Empowering Advocacy: Advocating for Equitable Buprenorphine Rules in Ohio

OHSAM Advocacy Committee

Ohio Society of Addiction Medicine

When poll is active respond at **PollEv.com/carolynchan286** Send **carolynchan286** to **37607**

Introductions

Ashley Collins, MBA, CDCA

Krisanna Deppen, MD

Carolyn Chan, MD, MHS-MedEd

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Which best describes your current profession?

Med Student	0%
Resident or Fellow	0%
Addiction Medicine or Addiction Psychiatrist Clinician	0%
Outpatient Physician (internist, family med, primary care, etc)	0%
Physician Assistant	0%
Nurse Practitioner	0%
Hospitalist	0%
Other	0%

Learning Objectives

1. Describe OH's 6-step rule-making process
2. List strategies to submit effective comments on office-based buprenorphine treatment OBOT rules
3. Describe OH's proposed OBOT rules
4. Compose a comment on OH's proposed OBOT rules

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What are you hoping to learn this session?

Nobody has responded yet.

Hang tight! Responses are coming in.

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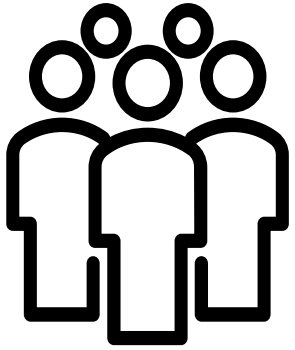
2. List strategies to submit effective comments on OBOT regulations

3. Describe OH's proposed office-based buprenorphine treatment (OBOT) rules

4. Compose a comment on OH's proposed OBOT rules

Step One**

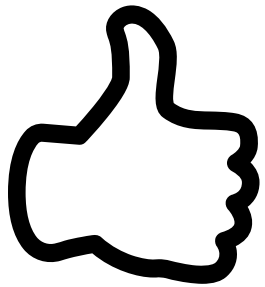
- Rules are required to be reviewed every five years.



- The Medical Board seeks interested party input for possible amendments.

https://med.ohio.gov/laws-and-regulations/rules/rule-making-guide

Step Two



- Upon Medical Board member approval, the proposed rule is filed with the Common Sense Initiative Office ("CSI").
- CSI's goal is to establish a regulatory framework in Ohio that meets four essential criteria:

1. Regulations should facilitate economic growth;
2. Regulations should be transparent and responsive;
3. Compliance should be easy and inexpensive; and
4. Regulations should be fair and consistent.

https://med.ohio.gov/laws-and-regulations/rules/rule-making-guide

Step Three

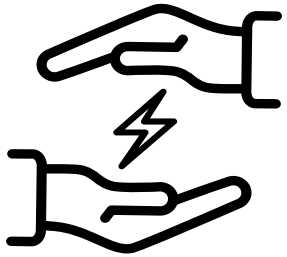
- CSI recommends the rule be filed
- Rule is filed with the Joint Committee on Agency Rule Review
- JCARR = Committee with Ohio House of Reps + Senate

House Members

Senate Members

https://med.ohio.gov/laws-and-regulations/rules/rule-making-guide

Step Four**



- JCARR jurisdiction for 65 days

- Agency has a **PUBLIC** hearing on the proposed rule

- JCARR reviews rules under eight criteria, **https://www.jcarr.state.oh.us/about**

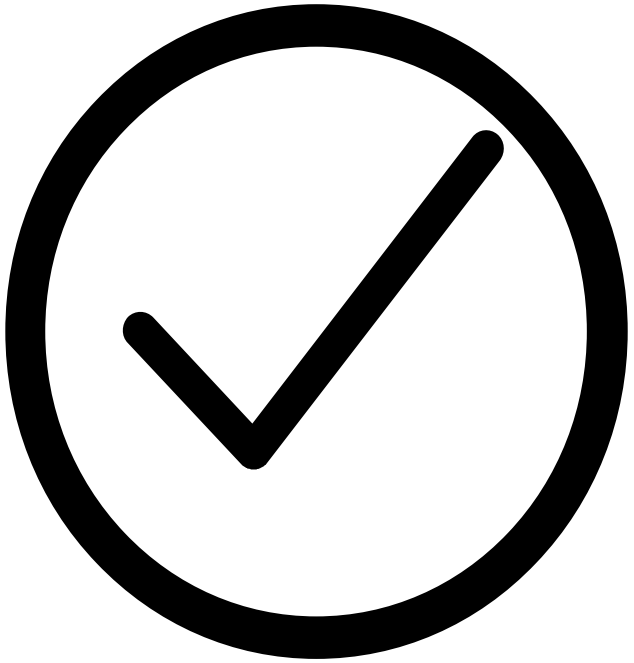
https://med.ohio.gov/laws-and-regulations/rules/rule-making-guide

Step Five

After the agency's public hearing, the proposed rule will be revised to reflect comments received.

https://med.ohio.gov/laws-and-regulations/rules/rule-making-guide

Step Six



After the JCARR jurisdiction ends, the agency is able to officially adopt the proposed rule and assign an effective date.

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Have you ever submitted comments on a specific rule or legislation to a governing body?

Yes

0%

No

0%

At this time, public comment is being sought on the proposed language for the following rules. The rules title is a link to the rule(s) and a memo explaining the proposed action.

Physicians:

4731-33-01	Definitions	Proposed to Amend
4731-33-02	Standards and Procedures for Withdrawal Management for Substance Use Disorder	Proposed to Amend
4731-33-03	Office-Based Treatment for Opioid Addiction	Proposed to Amend
4731-33-04	Medication-Assisted Treatment Using Naltrexone	Proposed to Amend

Physician Assistants:

4730-4-01	Definitions	Proposed to Amend
4730-4-02	Standards and Procedures for Withdrawal Management For Substance Use Disorder	Proposed to Amend
4730-4-03	Office-Based Treatment for Opioid Addiction	Proposed to Amend
4730-4-04	Medication-Assisted Treatment Using Naltrexone	Proposed to Amend

Deadline for submitting comments: October 6, 2023

Comments to: Kimberly Anderson
State Medical Board of Ohio
Kimberly.Anderson@med.ohio.gov

Do we need to have these rules at all?

Ohio Revised Code 4731.056(B)

- (B) The **state medical boar**d shall adopt **rules** that establish **standards** and **procedures** to be followed by **physicians** in the use of all drugs approved by the United States food and drug administration for use in **medication-assisted treatment,** including controlled substances in schedule III, IV, or V.
- The rules shall address **detoxification, 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.

Effective:
September 29, 2017
Latest Legislation:
House Bill 49 - 132nd General Assembly

Ohio Revised Code 4731.056(B) (cont

- The **board may apply the rules to all** circumstances in which a physician prescribes drugs for use in medication-assisted treatment

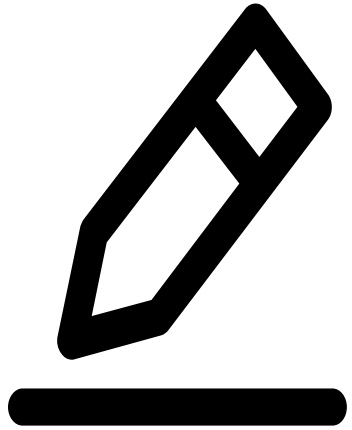
- **or limit the application of the rules** to prescriptions for **medication-assisted treatment** for patients being treated in **office-based practices or other practice types** or locations **specified by the board.**

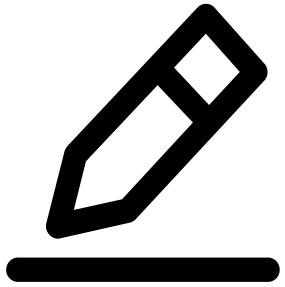
- Standards in Addiction = Retention in Treatment
- Procedures = Flexibility, as in any chronic disease management
- “Limit the application of rules”

Submitting Effective Comments on Rules

Read the proposed rule. When reading rules and regulations to provide feedback, consider….

- Specific language
- Your interpretation
- Ways others could interpret
- Intent
- Implementation





Big Picture on Letter Writing

General Comments

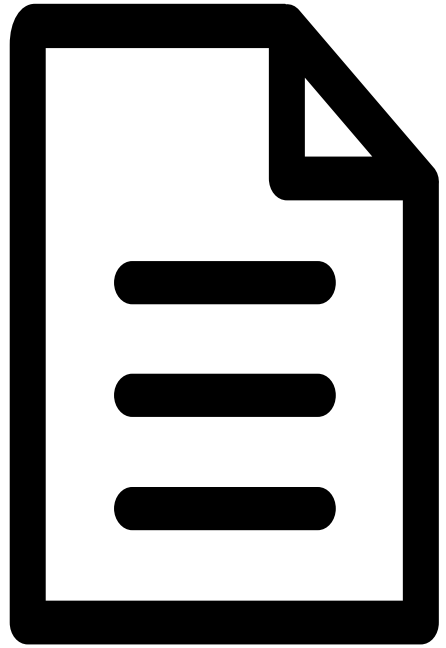
- [ ] Introduction
- [ ] Support or Oppose Rule
- [ ] Why

Specific Comments

- [ ] Identify text
- [ ] Provide rationale
- [ ] Suggest revised language

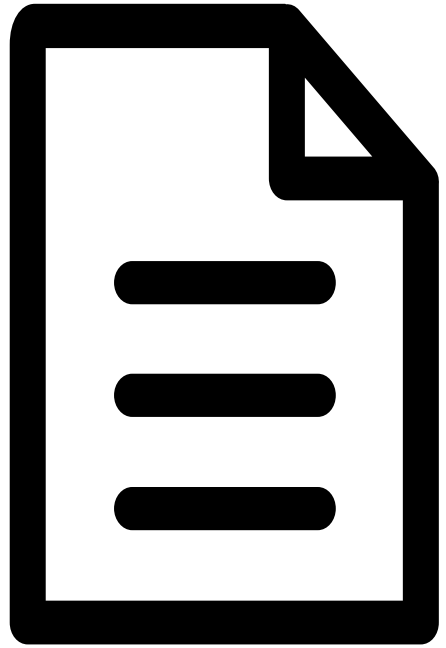
What do I actually write?

- Introduce yourself
- Address the pros and cons
- Add facts (cite papers)
- Provide sound reasoning
- **Examples** of how you, your patients, would be **impacted** negatively or positively
- If you disagree, **suggest an alternative** that includes revised language



Storytelling

- Do you want them to?
  - Support or oppose a policy?
  - Better understand an issue?
- Tailor your story to support your ask
- PATIENT storytelling is compelling



General Comment: Addressing Pros and Cons of Removing the Rule

Pros	Cons
• Decrease stigma • Empower clinicians to prescribe • Encourage low-barrier Rx • Expand treatment	• Rule as education is thought to improve the quality of care • Risk of diversion • Risk of non-medical use & overdose

Rules act as a checklist, they do not teach the "how" to take a hx or tailor a care plan.

Quality of care = more likely from interactive CME. Encourage mentorship models

Most diversion is for therapeutic purposes.

Loosening of telehealth regs = did not increase bup overdoses

Specific Comments

- Direct comment on text of the proposed regulation
- Clearly ID the specific section/subsection (e.g. 4D)
- Provide Rationale
- Provide Factual Information and/or Clinical Experience
- Suggest Alternative Wording

Specific Commentary Example

- **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.

Identified and labeled section.

Provided rationale

Provided factual citation

Recommended alternative language

Finishing Touches

- Proofread
- Do not submit more than once
- Submit by deadline

OCTOBER 6th

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State Medical Board of Ohio
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Learning Objectives

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What are the current standards and procedures in substance use disorder care?

- Standards in Addiction = Retention in Treatment
- Standards = Chronic Disease Management
- Procedures = Flexibility

Key Point Review of Proposed Rules

Patient Selection

Assessment + Treatment (OBOT)

Patient Monitoring

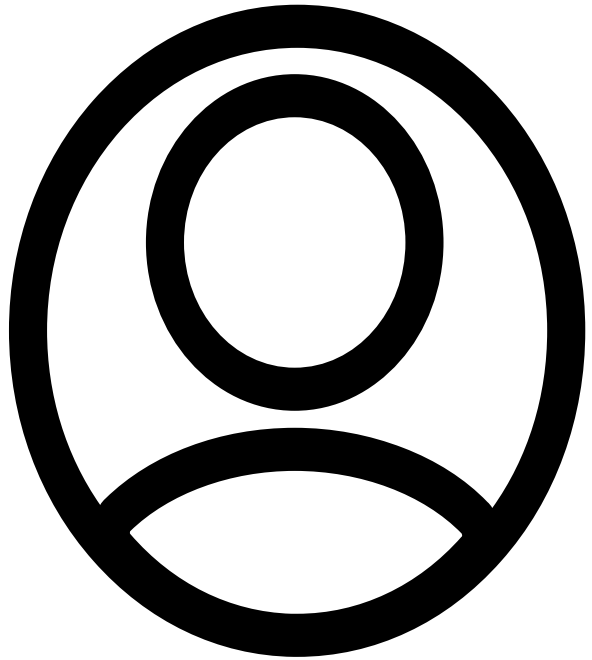
Enhanced Clinician Monitoring

Documentation

Mr. B.

A 45-year-old male with OUD, PMHx: HTN, currently he is unhoused and living in a shelter. He has been in treatment for OUD on bup 2x, but was lost to follow-up. He recently lost his job and takes the bus for transportation. He currently does not have insurance.

He presents to your office to restart buprenorphine for both withdrawal management and maintenance of his OUD.



Patient Selection - Standards and procedures for withdrawal management for substance use disorder

- The patient has adequate **social**, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management."

- "The patient has a **high likelihood of treatment adherence and retention in treatment**; and."
- There is **little risk of medication diversion**".

- Consents: Recruitment for written informed consent, and treatment agreement written/signed

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Based on your interpretation of OH's "Patient Selection", can you legally prescribe Mr. B buprenorphine for opioid withdrawal?

Yes! Crystal clear - I can prescribe buprenorphine! 0%

No! Crystal clear - I can NOT prescribe buprenorphine 0%

I am unsure if I can prescribe buprenorphine. 0%

Yes - I can prescribe it, but worry other clinicians may not prescribe it based on the language 0%

Patient Selection

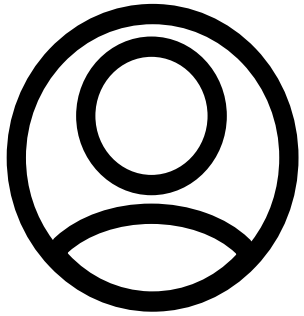
- The patient has adequate **social**, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management."
- "The patient has a **high likelihood of treatment adherence and retention in treatment**; and."
- There is **little risk of medication diversion**".
- Consents: Recruitment for written informed consent, and treatment agreement written/signed

- Concern could stigmatize unhoused individuals
- Implicit bias
- No evidence that written consent improves care

Assessment + Treatment

- Physical Exam
- Lab Requirement: UDT, pregnancy test, HIV, hep B, hep C, consider TB + STI

- **Mr. B**. never obtains the ordered labs due to cost concerns. Last lab: 8 years ago

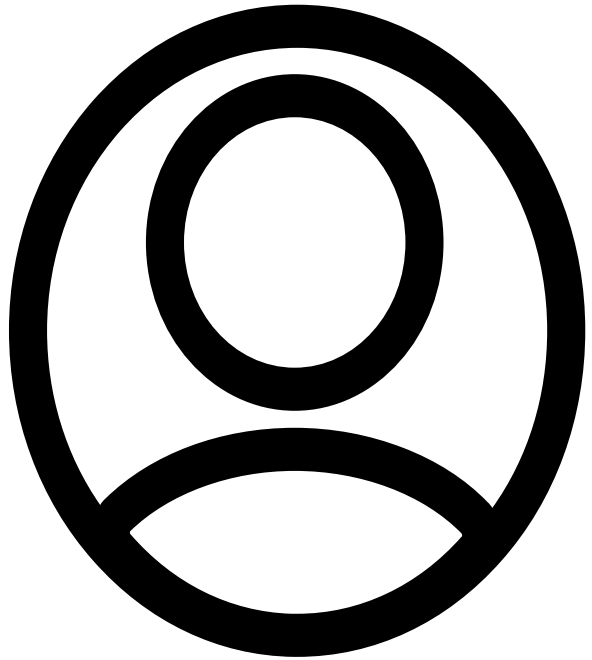


- Telehealth
- Pt can defer labs

Mr. B.

Has tried to take buprenorphine off the street, he waited 8 hours from his last use, and took 4mg of buprenorphine, which he reports instantly made him sick and within 10 minutes he was vomiting profusely, had worsening chills, and diarrhea.

He presents to your office to restart buprenorphine but is nervous about experiencing buprenorphine-precipitated withdrawal.



Assessment + Treatment

- Induction: TIPS-65 or ASAM 2020 Guidelines
- Dose Caps: Document the rationale for prescribing more than 16mg, and a dose cap of 24mg unless the prescriber is board-certified addiction. Dose should not exceed 32 mg a day.
- No methadone to manage W/D

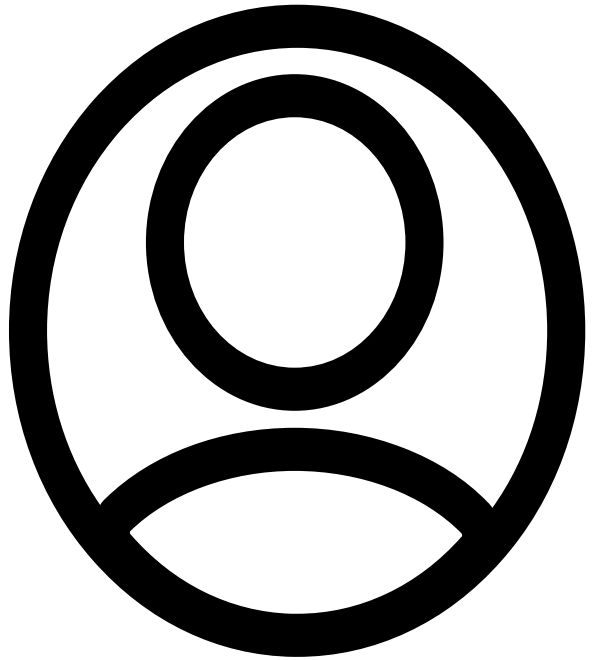
- Add low-dose and high-dose inductions
- Remove documentation burden, 24mg is standard
- Remove methadone, 3-day rule

Mr. B.

Successfully starts buprenorphine using a high-dose initiation!

He has multiple job interviews scheduled, and the only appointment slot you have for him in 1 week is during one of these interviews.

You agree to do a phone check-in in 1 week, and schedule him in-person in 2 weeks.



Patient Monitoring

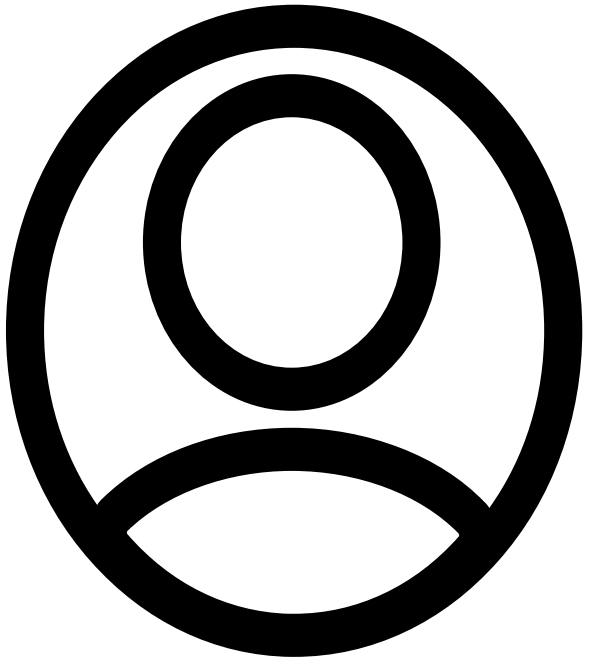
- Visit Frequency: Induction Phase – Pt will be seen at least 1x per week
- Reduce the risk of diversion with appropriate office visits, random pill counts, check OARRS
- Toxicology: Required UDT at least 2x per quarter during the first year **(8x a year**), and at least once per quarter thereafter (4x the following years)

- Lack of flexibility for pts
- Social determinants of health, lack of transportation, employment, childcare
- **Instead:** tailor to medical necessity, clinic capacity, patient preference

Mr. B.
Has been on buprenorphine for 1 month with no use on 24mg!

He finds a job as a crew member on a tugboat, that will be on the sea for 6 weeks.

He requests a 6 week supply of medication while he is on the boat.



Enhanced Clinician Monitoring

- Script Supply: "**first ninety days** of treatment, the physician shall **prescribe no more than a two-week supply** of the bup…
- "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 bup"

- Lack of flexibility for pts
- **Instead:** tailor monitoring to medical necessity, clinic capacity, patient preference
- Tell your patient stories in your letter

Mr. B.

Has been on buprenorphine for 1 year and doing very well.

He has his wisdom teeth extracted, and the clinician defers providing him 3 days of oxycodone for acute pain as they are unable to reach your office on Friday afternoon to coordinate care.

Mr. B buys oxycodone from the street to manage his pain, as he did not have relief from ibuprofen.

Documentation

- **Documentation burden, 28x in these rules!**
- "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."
- "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…".

- Look for unnecessary medical documentation to remove in the rule
- Is this practical?
- How is this implemented in real life?
- Is this the standard of care for other chronic diseases?

Summary of Considerations: Standards

- Standards = quality = **retention in treatment is the standard**
- Addiction treatment plans must be individualized
- Addiction is a chronic disease = Treat it like such.
- It should not be more burdensome to document a pt visit for OUD compared to a HTN visit.

Summary of Considerations

The board must write “Standards and Procedures”

Stay tuned for advocacy efforts to remove this Ohio revised code

- Ask to limit the application of rules for MOUD in outpatient practice; and to not apply these rules to those with < 150 patients on MOUD

- Increase physician **flexibility** in **procedures**
- **Decrease documentation** burden
- Create rules for the minimum required by legislation

Summary of Considerations: Procedures

- Is this procedure standard for other chronic diseases, or is this language creating additional burdens?
- Increased flexibility is needed in UDT monitoring, scripts, etc.
- Soften the language, provide opportunities for exceptions in all procedures
- Remove unnecessary topics in the rules

We can help!
Borrow our Templates!

Questions?

Ohio Society of Addiction Medicine

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Deadline

OCTOBER 6th

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Breakout rooms: Pick reporter and scribe

- **Group 1: Page 1** “Office-based treatment for addiction”: **(B1):** Assessment should include the following…

- **Group 2: Page 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:

- **Group 3: Page 6-7: (5a)** first 90 days of treatment, shall prescribe no more than a 2-week supply of bup.