the intent of these rules is to provide education to clinicians on appropriate treatment, they are ineffective and not consistent with any principles of adult learning theory. The rules do not effectively guide medical practice in assessing and treating individuals with OUD. They lack practical instructions on how to take a substance use disorder history, how to apply diagnostic criteria, and they must be adapted to different clinical scenarios and patients' responses. Most clinicians will utilize resources such as up-to-date research and evidence based reviews which reflect the modern adult learning theory of self-regulation and master adaptive learning (Cutrer et al., 2018; Murad et al., 2010). These are the learning theories on which models of CME are based. The rules currently regulate the frequency of visits, toxicology testing, duration of prescriptions, lab requirements, and documentation requirements when physicians require flexibility to best care for their patients. They do not provide education in assessment and developing a treatment plan for OUD.

Furthermore, these rules are subject to 5-year reviews, so they cannot stay current on the latest medical practices. Medicine changes rapidly. Over the past three years, fentanyl has overtaken the drug supply, changing clinical practice recommendation to include low and high-dose inductions as needed to start buprenorphine. The rules reference induction guidelines that are out of date. Physicians are experienced in finding clinical guidelines to inform their care, as medicine constantly evolves. By using the rules, physicians lose their ability to integrate the newest recommendations and techniques at significant cost to best practices in patient care. The DEA recently instituted a mandatory 8 hours of education on substance use disorders to obtain a license, and after 20 years of medication availability, the X-waiver has been removed, signaling that special training on this medication is no longer necessary. In addition, residency programs such as the ACGME now require education for internists on addiction during their residency.

We are confident that the board is most concerned about quality of care. In that case, we recommend providing examples of free interactive CME materials within an abbreviated rule, which are evidence-based ways to impact the quality of care. They might also recommend facilitators for new primary care providers (PCP) prescribing buprenorphine. The board could consider language encouraging physicians new to prescribing buprenorphine to utilize a mentorship model through PCSS or contact the National Clinician Consultation Warmline for Substance Use Disorders. Not all clinicians may be aware of these resources.

Overall, the current regulations are outdated, prevent access to care by overburdening outpatient providers, and lack the flexibility for physicians to make medically appropriate decisions for their patients. Evidence supports that increased regulatory flexibility did not increase buprenorphine overdose deaths. Forty states do not regulate buprenorphine; evidence supports that it is used for therapeutic purposes even if diversion occurs, and we should treat this medication as any other chronic disease by encouraging routine CME education on substance use disorders. In fact, by removing these regulations, we are likely to see a decrease in buprenorphine diversion and an increase in treatment access. The existence of these rules contributes to the stigma our patients face daily. **We need to remove unnecessary barriers to treatment with buprenorphine for OUD urgently to address the overdose crisis.**

Thank you for consideration of our feedback. Should the rules remain place, we have provided specific commentary below that might improve the proposed rules based on the most recent evidence in addiction treatment. These would provide evidence-based updates to care, focus on the standard of retention in treatment, provide clinicians the flexibility they need to treat addiction as a chronic disease, and decrease documentation burden.

Specific Commentary

4731-33-01: Definitions

1. (C) The term **medication-assisted treatment (MAT),** is no longer recommended.

Comment: It is considered inaccurate as it could imply that pharmacotherapy is inferior to psychosocial pathways. Instead, the term medications for opioid use disorder (MOUD) or medications for alcohol use disorder (MAUD) should be used. Please see the following editorial from the American Society of Addiction Medicine (ASAM) Journal of Addiction Medicine for more information (Saitz et al., 2021). We recommend replacing MAT with either MOUD or MAUD, depending on the context throughout the document.

2. (J and K) The definitions of the **induction** and **maintenance** phases are clinically inaccurate.

Comment: Induction is the medical phase of MOUD during which the dosage levels are adjusted until a patient is no longer in physiological opioid withdrawal We recommend replacing the definition for maintenance as "the phase in which a person has been sustained on a steady dose of buprenorphine."

3. (L) We recommend **removing the word "substance abuse**" and replacing it with substance use disorder which is the correct terminology.

Comment: Substance abuse is considered outdated and stigmatizing terminology (Saitz et al., 2021) .

4731-33-02: Standards and procedures for withdrawal management for substance use disorder

1. **B1**: "The patient shall be provided information about all medications approved… and **shall be documented** in the patient record".

Comment: We recommend removing the documentation requirement as this is unnecessarily burdensome on the clinician. In general medical practice, physicians do not typically document all the medications discussed; it is implied as part of a routine visit when starting any chronic disease medication.

2. **B2:** "and **confirmation of acceptance** of the referral by the program, physician, physician assistant or advanced practice registered nurse shall be documented in the patient record."

Comment: We recommend removing the requirement for confirmation of acceptance and documentation. Confirmation of referral acceptance is not required for any other primary care referral. This would deter primary care physicians from referring/offering OBOT as this is currently not a standard of care for any other chronic condition.

3. **D1a :"**The patient has adequate **social**, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management."

Comment: This statement may deter individuals from providing low-barrier buprenorphine to homeless patients or individuals in shelters as their social situation could be interpreted as inadequate. OBOT has been successfully implemented for homeless individuals and had comparable outcomes to housed patients regarding treatment failure, return to use, and treatment utilization (Alford et al., 2007). We recommend removing the word "social" from this line. In general, allowing a clinician to utilize their medical judgement without adding the word social would make this clause less likely to be misinterpreted.

4. **D1b**: "The patient has a **high likelihood of treatment adherence and retention in treatment**; and…"

Comment: This statement may further stigmatize a high-risk patient population and could predispose physicians to implicit bias. There is already a significant disparity in who receives buprenorphine, with Black patients with a lower odds of receiving buprenorphine compared to white patients (Lagisetty et al., 2019). We are concerned that this phrase could be used or interpreted to deny at risk-populations OBOT.

5. **D1c**- "There is **little risk of medication diversion**".

Comment: We recommend removing this statement because there is no evidence that clinicians can accurately determine whether a patient is at risk of medication diversion before offering treatment. For example, a homeless individual could be perceived as being at risk of medication diversion, yet studies support that this population can be effectively treated with OBOT (Alford et al., 2007). Again, this statement could be used or interpreted to deny at-risk populations OBOT.

6. **D4.** "**Prior to providing** ambulatory withdrawal management detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient, to include the following…"

Comment: We recommend moving clause (4m), "If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall document the reason in the medical record" to the top of the document so it is clear that it is not necessary to delay life-saving treatment if a full assessment cannot be completed for valid medical reasons.

7. **4e:** "**Appropriate physical examination**".

Comment: We recommend this be adjusted to "Appropriate physical examination, which can be conducted in-person or via telehealth," which was shown during the COVID emergency to be safe and effective for OBOT treatment. Telehealth OBOT expansion during the pandemic was associated with individuals staying in treatment longer and decreasing their risk of overdose (Jones et al., 2023; Krawczyk et al., 2023).

8. **D4g-k**: "Prior to providing ambulatory withdrawal management detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient, to include the following…" **pregnancy testing, HIV, Hepatitis B, and Hepatitis C**

Comment: We do not recommend mandatory laboratory tests as patients have autonomy to decline lab tests without impacting their receipt of needed treatment. Physicians can provide education on risks and benefits and make a clinical decision whether they believe treatment is appropriate if lab testing is not completed. None of the listed laboratory tests are required for patient safety when initiating MOUD.

1. **D9** "The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs;

Comment: We recommend changing the wording to, "**If clinically appropriate,** the physician will obtain urine and/or other toxicological screenings during withdrawal management if it will inform the care of the patient." Extremely frequent toxicological testing is not clinically helpful due to the window of detection of substances in these tests. For example, urine testing for alcohol metabolites (for example, urine ethyl glucuronide) has a window of detection for heavy drinking of 2-5 days; therefore, it would be positive throughout the entire process of ambulatory alcohol withdrawal without necessarily indicating additional consumption of alcohol.

2. **10bi:** "The physician shall not use any of the following drugs to treat the patient's withdrawal symptoms: **Methadone**"

Comment: There is a DEA exception to using methadone for three days to manage opioid withdrawal outside of OTPs called the "3-day rule". The wording of this phrase would make it illegal to use this rule in Ohio. This clause should be removed and deferred to federal regulations. Since OTPs do not always have 7-day-a-week availability, the intent of this rule is to let providers, in very certain and limited circumstances, provide and dispense methadone for up to 3 days. Please see the federal registrar rule here: https://www.federalregister.gov/documents/2023/08/08/2023-16892/dispensing-of-narcotic-drugs-to-relieve-acute-withdrawal-symptoms-of-opioid-use-disorder . The provider must be separately registered with the DEA to provide this care, and many regulatory burdens around this are already in place. In a recent study of a clinic using the 3-day rule, 87% of patients who received methadone under this three-day rule were successfully linked to an OTP (Taylor et al., 2022). Another example of the use of the 3 day rule can be found here: https://medicine.yale.edu/news-article/addiction-medicine-team-dispenses-first-three-day-supply-of-methadone-at-yale/

4731-33-03 OFFICE BASED TREATMENT FOR OPIOID ADDICTION

1. **D: "**The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following…" **TIP-63 and ASAM 2020 protocols**

Comment We recommend removing this requirement. Both the TIP and ASAM documents listed are outdated, and do not include newer standards of care for buprenorphine induction. Low-dose and high-dose inductions are considered reasonable treatment plans to offer as a standard of care, and neither document discusses those options. It is likely that any new protocol added to rules that are reviewed every 5 years will also be outdated by the time of the next review.

2. **G3a:** "The physician shall verify the diagnosis for which the patient is receiving the other drug and **coordinate care with the prescriber for the other drug**, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue…"

Comment: We recommend that this wording be changed to, "**If the patient is receiving the medication for a chronic condition**, the physician shall verify the diagnosis for which the patient is receiving the other drug and **attempt to coordinate care with the prescriber for the other drug.**" We agree that a good faith effort should be made to coordinate care, but if another physician is unresponsive, **buprenorphine should NOT** be withheld due to an inability to speak to another provider, as the risk of an opioid overdose without buprenorphine outweighs any risk of co-prescribing. We additionally recommend this **clause apply only to chronic medications** to avoid burdening physicians with coordination for low-risk scenarios.

3. **G4**: "During the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. **The physician shall see the patient at least once a week during this phase.**"

Comment: We recommend removing the requirement that patients be seen at least once a week during the induction phase. There is no evidence to suggest that this is necessary, though it may be appropriate for some patients. Visit frequency is best decided between the physician and patient. Visit frequency should be decided based on medical necessity, clinic capacity, and patient preference. We recommend changing the wording to "**The physician shall determine when to see the patient based on medical necessity, clinic capacity, and patient preference."**

4. **G5a:** "During the first ninety days of treatment, the physician shall **prescribe no more than a two-week supply** of the buprenorphine product, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants."

Comment: There is no evidence to suggest that only providing a 2-week supply will decrease diversion or overdose risk. While this may be clinically appropriate for OUD treatment, a physician should individualize the supply duration based on the patient's needs. We recommend that this clause be removed or changed to the following: "During the first ninety days of treatment, the physician shall **prescribe an appropriate duration** of buprenorphine product based on their **clinical OUD stability, medical necessity, and clinical judgment."**

5. **G5b:** "Starting with the **ninety-first day** of treatment and until the completion of twelve months of treatment, the physician shall **prescribe no more than a thirty-day supply of** the buprenorphine product, unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implant."

Comment: See rationale in comment 13.

6. **G6**: "The physician shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, and checking OARRS. The physician **shall require urine drug testing**, serum medication levels, or oral fluid testing at **least twice per quarter for the first year of treatment and at least once per quarter thereafter.**"

Comment: There is no evidence to suggest that required UDT decreases diversion. A physician should determine the optimal frequency for UDT testing. We recommend this be revised to: "The physician shall take steps to reduce the risk chances of buprenorphine diversion, **which may include any of the following strategies**: using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, checking OARRS. The physician **shall use any combination of urine drug testing screens**, **serum medication levels, or oral fluid testing to monitor adherence to the medication at a frequency based on medical necessity for treatment and clinical judgment."**

7. **G7:** "When using any oral formulation of buprenorphine, the physician **shall document** in the medical record the rationale for prescribed **doses exceeding sixteen milligrams** of buprenorphine per day. The physician shall **not prescribe a dosage exceeding twenty-four milligrams** of buprenorphine per day, unless the prescriber is a board-certified addiction specialist or addiction psychiatrist, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day."

Comment: A recent study compared buprenorphine retention in treatment for patients taking 16 mg vs 24 mg doses (Chambers et al., 2023). Patients on the 24 mg dose were statistically more likely to remain in treatment than those on the 16 mg dose. The 2023 ASAM clinical considerations for buprenorphine in the era of HPSO acknowledge that individuals who use fentanyl have more challenges stabilizing their OUD on buprenorphine and likely need a higher dose of 24 – 32 mg of buprenorphine (Weimer et al., 2023). A recent review on buprenorphine dose limits supports evidence for dose-dependent benefits up to at least 32mg/day (Grande et al., 2023). We recommend deleting this requirement and allowing the physician to use clinical judgement to determine appropriate dosing, as is done for all other prescribed medications.

8. **G9a-d:** "The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

Comment: Due to the already existing federal regulations on ER buprenorphine requiring Risk Evaluation and Mitigation Strategy (REMS), I recommend removing this clause to decrease the documentation burden. REMS have appropriate high standards, and since this medication must be administered in person due to this clause, there is zero risk of patient diversion. Evidence suggests ER buprenorphine is superior to SL buprenorphine for overdose prevention and additionally improves medication adherence (Lee et al., 2023).

Medication-assisted treatment using naltrexone

Comment: Naltrexone is not a controlled substance, cannot be misused, is very safe, and requires almost no monitoring to be medically safe for an individual. We do not believe the medical board needs a separate rule on this topic.

Thank you for reviewing and considering our specific comments. Feel free to reach out if you have any questions or would like additional citations.

Sincerely,

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OHIO PSYCHIATRIC PHYSICIANS ASSOCIATION

A District Branch of the American Psychiatric Association

Dedicated to promoting the highest quality care for people with mental disorders and to serving the professional needs of Ohio's psychiatric physicians.

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October 6, 2023

Stephanie Loucka, Director
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Re: Proposed Rules on Office-Based Treatment for Addiction
- 4730-4-03 (PA): Office-Based Treatment for Addiction
- 4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone
- 4731-33-04: Medication-Assisted Treatment Using Naltrexone
- 4731-33-93: Office-Based Treatment for Addiction

Dear Stephanie and Members of the State Medical Board of Ohio,

The Ohio Psychiatric Physicians Association (OPPA) is a medical specialty organization that represents nearly 1,000 physicians who specialize in psychiatry, many of whom sub-specialize in addiction psychiatry. We have within the scope of our mission to promote the highest quality care for individuals with mental health disorders, which include substance use disorders. As physicians who are dedicated to the health and well-being of the patients we treat, we are writing about the Proposed Rules on Office-Based Treatment for Addiction (specifically identified by rule number above), which impact our members' practices and the patients for whom they care.

Based on numerous studies, buprenorphine has been proven to be an extremely effective, evidence-based treatment for opioid substance use disorder. We understand the concerns with diversion and misuse of the medication however, we must balance those concerns with concerns about adding language to the rules that would restrict access to patients whose lives can be saved with the use of the medication. Studies have found that only 22% of individuals suffering from opioid use disorder receive treatment.

The current rules already deter many physicians from prescribing buprenorphine to their patients. We must include language that reduces the burden and fear on the part of physicians, in order to broadly increase access for patients who would benefit from treatment with buprenorphine. Restrictions on MAT can lead to prolonged suffering for those with substance use disorders as well as create barriers to treatment. Stigma and discrimination are already significant obstacles to addiction treatment, and limiting MAT access only exacerbates these issues. Additionally, the opioid epidemic is a public health crisis, and MAT has been recognized as a crucial tool in combatting it. Limiting access to MAT can hinder efforts to reduce opioid-related fatalities and the overall societal burden of addiction.

Overall, OPPA supports access to buprenorphine treatment as an important development in addressing addiction and mental health challenges within the state. Suboxone, as well as naltrexone are valuable medication-assisted treatment options for individuals with opioid use disorder. While the proposed rules encourage increased access there is an undue burden placed on physicians who want to prescribe these lifesaving medications. In general, our support underscores the organization's dedication to ensuring that individuals receive comprehensive and evidence-based care, which includes addressing the intersection of addiction and mental health, ultimately leading to better outcomes for those in need of treatment.

We look forward to ongoing dialogue about these proposed changes.

Sincerely,

Alyse N. Stolting, MD
President

October 2, 2023

Regarding Rule Proposed Amendment

4731-33-93: Office-Based Treatment for Addiction

4731-33-04: Medication-Assisted Treatment Using Naltrexone

4730-4-03 (PA): Office-Based Treatment for Addiction

4730-4-04 (PA): Medication-Assisted Treatment Using Naltrexone

Dear State Medical Board of Ohio,

My name is Michael Binder and I am a physician who works in Cincinnati. The regulation of addiction treatment impacts patients in Ohio.

I have reviewed the proposed amendment to the rules listed above, and strongly support removing the physician and physician assistant regulations for office-based addiction treatment and medication-assisted treatment using naltrexone. With the removal of the X-waiver, any individual with a DEA can now prescribe buprenorphine for opioid use disorder (OUD). Removing outpatient addiction treatment regulations on buprenorphine and naltrexone in Ohio is a vital step towards combating the opioid crisis and promoting effective addiction treatment.

There are already federal regulations related to prescribing of medications and it is my understanding that most states to not have additional buprenorphine regulations. These further regulations make prescribing a life-saving medication (buprenorphine) much more burdensome.

When the x-waiver was removed, I spoke to a group of dozens of primary care physicians in my community to encourage them to treat patients with opioid use disorder. There was low interest among those physicians in treating patients with opioid use disorder, and the regulations for office-based addiction treatment are a major reason why. These doctors spoke to me about the large burden of these regulations. Treating a patient who has opioid use disorder with buprenorphine can drastically lower their risk of dying.

On average, over one person per day dies of a drug overdose in Hamilton County, Ohio, where I live and practice medicine. Buprenorphine is a life-saving medication. It is already being regulated tightly at a federal level. Adding further regulations at the state level effectively make it less accessible to the people who need it most.

I appreciate your consideration of my comments. Feel free to reach out to me with any additional questions or concerns. I genuinely support removing these regulations.

Thank you greatly for your time and attention, and for all that you do.

Sincerely,

Michael C. Binder

Michael Binder, MD, MPH

Cincinnati, OH

MichaelCBinder@gmail.com

OATOD
OHIO ASSOCIATION FOR THE TREATMENT OF OPIOID DEPENDENCE

October 9, 2023

Ms. Kimberly Anderson
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, Ohio 43215

Subj: Comments on the Medication-Assisted Treatment Rules for Physicians/PAs

Dear Ms. Anderson,

The Ohio Association for the Treatment of Opioid Dependence (OATOD) appreciates the opportunity to offer comments on the above-referenced proposed rules. OATOD – a division of the Ohio Council of Behavioral Health and Family Services Providers – is a statewide advocacy coalition consisting of twenty (21) organizations that operate approximately one hundred (100) out of the one hundred thirteen (113) federally certified and state-licensed opioid treatment programs (OTP) in Ohio. OTPs are the only recognized healthcare sites where all three forms of medication-assisted treatment (methadone, buprenorphine, and naltrexone) can be offered, and the exclusive healthcare entity authorized to provide methadone as treatment for opioid use disorder. OATOD and the Ohio Council applaud the Medical Board's willingness to listen to stakeholder feedback throughout this rule-making process.

Overall, the draft rules (OAC 4730-4 and 4731-33) appear to make positive changes, including streamlining and clarifying requirements; updating certain terms and definitions; recognizing peer supporters and case management; and emphasizing a harm-reduction or patient-centered approach to medication-assisted-treatment.

OATOD encourages OBOT practitioners to consult, collaborate and refer patients in need of a higher level of care to community MH/SUD providers for psychosocial services and more intensive MAT services if needed – amended paragraphs (E) of rules 4731-33-03 and 4730-4-03 largely appear to reflect this practice. OATOD recommends that both rules continue to require physicians and PAs to document the referral of psychosocial services to patients. This should help to keep OBOT practitioners aware of such resources in their communities.

Thank you for the opportunity to provide feedback on this rule. If you have any questions or would like to discuss this matter in greater detail, please contact me at your convenience.

Respectfully,

Geoffrey Collver
collver@theohiocouncil.org
202-421-6033

From: Anderson, Kimberly
To: janetbaker@foresthills.edu
Cc: Contact
Subject: RE: Vivitrol
Date: Wednesday, November 8, 2023 1:34:00 PM
Attachments: image006.png
image007.png
image008.png
image009.png
image010.png

Ms. Baker,

Thank you for your comment regarding Rule 4731-33-01, OAC. It will be shared with the Medical Board.

Kimberly C. Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
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O: (614) 466-7207
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From: Janet Baker <janetbaker@foresthills.edu>
Sent: Wednesday, November 8, 2023 8:39 AM
To: Contact <Contact@med.ohio.gov>
Subject: Fwd: Vivitrol

I sent this letter a week ago and have received no reply. When might I expect to hear something?

Thank you.

Janet G. Baker, Ph.D.

---------- Forwarded message ---------
From: **Janet Baker** <janetbaker@foresthills.edu>
Date: Wed, Nov 1, 2023 at 2:12 PM
Subject: Vivitrol
To: <contact@med.ohio.gov>

To the Board:

I use Vivitrol to assist in maintaining sobriety from alcohol. It has been a very helpful medication for me for almost a year. I have always been able to order it from my specialty pharmacy and have it injected at my Primary Care Physician's office (affiliated with Christ Hospital in Cincinnati) which happens to be right next door to my work. The entire enterprise would take ten minutes monthly. Recently, the medical division for Christ Hospital made the decision that Vivitrol should no longer my administered by their offices. I was told by my physician that Christ was advised by the Board of Medicine to interpret the law/rules in the most conservative manner. The guideline 4731-33-01 specifically referenced That is what led to the policy..

Obviously, I don't know that guideline or its implications. What I suspect is that Vivitrol is being thought about in the same way Methadone and Suboxone are. Of course, it couldn't be more different. Vivitrol is NOT any kind of substitute for mood altering medication. Indeed, it prevents mood alteration.

Here is what I have to do now. Brightview Addiction Center is the closest place where I can get Vivitrol. It's 30 minutes away. At that appointment each month, I have to take a number of steps I did not have to take before. I have to have urine screened. I have to have my vitals and bloodwork taken. I have to have a medical consultation. Then, I have the shot. The enterprise just within the office takes 90 minutes. So, I went from ten minutes to two hours. Further, I believe that I am having to take all of these steps not because of the medication but in order to provide more billing opportunities for the organization.

As it happens, I am persistent. I will get my medication, but I wonder about the consequences of making that medication substantially more difficult to get for everyone. It can't be good.

So, why am I contacting you? I'd like to ask that the guideline as enshrined in 4731-33-01 be reconsidered. Christ has indicated that it will be guided by the Board of Medicine. What I'm asking is that the relevant guidelines be reviewed for a potential reconsideration. I am not a physician. There may be other elements to the advice I am unaware of. But there are real-world implications here. I would like to be provided with a rationale for the current guideline as well.

I would be grateful for any help I can get.

Sincerely,