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 State Medical Board of Ohio

9/21/2023

My name is Carolyn Chan, MD, MHS, I am a board-certified internist and addiction medicine physician. I completed my internal medicine residency at CWRU/UH Hospitals in Cleveland, an addiction medicine fellowship in 2021 at Yale Program in Addiction Medicine, a medical education fellowship at Yale in 2023. 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 comments from a primary care provider and an addiction treatment expert perspective.

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, I strongly recommend 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. 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 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.

Suppose the state medical board is highly concerned about "pill mills." In that case, 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.

Some may argue that these rules educate and can improve the quality of care for treating OUD among those who do not routinely care for those with substance use disorders. As a clinician-educator with a master's in health science medical education, this thought is unlikely based on what we understand about adult learning. In addition, the metrics the board proposes such as requiring a set number of toxicology tests, script supply, visits, and lists of outdated guidelines would not achieve this goal.

First, 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, as they must be adapted to different clinical scenarios and patients' responses. Most clinicians will utilize resources such as up-to-date, clinical reviews and podcasts, 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. If individuals use these OH rules to provide care and monitor quality, it is grossly inadequate. 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 to recommend low and high-dose inductions as needed to start buprenorphine. The rules themselves admit that they are inadequate education to provide instruction on how to perform a buprenorphine initiation, as they reference guidelines (that are out of date). Physicians are experienced in finding clinical guidelines to inform their care, as medicine constantly evolves. Already, the guidelines the rules reference (see comment on page 8) to start buprenorphine are out of date. By using the rules set on a 5-year review as education, physicians lose their ability to integrate the newest recommendations and techniques at significant cost to best practices in patient care.

In addition, these rules add stigma to those with OUD. We do not mandate rules for updates in diabetes or heart failure care, disease processes that affect many more individuals. Many medicines I prescribe now did not exist while I was training in residency. I have kept up to date with these through CME requirements, which must include learning objectives, and many involve interactive components that have been demonstrated to improve the quality of care (Bloom, 2005). 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.

Suppose the board is most concerned about the quality of care. In that case, I encourage them to leave the additional CME requirements on substance use disorder treatment and provide examples of free interactive CME materials within an abbreviated rule, which are evidence-based ways to impact the quality of care. Furthermore, research has described which facilitators are needed to have primary care providers (PCP) prescribe buprenorphine. PCP's described facilitators to prescribing as "access to mentors" and "seeing it in person," which is not accomplished via these current (Lanham et al., 2022). 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 your time and consideration of my commentary. Should the rules remain place, I have provided specific commentary below to 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. Feel free to contact me at cachan00@gmail.com with any questions or concerns.

Sincerely,
Carolyn Chan, MD, MHS
Internal Medicine/Addiction Medicine
Assistant Professor of Medicine
University of Cincinnati College of Medicine

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 place individuals at risk of overdose and death unnecessarily.

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.

If the board is concerned about the quality of care, no evidence supports that these rules increase physicians' knowledge of addiction medicine. Routine CME is not unreasonable, as this is the standard for any other chronic disease and medication.

Documentation Burden

The burden of documentation in these regulations is heavy, and it appears there is a **request to document 28 times** in this rule! 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 this could be removed. 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, should be removed, and 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 term medications for opioid use disorder (MOUD) is recommended, or 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."

1. (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 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: 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 would deter primary care docs 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 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). I recommend removing the word "social" from this line; as an experienced addiction physician, I cannot think of a single social barrier to providing buprenorphine as a lifesaving medication.

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 biased 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. It 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, 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). 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 so it is less likely to be misinterpreted as a requirement PRIOR to receiving MOUD.

7. 4a " (a) The physician shall require the patient to undergo urine and/or other toxicological screenings in order to assess for the presence of alcohol metabolites, licit or demonstrate the absence of illicit drugs;

Comment:
Ambulatory alcohol withdrawal management can be completed in 2-5 days. At my practice in CT we did not do additional UDT during the actual ambulatory withdrawal protocols because it is not clinically helpful due to the window of detection of substances in these tests. For example, urine testing for alcohol

metabolites is performed through urine ethyl glucuronide, the window of detection for heavy drinking is for 2-5 days. I would expect it to be positive throughout the entire process of ambulatory alcohol withdrawal, but it does not necessarily mean the patient was consuming alcohol. Similarly depending on the substance the window of detection could be 2-5+ days. Saliva testing takes a long time for testing to return. It is rare for toxicology testing to be helpful after an ambulatory withdrawal protocol has started. I recommend changing the wording to " **If clinically appropriate,** the physician will obtain a urine and/or other tox screenings during the ambulatory withdrawal practice if it will inform the care of the patient."

8. **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.

9. **4e:** "**Appropriate physical examination**".

Comment: I recommend that it be adjusted 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., 2023; Krawczyk et al., 2023)).

10. 4a " (a) The physician shall require the patient to undergo urine and/or other toxicological screenings in order to assess for the presence of alcohol metabolites, licit or demonstrate the absence of illicit drugs;

Comment:
Ambulatory alcohol withdrawal management can be completed in 2-5 days. At my practice in CT we did not do additional UDT during the actual ambulatory withdrawal protocols because it is not clinically helpful due to the window of detection of substances in these tests. For example, urine testing for alcohol metabolites is performed through urine ethyl glucuronide, the window of detection for heavy drinking is for 2-5 days. I would expect it to be positive throughout the entire process of ambulatory alcohol withdrawal, but it does not necessarily mean the patient was consuming alcohol. Similarly depending on the substance the window of detection could be 2-5+ days. Saliva testing takes a long time for testing to return. It is rare for toxicology testing to be helpful after an ambulatory withdrawal protocol has started. I recommend changing the wording to "**If clinically appropriate,** the physician will obtain a urine and/or other tox screenings during the ambulatory withdrawal practice if it will inform the care of the patient."

11. **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 as it currently stands 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 it 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. 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 written informed consent requirement 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 it adds an unnecessary document burden and does not improve care. In addition, this will assist with decreasing 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 describes both of these treatment 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 due to "**attempt to coordinate,"** in the real world 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 benzos who are on buprenorphine are more likely to be retained in treatment (Park et al., 2020).

In addition, I recommend this **clause apply only to 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 benzo 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 is necessary, though it may be appropriate for some patients. A physician and patient best determine the visit frequency. Primary care doctors prescribe most buprenorphine, and fitting patients in can be very challenging. Visit frequency should be decided based on medical necessity, clinic capacity, and patient preference. In practice, several patients work night shifts and can only come in every two 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 as often this may be interpreted as. In the era of drug shortages, I have had a patient on the "zubsolv" formulation of buprenorphine, and it was challenging for their pharmacy to keep it in stock, so having longer prescriptions was practical to prevent a delay in access to the medication. I also had a patient with an unusual prescription insurance plan, where they were charged per script, so a 30-day supply, cost the same as a 2-week supply, thus doubling the cost to the patient to write 2 - 2 week scripts. In this scenario due to the context, it was reasonable to prescribe a 30-day supply within the first 90 days of treatment.

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 clinical judgment,** unless utilizing a formulation with a 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 best determines 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 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 a minimum, they will use urine drug testing at least twice per year, once in each half of the year.**" **If a patient has a medical condition in which they are unable to provide a urine drug test (e.g. ESRD on hemodialysis), 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 patients with 16 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 24 mg dose (Chambers et al., 2023). 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). The challenge with the original 16mg dose suggestion is the studies suggesting that dose 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 on up to 24mg. It is reasonable for an addiction provider to be involved if patients need more than 24mg 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 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 since it's 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 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 like the medical board needs a separate rule on this topic. Even IM naltrexone is not considered a standard of care, though 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 documentation burden and rules on standards, I think that this entire 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.
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Thank you for reviewing and considering my specific comments. Feel free to reach out to me if you have any additional questions, or would like additional citations.

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References

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