Notice of Agency Rulemaking Proposal

AGENCY: 02-373 Board of Licensure in Medicine; 02-380 State Board of Nursing; 02-383 Board of Osteopathic Licensure

CHAPTER NUMBER AND TITLE: 12 Joint Rule Regarding Office Based Treatment of Opioid Use Disorder

TYPE OF RULE *(check one)*: ☒ Routine Technical ☐ Major Substantive

PROPOSED RULE NUMBER (*leave blank; to be assigned by Secretary of State*):

BRIEF SUMMARY: The Board of Licensure in Medicine, State Board of Nursing, and Board of Osteopathic Licensure (Boards) propose amendments to a joint rule regarding office-based treatment of opioid use disorder. The originally proposed amendments: eliminate gender terms, change the term "medical records" to "patient records", and update the definition of telemedicine to telehealth to comport with the definition in 2021 P.L. Chapter 291 enacted June 21, 2021.

Following receipt and review of written comments to the originally proposed amendments to the rule, the Boards made the following substantive changes to the proposed amendments to the rule: amending section 1 to add a definition for "medical emergency;" amending section 1 regarding the definition of "telehealth" to include the use of audio-only technology for the delivery of telehealth under certain circumstances, and clarifying that telehealth shall not include the provision of health care services only through email, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof between a licensee and a patient with or without an intervening health care provider; amending section 3.1.D regarding qualifications to read "When required by State law, physician assistants must work in collaboration with a licensed physician when prescribing medications for the treatment of opioid use disorder;" amending section 5.4.D regarding "Informed Consent, Patient Treatment Agreement, Releases" to provide an exception to obtaining informed consent prior to OBOT "as a result of a genuine medical emergency" as defined in section 1 of the rule; and amending section 5.4.D.1 to require that a clinician "obtain and document voluntary informed consent" in lieu of obtaining written informed consent from the patient.

Date, time and location of PUBLIC HEARING *(if any)*: None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person. This is a publication of substantive proposed changes to a proposed rule in order to allow public comment on the proposed changes as required by Title 5 M.R.S. § 8052(5)(B).

COMMENT DEADLINE: Friday, April 29, 2022 by 4:30 p.m.

CONTACT PERSON FOR THIS FILING *(include name, mailing address, telephone, fax, TTY, email)*:

Dennis E. Smith, Executive Director, Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333-0137, tel. (207) 287-3605 fax (207) 287-3605, dennis.e.smith@maine.gov

Kimberly S. Esquibel, Executive Director, State Board of Nursing, 158 State House Station, Augusta, ME 04333-0158, tel. (207) 287-1148 fax (207) 287-1149, kim.esquibel@maine.gov

Susan E. Strout, Executive Secretary, Board of Osteopathic Licensure, 142 State House Station, Augusta, ME 04333-0142, tel. (207) 287-2480 Fax (207) 536-5811, susan.e.strout@maine.gov

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT *(if different)*:

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES *(if any)*:

STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 3269(3),(7), 3300-F, 3300-EE; (Board of Licensure in Medicine); 32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210, 2270; (State Board of Nursing); 32 M.R.S. §§ 2562, 2600-C, 2600-EE; (Board of Osteopathic Licensure)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED *(if different)*:

AGENCY WEBSITE: www.maine.gov/md (Board of Licensure in Medicine); www.maine.gov/boardofnursing (State Board of Nursing); www.maine.gov/osteo (Board of Osteopathic Licensure)

EMAIL FOR OVERALL AGENCY RULEMAKING LIAISON: maureen.s.lathrop@maine.gov (Board of Licensure in Medicine); kim.esquibel@maine.gov (State Board of Nursing); susan.e.strout@maine.gov (Board of Osteopathic Licensure)

** Check one of the following two boxes.*

X *The summary provided above is for publication in both the newspaper and website notices.*

☐ *The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rulemaking notice posted on the Secretary of State's website. Title 5 §8053, sub-§3, ¶D & sub-§6.*

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT_____ DATE:_____
(*authorized signature)*

Please split cost equally among the Boards.

Board of Licensure in Medicine

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02M	0376	01					

State Board of Nursing

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02N	1310	01					

Board of Osteopathic Licensure

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02C	0383	01					

Rulemaking Fact Sheet

(5 MRSA §8057-A)

AGENCY: 02-373 Board of Licensure in Medicine; 02-380 State Board of Nursing; 02-383 Board of Osteopathic Licensure

NAME, ADDRESS, PHONE NUMBER, EMAIL OF AGENCY CONTACT PERSON:

Dennis E. Smith, Executive Director, Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333-0137, tel. (207) 287-3605 fax (207) 287-3605, dennis.e.smith@maine.gov

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CHAPTER NUMBER AND RULE TITLE: 12 Joint Rule Regarding Office Based Treatment of Opioid Use Disorder

TYPE OF RULE *(check one)*: ☒ Routine Technical ☐ Major Substantive

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DATE, TIME AND PLACE OF PUBLIC HEARING: None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person. This is a publication of substantive proposed changes to a proposed rule in order to allow public comment on the proposed changes as required by Title 5 M.R.S. § 8052(5)(B).

COMMENT DEADLINE: Friday, April 29, 2022 by 4:30 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

To amend an existing joint rule to update the definition of telemedicine to telehealth to comport with the definition in P.L. 2021, c. 291, "An Act Regarding Telehealth Regulations."

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES __X__NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

The Board of Licensure in Medicine, State Board of Nursing, and Board of Osteopathic Licensure (Boards) originally proposed amendments to a joint rule regarding office-based treatment of opioid use disorder. The originally proposed amendments: eliminate gender terms, change the term "medical records" to "patient records", and update the definition of telemedicine to telehealth to comport with the definition in 2021 P.L. Chapter 291 enacted June 21, 2021.

Following receipt and review of written comments to the proposed amendments to the rule, the Boards made the following substantive changes to the proposed amendments to the rule: amending section 1 to add a definition for "medical emergency;" amending section 1 regarding the definition of "telehealth" to include the use of audio-only technology for the delivery of telehealth under certain circumstances, and clarifying that telehealth shall not include the provision of health care services only through email, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof between a licensee and a patient with or without an intervening health care provider; amending section 3.1.D regarding qualifications to read "When required by State law, physician assistants must work in collaboration with a licensed physician when prescribing medications for the treatment of opioid use disorder;" amending section 5.4.D regarding "Informed Consent, Patient Treatment Agreement, Releases" to provide an exception to

obtaining informed consent prior to OBOT "as a result of a genuine medical emergency" as defined in section 1 of the rule; and amending section 5.4.D.1 to require that a clinician "obtain and document voluntary informed consent" in lieu of obtaining written informed consent from the patient.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [*see* §§8057-A(1)(E) & 8063-B] The original joint rule was based upon the following information: The Federation of State Medical Boards (FSMB) "Model Policy on Data 2000 and Treatment of Opioid Addiction in the Medical Office" – 2013; Washington State Health Care Authority – "Clinical Guidelines and Coverage Limitations for Medication Assisted Treatment" – Effective January 17, 2018; Vermont Department of Health – "Medication Assisted Treatment (MAT) for Opioid Addiction"; State of Vermont "Rules Governing Medication-Assisted Therapy for Opioid Dependence for 1. Office-Based Opioid Treatment (OBOT) Providers Prescribing Buprenorphine 2. Opioid Treatment Providers (OTP)"; State of Vermont, Dep. Of Health, Div. of Alcohol and Drug Abuse Programs – "Medication Assisted Treatment Rules (MAT) – Frequently Asked Questions for Providers"; SAMHSA – "Medications for Opioid Use Disorder" – Treatment Improvement Protocol 63, HHS Publication No. (SMA) 18-5063 FULLDOC Printed 2018; Tennessee Nonresidential Buprenorphine Treatment Guidelines – Dec 21, 2017; American Society of Addiction Medicine (ASAM) – "Public Policy Statement on Office-Based Opioid Agonist Treatment (OBOT) – January 17, 2018; Position Paper: American College of Physicians "Treating Substance Use Disorder" 2017 Ann Intern Med; Journal of the American Osteopathic Association: "Buprenorphine for Treatment of Opioid Addiction" – JOAO, Supp. 3, vol. 105 – June 2005; and Annals of Family Medicine (Ann Fam Med 2017; 15: 281) - "Providing Office-Based Treatment of Opioid Use Disorder." The originally proposed amendments to the rule are based upon 2021 P.L. Chapter 291 enacted June 21, 2021.

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)] Minimal

FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS: [*see* §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [*see* §8057-A(2)(B)]

BENEFITS OF THE RULE: [*see* §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

ECONOMIC IMPACT STATEMENT
[5 M.R.S. § 8052 (5-A)]

AGENCY: 02-373 Board of Licensure in Medicine; 02-380 State Board of Nursing; 02-383 Board of Osteopathic Licensure

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON:

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CHAPTER NUMBER AND RULE TITLE: Chapter 12 Joint Rule Regarding Office Based Treatment of Opioid Use Disorder

TYPES AND NUMBER OF SMALL BUSINESSES SUBJECT TO THE RULE:

The Board of Licensure in Medicine licenses 7,883 physicians and physician assistants; The State Board of Nursing licenses 33,023 advanced practice registered nurses, registered professional nurses and licensed practical nurses; and the Board of Osteopathic Licensure licenses 1,521physicians and physician assistants.

Title 5 M.R.S. § 8052(5-A) defines “small business” as businesses that have 20 or fewer employees. The Boards do not collect sufficient information to reliably estimate the number of licensees that are small businesses as defined in 5 M.R.S. § 8052 (5-A).

PROJECTED REPORTING, RECORDKEEPING AND OTHER ADMINISTRATIVE COSTS REQUIRED FOR COMPLIANCE WITH THE PROPOSED RULE, INCLUDING THE TYPE OF PROFESSIONAL SKILLS NECESSARY FOR PREPARATION OF THE REPORT OR RECORD:

The proposed rule includes a provision regarding maintenance of patient records which reflects the current standard. There are not any recordkeeping or other compliance costs that licensees do not currently bear.

PROBABLE IMPACT ON AFFECTED SMALL BUSINESSES: Minimal

LESS INTRUSIVE OR LESS COSTLY, REASONABLE ALTERNATIVE METHODS OF ACHIEVING THE PURPOSES OF THE PROPOSED RULE: none

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
380 STATE BOARD OF NURSING
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 12: JOINT RULE REGARDING OFFICE BASED TREATMENT OF OPIOID USE DISORDER

Summary: Chapter 12 is a joint rule of the Board of Licensure in Medicine, the State Board of Nursing, and the Board of Osteopathic Licensure to ensure safe and adequate treatment of opioid use disorder with Approved Medications in an outpatient medical setting that is not a certified Opioid Treatment Program.

RULE INDEX

SECTION 1. DEFINITIONS

1. **Administrative Discharge** means the involuntary process of medically supervised withdrawal from medications for Opioid Use Disorder.

2. **Approved Medications** means medications that are FDA approved for the treatment of Opioid Use Disorder (OUD) in an office based setting that is not a certified Opioid Treatment Program (OTP).

3. **ASAM** means the American Society of Addiction Medicine.

4. **Board** means the Board of Licensure in Medicine, the State Board of Nursing, and the Board of Osteopathic Licensure.

5. **Clinical Discharge** means the voluntary process, agreed upon by both the patient and provider, of medically-supervised withdrawal by gradually tapering medication for ultimate cessation of therapy.

6. **Clinician** means a Maine-licensed physician, physician assistant, or advanced practice registered nurse.

7. **Co-occurring Disorder** means an individual who has a co-existing mental illness and a substance use disorder.

8. **DATA 2000** means the federal Drug Addiction Treatment Act of 2000, which permits clinicians who meet certain qualifications to treat individuals with OUD by prescribing FDA Approved Medications such as buprenorphine.

9. **DATA 2000 Waiver** means a DEA authorization for a licensed clinician who has met the training and credentialing registration requirements of DATA 2000 to prescribe Approved Medications to patients in settings other than OTPs.

10. **DEA** means the Drug Enforcement Administration in the U.S. Department of Justice.

11. **Drug Diversion** means the transfer of a controlled substance from authorized legal and medically necessary use or possession to illegal and unauthorized use or possession.

12. **FDA** means the U.S. Food and Drug Administration.

13. **Informed Consent** means written agreement by a patient to a medical procedure, or for participation in OBOT, after achieving an understanding of the relevant medical facts, risks and benefits, and alternative treatments.

~~13.~~14. **Medical Emergency** means an acute injury or illness that poses an immediate risk to a person's life or long-term health.

~~14.~~15. **Misuse** means all uses of a prescription medication other than those that are directed by a clinician in accordance with the plan of treatment.

~~15.~~16. **Office Based Opioid Treatment (OBOT)** means providing medication and other non-pharmacologic modalities to treat OUD in outpatient medical settings other than certified OTPs. OBOT does not include the administration of buprenorphine in any setting that allows a clinician who is not certified as a waivered DATA 2000 clinician to administer (but not prescribe) buprenorphine to a patient for the purpose of relieving acute withdrawal symptoms while arranging for a patient's referral for treatment and provided that in accordance with Title 21, Code of Federal Regulations, Part 1306.07(b): (1) not more than one day's medication may be administered to a patient at one time; (2) the treatment may not be carried out for more than 72 hours; and (3) the 72 hour period cannot be renewed or extended.

~~16.~~17. **Opioid Treatment Program (OTP) -** (sometimes referred to as a "methadone clinic" or "narcotic treatment program") means any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication assisted treatment of patients with OUD. **Only**

federally certified and accredited OTPs may prescribe and/or dispense methadone for the treatment of OUD.

~~17.~~18. **Opioid Use Disorder (OUD)** means the criteria in the current edition of the Diagnostic and Statistical Manual of Mental Disorders for OUD.

~~18.~~19. **Outpatient** means a health care setting where the patient is not admitted to a hospital, skilled nursing facility or long-term care facility.

~~19.~~20. **Psychosocial Assessment** means an evaluation of the psychological and social factors that are experienced by an individual or family as the result of addiction. The factors may complicate an individual's recovery or act as assets to recovery.

~~20.~~21. **Recovery** means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

~~21.~~22. **SAMHSA** means the federal Substance Abuse and Mental Health Services Administration.

~~22.~~23. **Telehealth** means the ~~practice of medicine or the~~ provision of health care services using electronic audio-visual communications and information technologies or other means, including interactive audio with asynchronous store-and-forward transmission, between a clinician in one location and a patient in another location with or without an intervening health care provider. Telehealth includes asynchronous store-and-forward technologies, telemonitoring, and real-time interactive services, including teleradiology and telepathology. When necessary and appropriate under the circumstances and if in compliance with the applicable standard of care, telehealth includes the use of audio-only technology. Telehealth shall not include the provision of ~~medical services~~ health care services between a licensee in one location and a patient in another location with or without an intervening health care provider only through e-mail, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof.

~~23.~~24. **Toxicology Tests** means any laboratory analysis for the purpose of detecting the presence of alcohol and/or various scheduled or illicit drugs.

SECTION 2. PURPOSE

The Board is obligated under the laws of the State of Maine to protect the public health and safety. The Board recognizes that medical and advanced nursing practice dictate that the people of the State of Maine have access to appropriate, empathetic and effective treatment of opioid use disorder (OUD). This rule establishes minimum requirements for qualified Office Based Opioid Treatment (OBOT) clinicians to prescribe, and in limited circumstances, dispense approved medications to individuals requiring and seeking treatment for OUD.

The Board recognizes the body of evidence regarding the effectiveness of Approved Medications in the office based treatment of OUD, when such treatment is delivered in accordance with current

standards of care, the requirements of the Drug Addiction Treatment Act of 2000 (DATA 2000), and this joint rule. Overdoses and deaths due to approved medications can occur and have been reported. Most overdoses, especially fatal ones, involve the concurrent use of another central nervous system (CNS) depressant such as benzodiazepines, other opioids, or alcohol. Approved Medications such as buprenorphine also pose a significant risk to non-tolerant individuals, especially children. The goal is to provide appropriate treatment of the patient's OUD (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and psychosocial issues.

The Board also recognizes the importance of appropriate training and education for clinicians providing OBOT. Clinicians providing OBOT are strongly encouraged to complete continuing education in OBOT and to review the published guidelines of SAMHSA and ASAM that are referenced in this rule, as the Board may use these guidelines, as well as other sources and outside expert reviews, as the standard of care when evaluating OBOT provided by clinicians.

The Board will evaluate allegations of inappropriate OBOT by referring to the rules, current clinical practice guidelines, and standards of care. Clinicians should not fear disciplinary action by the Board for providing OBOT if they are following standards of care, established guidelines and the requirements of this rule. Judgment regarding the propriety of any specific course of action must be based on all of the circumstances presented, and thoroughly documented in the patient's medical record.

SECTION 3. QUALIFICATIONS

1. Clinicians who wish to provide Approved Medications for OUD in an OBOT must:

    A. Hold a current license issued by the Board;

    B. Hold a current controlled substance registration issued by the DEA;

    C. Obtain a DATA 2000 Waiver and complete buprenorphine training in accordance with applicable State and federal laws, rules, and regulations;

    D. ~~In the case of a physician assistant, be delegated the authority to provide OBOT pursuant to a written plan of supervision by a supervising physician who also meets the criteria for providing OBOT~~ When required by State law, physician assistants must work in collaboration with a licensed physician when prescribing medications for the treatment of opioid use disorder; and

    E. Comply with this joint rule.

2. Patient limits. Clinicians must be aware of and comply with limits established by the DEA regarding the number of patients that can be treated with Approved Medications in OBOT.

SECTION 4. PRESCRIPTION REQUIREMENTS

Prescriptions for Approved Medications to treat OUD must include:

1. The full identifying information for the patient, including the patient's name and address;
2. The drug name, strength, dosage form, and quantity;
3. Directions for use;
4. The date on which the prescription is signed, which must be the same day it is issued;
5. If the date the medication is to be filled is different from the date it is written, it must be indicated on the prescription;
6. Both the clinician's regular DEA registration number and the clinician's DATA 2000 identification number (which begins with the prefix X) so long as the DEA requires and issues DATA 2000 identification numbers;
7. The appropriate ICD code; and
8. The specific DHHS exemption code for dosage limits (if applicable).

SECTION 5. PRINCIPLES OF PROPER OBOT

1. **Develop and Maintain Competency**

   A. The diagnosis and medical management of OUD should be based on current knowledge and research, and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before beginning to treat patients for opioid addiction, clinicians must be knowledgeable about OUD and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies. Clinicians should consult the DEA regulations and the resources available on the DEA's website. Clinicians are encouraged to complete continuing education in OBOT and to access the following published guidelines on the use of medications for OUD:

      1. SAMHSA - TIP 63 - Medication for Opioid Use Disorder ; and
      2. ASAM National Practice Guidelines For the Use of Medications in the Treatment of Addiction Involving Opioid Use .

2. **OBOT Administration and Operations Requirements**

OBOT clinicians shall ensure that all OBOT medical settings have and maintain all of the following in order to initiate and continue prescribing Approved Medications:

A. Sufficient space and adequate equipment to provide appropriate patient care and monitoring, including but not limited to ensuring:

1. Security and privacy for the collection of toxicology samples if samples are to be collected on site;

2. Clean and well maintained environment;

3. Areas where privacy and confidentiality can be maintained; and

4. Protection of all confidential medical information and records in hard copy or electronic formats.

B. Referral arrangements with other clinicians and practitioners to evaluate and treat medical comorbidities and co-occurring disorders to ensure that OBOT is provided in the context of other health issues the patient may have.

3. **Clinician Absence and Closure Preparedness**

A. **Continuity of OBOT Services for Clinician Absence**

Each OBOT clinician shall develop and maintain a written plan for the administration of Approved Medications to treat established OUD patients in the event of an absence. The plan should include:

1. Informing patients of alternate care; and

2. Emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. This should include an agreement with another clinician authorized to prescribe Approved Medications or with an OTP. It should also include the ability to transfer or provide access to patient records.

B. **Permanent OBOT Program Closure**

Each OBOT clinician shall have a written plan for ensuring continuity of care in the event that a future voluntary or involuntary program closure occurs. Clinicians shall have an operational plan for managing a program closure. The plan shall include:

1. Orderly and timely transfer of patients and records to another OBOT clinician; and
2. Notifying patients of transition plans.

4. **Clinical Care and Management Requirements**

A. **Diagnosis of OUD and Acceptance for OBOT**

When commencing OBOT, and in addition to ensuring that any patient has an appropriate medical evaluation as described below in this rule, the OBOT clinician shall assess the patient and diagnose and document an OUD as defined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders.

B. **Evaluation of the Patient's Health Status**

1. Medical Evaluation

When commencing OBOT, the OBOT clinician shall conduct an appropriate medical, social, and family history, physical examination and necessary laboratory tests (including pregnancy testing when appropriate), or refer the patient to a medical professional who can perform such an evaluation. Identification of signs and symptoms of opioid use and/or withdrawal, comorbid medical and co-occurring psychologic conditions, and how they will be addressed, should be a goal of the medical evaluation. Long-term management is effective for many chronic diseases, including OUD.

2. **Psychosocial Assessment and Referral to Services**

a. OBOT clinicians shall conduct a psychosocial assessment, or shall refer the patient for such an assessment to another clinician qualified by education, training or experience, or to a licensed mental health provider, before or as soon as possible after the initiation of the OBOT.

b. Based on the outcomes of the psychosocial assessment, the OBOT clinician may recommend to the patient that "the patient" should participate in ongoing counseling or other behavioral interventions such as recovery programs. Patients should be advised to receive counseling from OBOT clinicians or other qualified licensed providers.

c. An OBOT clinician should employ appropriate clinical judgment in deciding whether to deny or discontinue OBOT based solely

on a patient's decision not to follow a recommendation to seek counseling or other behavioral interventions.

C. **Developing an OBOT Plan**

1. Individuals who are identified by OBOT clinicians as having higher needs for care (e.g. ASAM level 2 or higher), or needing more clinical oversight or structure than available through an OBOT, shall be referred to an appropriate OTP or other more intensive level of care (e.g. inpatient).

2. OBOT clinicians shall register with the Maine Prescription Monitoring Program (MPMP) and comply with Maine's laws and rules regarding reporting on dispensed controlled substances. OBOT clinicians shall check the MPMP prior to initiating OBOT and at least every ninety days thereafter or more frequently when clinically indicated.

3. OBOT clinicians shall adhere to all applicable standards of medical practice for providing treatment.

D. **Informed Consent, Patient Treatment Agreement, Releases**

~~—~~Unless unable to do so as a result of a genuine "medical emergency" as defined in Section 1 of this rule, ~~P~~prior to providing OBOT, an OBOT clinician shall:

1. Obtain and document voluntary~~, written,~~ Informed Consent to treatment from each patient, which shall include the known risks and benefits of the medication being prescribed.

2. Establish a written treatment agreement outlining the responsibilities and expectations of the OBOT clinician and the patient, which shall include possible reasons for discharge from the practice.

3. Provide OUD patients with education regarding the prevention of opioid overdose. In addition, OBOT clinicians should consider prescribing overdose rescue medications (e.g. naloxone) for all OUD patients.

4. Make reasonable efforts to obtain releases of information for any health care providers or others important for the coordination of care to the extent allowed by Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR, Part 2.

E. **Ongoing Patient Treatment and Monitoring**

In addition to following standard clinical practices, OBOT clinicians must adhere to the following provisions:

1. **Monitoring for Diversion**

   To ensure patient and public safety, each OBOT clinician shall develop a written policy outlining their clinical practices to minimize risk of diversion of medications to treat OUD. The frequency of monitoring procedures is based on the unique clinical treatment plan for each patient and the patient's level of stability. At a minimum, this plan shall include the following practices:

   a. Querying the MPMP;

   b. Informing OBOT patients that diversion is a criminal offense;

   c. Conducting toxicological tests;

   d. Conducting medication counts;

   e. For patients receiving services from multiple providers, the coordination of care and sharing of toxicology test results is encouraged;

   f. Collecting all toxicological specimens with a standardized protocol and in a therapeutic context; and

   g. Addressing and documenting the unexpected results of toxicological tests promptly with patients.

2. **Education and Rescue Medications**

   OBOT clinicians shall provide OUD patients with education regarding the prevention of opioid overdose. In addition, OBOT clinicians should consider prescribing overdose rescue medications (e.g. naloxone) for all OUD patients.

5. **Administrative Discharge from OBOT**

   A. Appropriate administrative discharge from OBOT does not constitute

patient abandonment. OBOT clinicians may opt to discontinue prescribing medications for OUD and involuntarily discharge patients from their OBOT in the following situations:

1. Disruptive behavior that has an adverse effect on the OBOT practice, staff or other patients. This includes, but is not limited to:
   a. Violence;
   b. Aggression;
   c. Threats of violence;
   d. Drug diversion;
   e. Trafficking of illicit or prescription drugs;
   f. Repeated loitering in or near the OBOT facility; and
   g. Conduct resulting in an observable, negative impact on the patient, and/or staff and/or other patients.
2. Incarceration or other relevant change of circumstance. However, if the incarceration follows criminal conduct that occurred prior to OBOT, then resumption of OBOT following incarceration is encouraged if clinically indicated.
3. Violation of or noncompliance with the treatment agreement.
4. Nonpayment of fees.

B. When an OBOT clinician or practice decides to administratively discharge an OBOT patient, the clinician must manage the appropriate tapering of buprenorphine or other medication, when it is clinically appropriate, and as long as it does not compromise the safety of patients, clinicians or program staff.

C. A patient who is involuntarily discharged from OBOT should be provided referral information for other OBOT clinicians, OTPs, or other OUD treatment programs. OBOT clinicians shall document referral efforts in the patient's medical record.

D. Factors contributing to the involuntary discharge from the program shall be documented in the patient's medical record.

6. **Patient Records**

OBOT clinicians shall keep accurate and complete patient records , with emphasis on documentation of and the patient's response to treatment. Information that shall be maintained in the patient record includes:

A. Copies of signed informed consent and treatment agreement;

B. The patient's medical history and any records from prior providers;

C. Documentation of MPMP queries and their effect on treatment;

D. Results of the physical examination, laboratory tests, and toxicological tests;

E. Treatment plan;

F. A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose, frequency and quantity);

G. Results of ongoing monitoring of patient progress (or lack of progress);

H. Notes on evaluations by and consultations with specialists; and

I. Other medical decision making to support the initiation, continuation, revision, or termination of treatment, and the steps taken in response to any abnormal toxicological test results or aberrant medication use behaviors.

7. Reportable Acts

Generally, information gained as part of the clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior should be addressed appropriately and documented. Use of the MPMP is mandatory in this situation.

8. Additional Requirements for Special Populations

A. Pregnant Patients:

The decision to treat a pregnant patient with buprenorphine or to refer her to an OTP for methadone is one that should be made in conjunction with the patient. Due to the risks of opioid addiction to pregnant women and their fetuses, a pregnant woman seeking OBOT should be given priority for

treatment, and every effort should be made for evaluation and treatment as soon as possible. Because of the high risk to the fetus, every effort should be made to maintain pregnant women on medications for OUD during pregnancy. If there is a compelling reason for involuntarily withdrawing a pregnant woman from OUD medications for reasons specified in this rule, the clinician shall refer the woman to the most appropriate obstetric care available and an alternative provider for OUD treatment as soon as possible.

B. Adolescent Patients:

OBOT clinicians who do not specialize in the treatment of adolescent OUD should strongly consider consulting with or referring adolescent patients to a more qualified clinician, if available.

C. Patients with Co-occurring Disorders:

OBOT clinicians should be aware of potential interactions between medications used to treat co-occurring psychiatric conditions and OUD. All patients with psychiatric disorders should be asked about suicidal ideation and/or attempts behavior. Patients with a history of suicidal ideation or attempts should have OUD and psychiatric medication use closely monitored. OBOT clinicians should consider referral to a mental health clinician, if available.

SECTION 6 Telehealth Practice

1. Telehealth is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.

2. Clinicians using telehealth in providing health care will be held to the same standards of care and professional ethics as clinicians providing traditional in-person health care.

3. Failure to conform to the appropriate standards of care or professional ethics while using telehealth in providing health care may subject the clinician to potential discipline by the Board.

4. Clinicians shall follow all applicable rules regarding Telehealth, including the Chapter 11 Joint Rule Regarding Telehealth Standards of Practice.

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3),(7), 3300-EE, 3300-F; (Board of Licensure in Medicine)
32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210, 2270; (State Board of Nursing)

32 M.R.S. §§ 2562, 2600-C, 2600-E; (Board of Osteopathic Licensure)

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