APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-21
Rule Title: Policy on DATA 2000: Guidelines for the Treatment of Opioid Addiction in the Medical Office

X New ____ Amend X Repeal ____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety?	NO
Is there a reasonable relationship between the state=s police power and the protection of the public health, safety, or welfare?	YES
Is there another, less restrictive method of regulation available that could adequately protect the public?	NO
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	NO
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	NO
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?	YES
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?	NO

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Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

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Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer

Date: December 20, 2022

APA-2

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-21, Policy on DATA 2000: Guidelines for the Treatment of Opioid Addiction in the Medical Office

INTENDED ACTION: Repeal and replace chapter

SUBSTANCE OF PROPOSED ACTION: Repeal outdated rules and replace with rules adopted pursuant to the MAT Act of 2019 (Alabama Acts No. 2019-500; Ala. Code §§ 20-2-300 through 20-2-302).

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Carla H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including February 3, 2023. Persons wishing to submit data, views, or comments should contact Carla H. Kruger by email (bme@albme.gov) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: February 3, 2023

CONTACT PERSON AT AGENCY: Carla H. Kruger

(Signature of officer authorized to promulgate and adopt rules or his or her deputy)

ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-21
REQUIREMENTS FOR THE USE OF BUPRENORPHINE IN NON-RESIDENTIAL TREATMENT PROGRAMS

TABLE OF CONTENTS

540-X-21-.01 Purpose.

(1) The rules in this chapter implement the law regulating the use of buprenorphine in nonresidential treatment programs pursuant to Ala. Code §§ 20-2-300 through 20-2-302.

(2) These rules are promulgated for the purpose of creating standards for the treatment of substance use disorder by non-residential treatment facilities and programs previously unregulated prior to the enactment of the MAT Act of 2019. Accordingly, these rules shall not apply to any facility, or any licensed providers employed or contracted by any such facility, licensed by the Alabama Department of Mental Health pursuant to Ala. Code § 22-50-17, and certified by the U.S. Substance Abuse and Mental Health Services Administration pursuant to 42 C.F.R. Part 8, to dispense or administer any medication for the treatment of opioid use disorder.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.02 Definitions.

(1) Definitions of general terms used in these rules can be found in Ala. Admin. Code r. 540-X-2-.01 through .03.

(2) Definitions specific to this chapter are as follows:

(a) Diversion – the act of selling, sharing, or trading medication with unauthorized recipients.

(b) DMP – Diversion Mitigation Policy.

(c) Emergent conditions – a medical condition manifesting itself by acute symptoms of sufficient severity to require emergency medical intervention.

(d) FDA – U.S. Food and Drug Administration.

(e) LME – lorazepam milligram equivalent.

(f) Medication Assisted Treatment (MAT) –The combination of behavioral interventions and medications, specifically buprenorphine, used to treat opioid use disorder in nonresidential or office-based treatment programs.

(g) MAT Provider – Any physician licensed to practice medicine in Alabama or any advanced practice nurse or physician assistant holding a qualified Alabama Controlled Substances Certificate (QACSC) who provides or offers to provide in an office setting within the state of Alabama any treatment that requires buprenorphine for the treatment of opioid use disorder.

(h) PDMP – Alabama Department of Public Health Prescription Drug Monitoring Program database.

(i) Schedule II – medications listed in Schedule II of the Drug Enforcement Administration's and/or Alabama Department of Public Health's controlled substances list.

(j) Suboxone equivalents – [need definition; referred to in .04]

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.03 <u>Application of the Rules</u>.

(1) Every MAT provider offering or proposing to prescribe medications containing buprenorphine for the treatment of opioid use disorder shall comply with this Chapter.

(2) If any provision of these rules, or the application thereof to any person or circumstance, is held invalid, such invalidity shall not affect other provisions or

applications of these rules which can be given effect without the invalid provision or application, and to that end the provisions of these rules are declared severable.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.04 Appropriate Doses of Buprenorphine-Containing Medications for the Treatment of Opioid Use Disorder.

(1) The dosing of buprenorphine/naloxone in a transmucosal delivery shall not exceed 24mg/6mg Suboxone equivalents in a 24-hour dosing interval.

(a) Maximum dose of Zubsolv shall not exceed 17.1mg/4.4mg.

(b) Maximum dose of Bunavail shall not exceed 12.6mg/2.1mg.

(2) The majority of MAT patients should be managed on a Suboxone dose equivalent between 2mg and 16mg per day with an average Suboxone dose equivalent between 8mg and 12mg per day. Suboxone dose equivalents greater than or equal to 16mg/4mg should raise concerns for diversion.

(a) Any other rule to the contrary notwithstanding, patients requiring greater than 16mg/4mg Suboxone equivalents shall be evaluated in an office visit on a 14-day cycle (plus or minus 4 days).

(b) Schedule II stimulant medications shall not be prescribed in combination with buprenorphine in doses exceeding 16mg per day. Benzodiazepines shall only be prescribed in patients on 16mg of buprenorphine daily undergoing a cautious benzodiazepine tapered withdrawal.

(c) Patients undergoing buprenorphine therapy with long-acting injectable buprenorphine without the use of patient administered buprenorphine (transmucosal, transdermal or any other patient administered route) are exempt from the frequency of visit requirement found in subpart (2)(a).

(3) The conversion ratios found in subparts (1)(a) and (1)(b) may be used for conversion to transmucosal delivery systems such as Zubsolv and other microparticle-citric acid buffered deliveries, BEMA deliveries such as Bunavail and Belbuca, and transdermal deliveries such as Butrans.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.05 Guidelines for Co-Prescribing of Benzodiazepines, Stimulants, and Gabapentinoids with Medications Containing Buprenorphine.

(1) Due to the synergistic effects on reward and respiratory depression produced by the combination of benzodiazepines and/or barbiturates with buprenorphine, benzodiazepines and/or barbiturates may only be prescribed in such combination as part of a controlled medication taper in the patient with a physiologic benzodiazepine and/or barbiturate dependence. The ultimate goal of the taper is to achieve and maintain the lowest possible dose of benzodiazepine, not to exceed 1mg LME per day. MAT providers shall re-evaluate and periodically attempt complete abstinence from benzodiazepines.

(a) Benzodiazepines shall only be prescribed to patients who are being treated with Suboxone dose equivalents of 16mg per day or more in the course of a

cautious, tapered withdrawal of the benzodiazepine. The taper process should not take longer than six months. Any MAT provider who feels unqualified to manage withdrawal of the chemically dependent patient shall be responsible for referring the patient to an addiction medicine specialist, addiction psychiatrist, or another MAT provider who is more qualified to manage the withdrawal.

(b) For the purposes of this rule, the class of sedative hypnotic medications known as Z-drugs shall be considered and treated as benzodiazepines. Z-drugs are used in the treatment of insomnia and include zolpidem, eszopiclone and zaleplon.

(2) Due to the synergistic effects on the reward pathways of the brain, Schedule II psychostimulant medication shall only be prescribed in combination with buprenorphine in a patient with a substance use disorder for the treatment for Attention Deficit Hyperactivity Disorder (ADHD) or narcolepsy within the parameters outlined below.

(a) If psychostimulants are used for treatment of ADHD or narcolepsy, immediate-release psychostimulants shall not be used, and the prescribing provider should use formulations of psychostimulants that decrease the risk of misuse, such as using pro-drug formulations and tamper-resistant long-acting formulations.

(b) Schedule II stimulants shall not be prescribed in combination with Suboxone dose equivalents exceeding 16mg per day.

(c) ADHD.

(i) Psychostimulants may be prescribed chronically in combination with buprenorphine-containing medications for patients with an established diagnosis of ADHD.

(ii) All patients in whom psychostimulants are being used must be educated about non-pharmacologic techniques for managing ADHD symptoms such as exercise, sleep hygiene, avoidance of distractions, and mindfulness techniques.

(d) Narcolepsy.

(i) Psychostimulants may be prescribed chronically in combination with buprenorphine-containing medications for patients with an established diagnosis of narcolepsy.

(ii) All patients in whom psychostimulants are being used must be educated about non-pharmacologic techniques for managing narcolepsy symptoms including sleep hygiene.

(3) Gabapentin may be used in combination with buprenorphine up to a maximum dose of 2400mg per day. Pregabalin may be prescribed in combination with buprenorphine up to a maximum of 300mg per day.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.06 <u>Minimum Requirements for Counseling, Behavioral Therapy, and Case Management</u>.

(1) MAT treatment should include at least one of the following interventions:

(a) Motivational interviewing and motivational enhancement therapy that bolsters motivation to change substance use behaviors;

(b) Cognitive behavioral therapy that helps identify, recognize, and avoid thought processes, behaviors, and situations associated with substance use; manage cravings and negative emotions; and develop better problem-solving and coping skills;

(c) Community reinforcement approach that focuses on improving family relations, acquiring job skills, and developing alternative activities and associates to minimize substance use;

(d) Contingency management that alters behavior by rewarding constructive behaviors and discouraging unhealthy behaviors; and/or

(e) Behavioral couples/family therapy that improves communication and support and reduces conflict between couples and families that have a member with a substance use disorder.

(2) Case Management. At a minimum, a MAT provider's case management system should include:

(a) Screening. The screening process determines whether the patient is appropriate and eligible for admission to MAT. It is a process through which the MAT provider, a qualified staff member, patient, and available family members determine the most appropriate initial course of action given the patient's needs and characteristics and the available resources within the community.

(b) Patient Assessment. Patients being evaluated for possible opioid use disorder, and/or for possible medication use in the treatment of opioid use disorder, should undergo (or have completed) an assessment of mental health status and possible psychiatric disorders. The patient assessment usually begins at the time of the patient's first office visit and continues throughout treatment. The objectives of the

patient assessment are to determine a given patient's eligibility for MAT, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. The patient assessment should be designed to:

1. Establish the diagnosis of opioid use disorder, including the duration, pattern, and severity of opioid misuse; the patient's level of opioid tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status;

2. Document the patient's use of other substances, including alcohol and other drugs of abuse;

3. Identify comorbid medical and psychiatric conditions and disorders and determine how, when, and where they will be addressed;

4. Evaluate the patient's level of physical, psychological, and social functioning or impairment;

5. Assess the patient's access to social supports, family, friends, employment, housing, finances, and legal support;

6. Determine the patient's readiness to participate in treatment;

7. Determine whether testing for human immunodeficiency virus and hepatitis B and C is appropriate; and

8. Determine whether to screen for tuberculosis and sexually transmitted diseases in patients who have high risk factors.

(c) The assessment of women presents special considerations regarding their reproductive health. Fertile women of childbearing age shall be tested for pregnancy.

Due to the increase in fertility that results from effective opioid use disorder treatment, all women of potential childbearing age should be asked about and educated regarding methods of contraception.

(d) The physical examination and diagnostic procedures ordered, if performed during the initial assessment, can be focused on evaluating neurocognitive function, identifying sequelae of opioid use disorders, and looking for evidence of severe hepatic dysfunction if deemed necessary by the physician.

(e) Any psychiatric disorders that are identified and warrant treatment, either by referral or treated directly by the MAT provider, should be addressed. A co-occurring mental health condition shall not be a reason for denying treatment. Periodic attention must be paid to the existence or emergence of mental health disorders. The existence or emergence of psychiatric disorders which can hinder or prevent compliance and improvement through the MAT program should be addressed in the treatment plan.

(3) Counseling.

(a) The physician shall be responsible for determining and documenting that the patient has been advised of the importance of counseling. The physician must document whether the patient has agreed to engage in counseling.

(b) A refusal of counseling should not be the sole reason for termination of care.

(c) If counseling has been deemed necessary, the physician should review and modify the individualized treatment plan if it is determined that a patient is not following through with counseling referrals. If the physician determines that counseling is not necessary, this decision should be fully documented in the medical record.

(4) If the physician's own staff is utilized to provide counseling, the staff should be sufficient in number to allow for regularly scheduled counseling sessions and to allow patients access to their counselor if more frequent contact is merited by need or is requested by the patient. In addition, the staff should be trained to:

(a) Perform psychosocial assessments;

(b) Provide treatment planning;

(c) Provide individualized counseling; and

(d) Identify and make referrals as needed for a higher level of care. When referring patients for counseling, the staff should provide the patient, with the patient's consent, a list of treatment providers certified by the Alabama Department of Mental Health in accordance with Alabama Department of Mental Health Rules and/or or an appropriately licensed practitioner or program and assist the patient in accessing these services by offering to make appointments on the patient's behalf and by coordinating care.

(5) Treatment Plans: Treatment plans should utilize assessment information, describe the patient's disorder in behavioral terms, and specify in measurable steps the objectives that have been individually selected to help the patient reach identified goals. Treatment plans should assess the severity of the substance use disorder as well as any co-occurring disorders; identify the patient's goals for treatment in measurable, time-sensitive steps toward achieving the goals; address the motivation and readiness for change; and incorporate a strength-based quantitative approach.

(6) The physician who provides MAT should offer the patient a prescription for a naloxone kit.

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

(b) If the patient refuses the naloxone prescription, the physician shall provide the patient with information on where to obtain a kit without a prescription and document the refusal in the record.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.07 Appropriate Drug Screening.

(1) Permission for drug testing should be contained in the treatment agreement that is completed at time of intake into care.

(2) A urine drug screen or other toxicologic screen should be part of the initial evaluation to confirm recent opioid use and to screen for unreported use of other drugs. It should be completed prior to any prescription being written.

(3) The screen should include all opioids commonly prescribed and/or misused in the local community as well as benzodiazepines, stimulants, gabapentinoids, and illicit drugs that are available locally.

(4) Prescribers should have written procedures for the collection and submission of specimens. These procedures shall satisfy the following provisions:

(a) Collection and testing should be done in a manner that ensures that the samples collected from the patient are unadulterated.

(b) It is inappropriate for the person being tested to be their own specimen collector.

(5) Patients should be drug tested at a minimum once every 30 days. Increasing this frequency is an appropriate response when a patient has tested positive for illicit substances or non-prescribed substances.

(6) A positive or negative screen should not be the sole reason for discharge from care.

(7) A positive screen for illicit substances or non-prescribed substances should result in a re-assessment of the patient's status to include a possible intensification of services and/or dose changes. A negative screen for buprenorphine should follow the same protocol.

(8) Results of all drug screens and any therapeutic interventions provided as a result of a drug screen should be located in the patient's chart.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.08 Education to Patients Regarding Neonatal Abstinence Syndrome or Neonatal Opioid Withdrawal Syndrome.

(1) Opioid use disorder carries risk in pregnant patients and may increase the risk of preeclampsia, miscarriage, premature delivery, fetal growth restriction, and fetal death. Continued use of opioids during pregnancy can lead to neonatal abstinence syndrome or neonatal opioid withdrawal symptoms.

(2) At the time of initial screening, the MAT provider shall perform a pregnancy test on all fertile women. The MAT provider will refer and encourage pregnant women to establish appropriate prenatal care. The MAT provider shall document in the medical record that the patient has been educated on the risks associated with the continued use of illicit opioids, the risks and benefits of MAT, and detoxification treatments with buprenorphine containing products. Pregnant patients shall be educated that the use of buprenorphine during pregnancy can result in neonatal abstinence syndrome or neonatal opioid withdrawal symptoms.

(3) The MAT provider shall educate fertile women of the risks of opioid use during pregnancy including neonatal abstinence syndrome or neonatal opioid withdrawal symptoms. This discussion should include education regarding the risks and benefits of reversible long-acting contraception.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.09 Use of Buprenorphine for Pain Management.

(1) Daily doses of 4mg of buprenorphine or less per 24 hours by sublingual administration or 1800mcg by buccal (BEMA) delivery may be used for the treatment of pain and therefore may be exempt from these rules.

(2) Patients requiring greater than 4mg per day of buprenorphine in sublingual delivery system with naloxone equivalent to Suboxone or in monotherapy delivery system equivalent to Subutex (24-hour period), irrespective of the presence of somatic pain, must meet the regulatory requirements defined in these rules.

(3) Transdermal preparations are covered under federal guidelines.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.10 Co-Occurring Disorders.

(1) Co-occurring psychiatric disorders are very common among individuals with substance use disorders. Both psychiatric disorders and substance use disorders are associated with increased suicide risk.

(2) For individuals not already receiving ongoing psychiatric care, MAT providers shall assess for the presence of mental health needs and shall facilitate referral to appropriate mental health professionals. MAT providers should use evidence-based standardized measures, including, but not limited to, the Patient Health Questionnaire (PHQ-9) for depression and the Generalized Anxiety Disorder 7-item (GAD-7) scale for anxiety, to assist with identification of mental health needs. The MAT provider shall ensure ongoing coordination of care with the patient's psychiatrist or other mental health provider where applicable. If the MAT provider is a psychiatrist, mental health services can be provided by the prescriber.

(3) At time of initial assessment and as clinically indicated through the course of treatment, an assessment of suicidal thoughts shall be made. This should be done using a validated tool such as the Columbia-Suicide Severity Rating Scale (C-SSRS). Management of an actively suicidal patient should include reducing immediate risk through referral to a secure setting such as a psychiatric facility or hospital emergency department.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.11 Informed Consent by the Patient.

(1) All practitioners shall obtain informed consent from patients prior to initiating MAT. The practitioner shall document the informed consent conversation in the medical record and, when the patient has provided specific written consent, the consent form shall be included in the medical record.

(2) In seeking a patient's informed consent, practitioners should:

(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision; and

(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The practitioner should include information about:

1. The diagnosis;

2. The nature and purpose of recommended interventions; and

3. The burdens, risks, and expected benefits of all options, including declining treatment.

(3) All practitioners shall be familiar with and comply with federal law governing confidentiality for patients with a substance use disorder. Title 42 of the *Code of Federal Regulations* Part 2 places specific requirements on practitioners for obtaining

informed consent for disclosure of the patient's information. A valid consent form under these rules shall include:

(a) Name of patient;

(b) Name of provider;

(c) What information may be disclosed;

(d) Who may disclose the information;

(e) The names of entities and/or persons to whom disclosure is to be made;

(f) Purpose of disclosure;

(g) Statement about patient's right to revoke the disclosure;

(h) Statement about expiration of the patient's consent;

(i) Statement about redisclosure;

(j) Signature of patient;

(k) Date signed; and

(l) The redisclosure statement must include the following exact language: "This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate

or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65."

(4) All practitioners shall have a formal policy and procedure in place for rendering patient identifying information non-identifiable in a manner that creates a very low risk of re-identification for the purpose of complying with Board investigations in instances where the patient does not consent to disclosure of the patient's medical records to the Board.

Author: Alabama State Board of Medical Examiners and Working Group (Karen E. Avery, M.D.; Brent Boyett, D.O.; Michael G. Dean, Esq.; J. Luke Engeriser, M.D.; Carter English, R.Ph.; Patrick Scott Harris, M.D.; Boyde J. Harrison, M.D.; Kathy House; William Kennedy, LICSW; Paul O'Leary, M.D.; Dick Owens, M.D.; Sandra K. Parker, M.D.; George C. Smith, Jr., M.D.; Stephen M. Taylor, M.D.; Nicole Walden; Amanda Williams, M.D.; Kelley Williams-Jones, LMSW)
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302
History: Adopted

540-X-21-.12 Use of the State Prescription Drug Monitoring Program (PDMP).

(1) For the purpose of preventing controlled substance diversion, abuse, misuse, addiction, and doctor-shopping, the Board sets forth the following requirements for the use of the PDMP:

(a) Every MAT provider shall query the PDMP to review a patient's prescription drug history prior to issuing the first prescription and at least two times per year while therapy continues.

(b) When prescribing more than 8mg of buprenorphine or Suboxone 8mg/2mg equivalents and less than Suboxone 16mg/4mg equivalents per day, MAT providers shall query the PDMP to review the patient's prescription history prior to issuing the first prescription and at least one time per quarter while therapy continues.

(c) MAT providers shall query the PDMP to review a patient's prescription history every time a prescription is written for buprenorphine in an amount greater than or equal to Suboxone 16mg/4mg equivalents per day, or when a prescription for buprenorphine is written to a patient who is co-prescribed any other controlled substance, on the same day the prescription is written.

(2) Each MAT provider is responsible for documenting the required PDMP check in the patient's medical record. In addition, each MAT provider is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.13 Appropriate Number of Visits and Relapse.

(1) There are three phases of care in MAT (see Appendix A, Phases of Treatment Flowchart). The following guidelines may be used by the Alabama State Board of Medical Examiners and Medical Licensure Commission when evaluating whether a MAT Provider has prescribed, distributed, administered, dispensed, supplied, or furnished buprenorphine for a legitimate medical purpose.

(a) The first is the induction phase, the period during which the full opioid agonist is being replaced by the partial agonist, buprenorphine. This may occur very quickly as in the case of short-acting full opioid agonist drugs such as hydrocodone or heroin or it could take several days, as in the case of long-acting full agonist medications such as methadone. For the sake of structured management, the first

week of therapy is considered the induction phase and it is marked at the onset of the first visit and ends at the second visit, one week later.

(b) The second is the stabilization phase, the period required to stabilize drug craving without the use of any other controlled substances (prescription or illicit) not governed under these rules. As long as a patient continues to use drugs such as THC or other illicit substances, requires benzodiazepines or psychostimulants, except as otherwise exempted in these rules, or continues to require full agonist opioids, they are considered to be “unstable”. “Unstable patients” remain in the stabilization phase, which requires weekly visits until they can demonstrate “stability” for a minimum of two consecutive weeks before being released to monthly visits. Patients in the stabilization phase shall not receive prescriptions/dispensing for more than 14 days of buprenorphine therapy without documented office-based evaluation.

(c) The third is the maintenance phase, which is entered once the patient demonstrates stability in the stabilization phase. Patients in the maintenance phase are scheduled on a monthly basis with office evaluations, drug testing, and counseling to occur at each visit. The patient shall not receive prescriptions/dispensing for more than 42 days of buprenorphine therapy without documented office-based evaluation. There is no time limitation on the duration of this phase. However, if the patient fails to comply with the treatment agreement, the patient will be transferred from the maintenance phase, with monthly visits, back to the stabilization phase, requiring weekly visits. Once the patient demonstrates stability in the stabilization phase for two consecutive weeks, the patient may return to the lower level of care of the maintenance phase. Patients who

are transferred from one provider to another may remain in the maintenance phase with concurrence between the transferring and accepting providers.

(2) Patients should be seen and evaluated by the MAT provider on a weekly basis for a minimum of 3 weeks at the induction and stabilization phases. The interval between visits in the induction and stabilization phases shall not exceed 14 days. The quantity of buprenorphine dispensed during the induction and/or stabilization phases shall never exceed 14 days of therapy. At each visit, documentation shall include drug testing as well as subjective and objective evaluation of the patient's condition. The frequency of visits will be determined by the evidence of disease stability.

(3) Patients who are not evaluated for greater than 42 days shall be considered new patients and must satisfy the requirements of the induction and stabilization phases for three consecutive weeks.

(4) Examples of evidence of instability prompting transition from maintenance phase back into stabilization phase:

(a) Failed drug test (see requirement on drug testing).

(b) PDMP violation (patient may not receive prescriptions for controlled substances from other providers except for emergent conditions).

(c) Requirement for early refill of buprenorphine (lost/stolen prescription, overtaking medication, etc.).

(d) Evidence of drug diversion or drug abuse (consider transition from patient administered to long-acting injectable buprenorphine preparations).

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1

History:

540-X-21-.14 Diversion Control Plan.

(1) MAT providers shall develop and maintain a written diversion mitigation policy (DMP) to address evidence of diversion within their MAT practice. A written copy of this policy shall be made immediately available to the Alabama Board of Medical Examiners upon request. Patient care and the medical record shall reflect adherence to the office DMP. MAT providers shall ensure that written policies are in place and followed in the effort to mitigate the risk of diversion of controlled medications, including buprenorphine.

(2) DMP protocols and standard operating procedures may include:

(a) Scheduled and/or random pill/film and wrapper counts. Such policy shall be described in the patient treatment agreement.

(b) Scheduled and/or random drug testing for the presence of prescribed medication/medication metabolite and/or presence of unauthorized controlled substances. Such testing may include urine, hair, nails, and saliva and shall be described in the patient treatment agreement.

(c) Random and/or scheduled use of confirmatory (mass spectrometry, liquid and gas chromatography) testing on bodily samples.

(d) Encouragement to the patient to keep medications and prescriptions locked away in a secure location. The DMP shall describe in writing the policy for lost or stolen controlled substance prescriptions, including buprenorphine.

(e) Random or consistently observed collection of urine or body search as a documented part of the physical exam prior to urine collection.

(f) Increased office visit frequency for patients receiving greater than 16mg/4mg per day of Suboxone equivalents in transmucosal delivery systems.

(g) Encouraged use of long-acting injectable buprenorphine products or buprenorphine implants when appropriate.

(h) Appropriate use of the PDMP.

(i) Written policy regarding the practice of phoned in prescriptions.

(j) Written policy describing the standard operating procedure for storage of prescription pads in a locked and/or secure location.

(3) On the rare occasion that a prescriber elects not to follow the DMP, a protocol deviation shall be described in the office note detailing the rationale for the protocol deviation and the alternative plan of action. Such office notations should be clearly labeled in the chart as Diversion Mitigation Policy Protocol Deviation.

(4) Evidence of diversion should not necessarily result in patient dismissal, although the prescriber does have a duty to address the aberrant behavior. The action response to evidence of diversion should be described in writing in the DMP. Acceptable action responses to evidence of diversion may include:

(a) Movement of the patient from the maintenance phase back to the stabilization phase, prompting a more intense level of care (more frequent visits, frequent counseling requirements, drug testing, pill/film and wrapper counts).

(b) Transition from a self-administered, transmucosal delivery system to a long-acting buprenorphine injectable or implant.

(c) Transition from buprenorphine to another FDA approved but non-controlled medication for the treatment of opioid use disorder such as oral naltrexone or long-acting naltrexone injection (Vivitrol).

(d) Referral of the patient to a federally qualified opioid treatment program for methadone maintenance therapy.

(e) Referral of the patient for inpatient stabilization treatment or residential treatment.

(f) Offer the patient treatment options that are not subject to the risk of diversion in cases with evidence of ongoing diversion.

(g) Reduce the dose of the patient's medication.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.15 Use of Mono-Product Buprenorphine Formulations.

(1) Transmucosal preparations of patient administered buprenorphine for the treatment of opioid use disorder must contain the combination of buprenorphine and naloxone in a 4 to 1 ratio with the following exceptions:

(a) Pregnant females may be treated with a buprenorphine mono-product from the first detection of pregnancy through delivery. Patients should be transitioned back to combination therapy at the first follow up after delivery. Patients treated with buprenorphine/naloxone may be encouraged to breast feed.

(b) Treatment of patients with documented and observed objective allergic reaction to naloxone, not to include subjective adverse reactions such as headache and gastro-intestinal upset.

(c) Patients with adverse reactions to naloxone in combination with buprenorphine should consider the use of depo-buprenorphine injections or buprenorphine implants.

(2) The use of transmucosal monotherapy (buprenorphine only products) for the treatment of opioid use disorder in non-pregnant patients should not exceed two percent of the MAT prescriber's overall MAT practice.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.16 Registration of Persons Providing Medication Assisted Treatment (MAT).

(1) Any person who provides or offers to provide MAT in the state of Alabama shall register with the Board of Medical Examiners as a MAT provider. After initially registering as a MAT provider, it shall be the obligation of the registrant to advise the Board of any change in the practice location within the state of Alabama of that MAT provider.

(2) The form for registration as a MAT provider is incorporated as Appendix B to these rules.

(3) Annual registration as a MAT provider is required, and registration shall be by electronic means.

(4) Annual registration as a MAT provider shall be due by December 31 of each year at no cost to the registrant.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-21-.17 Appropriate Record Keeping Requirements.

(1) MAT providers shall adhere to the Joint Guidelines of the State Board of Medical Examiners and Medical Licensure Commission for Medical Records Management. In addition, MAT providers shall adhere to the following special requirements for appropriate record keeping practices:

(a) Billing records shall be maintained for a period of three years from the date of the patient's last treatment.

(b) Billing records shall be made for all methods of payment.

(c) Billing records shall include, but not be limited to, information detailing all of the following:

1. The amount paid for services.
2. Method of payment.
3. Date of the delivery of services.
4. Date of payment.
5. Description of services.

(d) Records of all bank deposits of cash payments for MAT shall be maintained, in any format, for a period of three years.

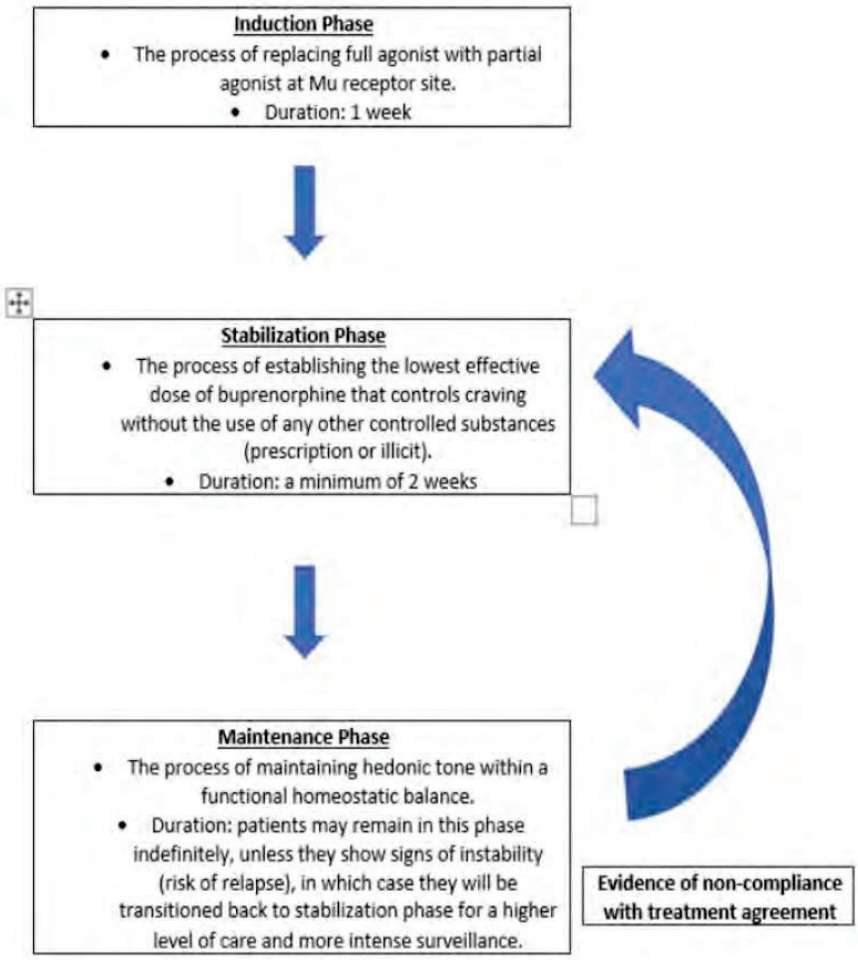
(2) All patients shall receive a fee agreement at their initial visit outlining the

services provided and cost for visits. This shall include, but not be limited to, the expected frequency of visits for the patient based on their phase of treatment. The patient shall be informed of service charges in the form of a fee agreement signed by the patient and placed in the medical record. The fee agreement should include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for the patient (or patient's legal representative) in the event they are unable to pay for treatment.

Author: Alabama State Board of Medical Examiners and MAT Act Working Group
Statutory Authority: Ala. Code §§ 20-2-300 through 20-2-302; 34-24-53; 34-24-53.1
History:

540-X-27, Appendix A

Flow Chart – Phases of Treatment



Alabama State Board of Medical Examiners
PO Box 946 – Montgomery AL 36101-0946

Medication Assisted Treatment Registration

Name: _____ AL License #: _____

DEA Number: _____ Expiration Date: _____

DEA "X" Number: _____ Expiration Date: _____

ACSC/QACSC Number: _____ Expiration date: _____

Primary Specialty: _____

List all Specialty Board and Advanced Practice Certification(s)_____

_____

(MDs/DOs: List only specialty boards approved by the American Board of Medical Specialties or the American Osteopathic Association)

Please provide the following information for each location where you provide medication assisted treatment services: (Attach additional pages if necessary)

Facility or Clinic Name: _____

Physical Address: _____
Street City State Zip

Please provide the full names of all physicians, advanced practice nurses, and physician assistants providing medication assisted treatment services at this location:

_____

_____

_____

I swear (affirm) that the information set forth on this Medication Assisted Treatment Registration form is true and correct to the best of my knowledge, information and belief. I also understand that the Alabama State Board of Medical Examiners may conduct an on-site inspection of my records at any time.

Signature of Physician/CRNP/PA: _____ Date: _____

(For electronic signature) I understand and agree that by typing my name, I am providing an electronic signature that has the same legal effect as a written signature pursuant to Ala. Code §§ 8-1A-2 and 8-1A-7. I attest that the

foregoing information has been provided by me and is true and correct to the best of my knowledge, information, and belief.

Knowingly providing false information to the Alabama State Board of Medical Examiners is a violation of Ala. Code §§ 34-24-360(17) and 20-2-54(a)(1).

REPEAL

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-21
POLICY ON DATA 2000: GUIDELINES FOR THE
TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE[1]

Table of Contents

540-X-21-.01 Introduction.

(1) Role of Federal Legislation.

(a) The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as "DATA 2000" (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically, DATA 2000 allows physicians to use buprenorphine and other controlled substances in the federal Controlled Substances Act (21 U.S.C. §§ 801, et. seq.) (CSA) Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met.

(b) DATA 2000 lifted the requirement that patients who need opioid agonist

[1]These rules are directly based on the Federation of State Medical Boards Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office, April 2013, and the authorities referenced and cited in that policy. The complete Federation of State Medical Boards Model Policy with references and citations may be accessed at www.fsmb.org.

treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as “methadone clinics.”

(c) For the implementation of DATA 2000, the Secretary of the Department of Health and Human Services (HHS) delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA).

(2) Role of State Medical Boards.

(a) The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increases the role of state medical boards in overseeing such treatment. For this reason, the Federation of State Medical Boards (FSMB) entered into an agreement with SAMHSA to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction.

(b) The agreement between FSMB and SAMHSA resulted in a Model Policy adopted by FSMB in 2002. The Model Policy was updated in April 2013. The Model Policy encourages state medical boards to adopt consistent standards, to promote the public health by making appropriate treatment available to opioid-addicted patients, and to educate the regulatory and physician communities about the potential of new treatment modalities for opioid addiction.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Alabama §§ 34-24-53
History: Approved for publication: January 21, 2015. Effective Date: April 23, 2015.

540-X-21-.02 Preamble.

(1) The Alabama Board of Medical Examiners (Board) Requirements.

(a) The Board is obligated under the laws of the state of Alabama to protect the public health and safety. The Board recognizes that the principles of high-quality medical practice dictate that the people of Alabama have access to appropriate, safe and effective medical care, including the treatment of addiction. The application of up-to-date knowledge and evidence-based treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from addiction.

(b) In this context, the Board recognizes the body of evidence for the effectiveness of buprenorphine in the office-based treatment of opioid addiction, when such treatment is delivered in accordance with current standards of care and the requirements of DATA 2000 and the Board.

(c) The Board will determine the appropriateness of a particular physician's prescribing practices on the basis of the physician's overall treatment of patients and the available documentation of treatment plans and outcomes. The goal is to provide appropriate treatment of the patient's opioid addiction (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and pressing psychosocial issues.

(2) Federal Requirements to Prescribe Buprenorphine for Addiction.

(a) Physicians who wish to treat opioid addiction with buprenorphine in their medical offices must demonstrate that they have met the requirements of the DATA 2000 legislation and obtained a waiver from SAMHSA[2]. To qualify for such a waiver,

[2]The "waiver" allows an exception to the Harrison Narcotics Act of 1914, which made it illegal for a

physicians must hold a current controlled substance registration with the U. S. Drug Enforcement Administration (DEA) and a current license in the state in which they practice. They also must meet one or more of the following qualifications:

1. Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;

2. Subspecialty board certification in addiction medicine from the American Osteopathic Association;

3. Addiction certification from the American Board of Addiction Medicine;

4. Completion of not less than eight hours of training related to the treatment and management of opioid addiction provided by the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other approved organizations; or

5. Participation as an investigator in one or more clinical trials leading to the approval of an opioid drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid-addicted patients.

(b) To obtain a waiver, a physician must notify SAMHSA in writing of his or her intent to prescribe an approved opioid medication to treat addiction, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants a waiver, DEA

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physician to prescribe an opioid to any patient with opioid addiction for the purpose of managing that addiction or acute withdrawal. Prior to DATA 2000, the only exception to the Harrison Act was federal legislation that allowed the establishment of methadone maintenance treatment (MMT) clinics, now referred to as Opioid Treatment Programs (OTPs). That exception only allowed the use of methadone to treat addiction or withdrawal within specially licensed and regulated facilities, but not in office-based medical practice.

will issue an identification number no later than 45 days after receipt of the physician's written notification. (If SAMHSA does not act on the physician's request for a waiver within the 45-day period, DEA will automatically assign the physician an identification number.) This process is explained, and can be accessed at the following website: http://buprenorphine.samhsa.gov/howto.html.

(c) If a physician wishes to prescribe or dispense an appropriately available and approved opioid medication for maintenance treatment or detoxification (so as to fulfill the requirements of DATA 2000) on an emergency basis before the 45-day waiting period has elapsed, the physician must notify SAMHSA and the DEA of his or her intent to provide such emergency treatment.

(d) In addition to a waiver, a physician who wishes to prescribe buprenorphine or another approved opioid for the treatment of addiction in an office setting must have a valid DEA registration number and a DEA identification number that specifically authorizes him or her to engage in office-based opioid treatment.

(3) Prescription Requirements. Prescriptions for buprenorphine and buprenorphine/naloxone must include full identifying information for the patient, including his or her name and address; the drug name, strength, dosage form, and quantity; and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day they are issued (21 CFR 1306.05[a]). Both the physician's regular DEA registration number and the physician's DATA 2000 identification number (which begins with the prefix X) must be included on the prescription (21 CFR 1301.28[d][3]).

(4) For detailed guidance, physicians are referred to the Buprenorphine Clinical Practice Guidelines published by CSAT/SAMHSA, which can be accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Alabama §§ 34-24-53
History: Approved for publication: January 21, 2015. Effective Date: April 23, 2015.

540-X-21-.03 Guidelines.

(1) General.

(a) Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics. However, as in the treatment of any medical disorder, physicians who choose to offer addiction treatment need to understand the nature of the underlying disorder, the specific actions of each of the available medications (as well as any associated contraindications or cautions), and the importance of careful patient selection and monitoring.

(b) The Board has adopted the following guidelines for the treatment of opioid addiction in office-based settings. **The guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.**

(2) Physician Qualifications.

(a) The diagnosis and medical management of opioid addiction 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, the physician should become knowledgeable about opioid addiction and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies.

(b) Physicians who wish to prescribe or dispense buprenorphine for the treatment of opioid addiction must meet the requirements of DATA 2000, which are that the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and hold a current waiver.

(c) In addition to these requirements, DATA limits the number of patients that a physician is permitted to treat at any one time to 30 in the first year after obtaining a waiver, and to 100 patients thereafter. The physician who wishes to treat more than 30 patients after the first year must file an application with the DEA to extend his or her waivered capacity to do so.

(d) DATA 2000 also requires that a physician who wishes to treat opioid addiction with buprenorphine in an office setting must demonstrate a capacity to offer (or refer patients for) appropriate counseling and other ancillary services, and to recognize when those services are needed.

(e) Physicians are not permitted to delegate the prescribing of buprenorphine to non-physicians. Even physicians who hold DEA registrations to prescribe controlled substances for other conditions are not allowed to prescribe buprenorphine for the

treatment of addiction unless they meet the DATA requirements and hold a waiver. However, non-physician professionals can play an active role in evaluating and monitoring patients and providing other elements of care, in accordance with state regulations and rules governing physician supervision and medical oversight.

(f) Physicians should consult federal regulations (21 CFR § 1301.28) and statutes (21 USC 823 (g)); the resources available on the DEA's website (at www.deadiversion.usdoj.gov); and Board rules governing the issuance of prescriptions for controlled substances.

(3) Patient Assessment.

(a) The objectives of the patient assessment are to determine a given patient's eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the assessment should be designed to achieve the following:

1. Establish the diagnosis of opiate addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status.

2. Document the patient's use of other substances, including alcohol and other drugs of abuse.

3. Identify comorbid medical and psychiatric conditions and disorders and determine how, when and where they will be addressed.

4. Screen for communicable diseases and address them as needed. Evaluate the patient's level of physical, psychological and social functioning or impairment.

5. Assess the patient's access to social supports, family, friends, employment, housing, finances and legal problems.

6. Determine the patient's readiness to participate in treatment.

(b) Assessment usually begins at the time of the patient's first office visit and continues throughout treatment. While the evidence is not conclusive, consensus opinion is that an initial patient assessment is of higher quality when it includes a medical and psychiatric history, a substance abuse history, and an evaluation of family and psychosocial supports, as well as a pregnancy test for all women of childbearing age. The physical examination, if performed during the initial assessment, can be focused on evaluating neurocognitive function, identifying sequelae of opioid addiction, and looking for evidence of severe hepatic dysfunction.

(c) As a general rule, a urine drug screen or other toxicologic screen should be part of the initial evaluation to confirm recent opioid use and to screen for unreported use of other drugs. Ideally, this drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs that are available locally. It also is advisable to access the patient's prescription drug use history through the Alabama Department of Public Health Prescription Drug Monitoring Program (PDMP), both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications.

(d) Information from family members and significant others can provide useful additional perspectives on the patient's status, as can contact with or records from clinicians who have treated the patient in the past.

(4) Treatment Planning.

(a) There is an emerging consensus among addiction experts that treatment medications such as buprenorphine should be considered as an option for every opioid-addicted patient. However, the failure to offer medication-assisted treatment does not in itself constitute substandard care. No single treatment is appropriate for all persons at all times. **Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning.**

(b) The treating physician should balance the risks and benefits of medication-assisted treatment in general -- and treatment with buprenorphine in particular -- against the risks associated with no treatment or treatment without medication. The various options include:

1. Simple detoxification and no other treatment;

2. Detoxification followed by antagonist therapy;

3. Counseling and/or peer support without medication-assisted treatment;

4. Referral to short-term or long-term residential treatment;

5. Referral to an OTP for methadone maintenance; or

6. Treatment with buprenorphine or buprenorphine/naloxone in an office-based setting.

Patients may be suitable candidates for treatment with buprenorphine even if

past treatment episodes were not successful.

(c) If a decision is made to offer the patient treatment with buprenorphine, the risks associated with possible misuse and diversion are such that the combination buprenorphine/naloxone product is preferable for most patients. The monoproduct should be used only rarely except in pregnant women, for whom it is the preferred formulation.

(d) Psychosocial and other nonpharmacologic interventions often are useful components of treatment. Such interventions typically work best in conjunction with medication-assisted therapies; in fact, there is some evidence that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone. **The ability to offer patients psychosocial supports, either on-site or through referral, is a requirement of the DATA 2000 legislation.**

(5) Educating the Patient.

(a) Every patient to whom buprenorphine is prescribed should be cautioned to follow the directions exactly, particularly during the induction stage. Critical issues involve when to begin dosing, the frequency of subsequent doses, and the importance of avoiding the use of any other illicit or prescription opioid.

(b) Concurrent use of non-opioid sedating medications or over-the-counter products also should be discussed, and patients should be advised to avoid the use of alcohol.

(c) Patients should be cautioned about potential sedation or impairment of psychomotor function during the titration phase of induction with buprenorphine.

(d) Finally, because opioids can contribute to fatal overdoses in individuals who have lost their tolerance to opioids or in those who are opioid-naive (such as a child or other family member), proper and secure storage of the medication must be discussed. Particularly where there are young people in the patient's home, the subject of safe storage and use should be revisited periodically throughout the course of treatment, with the discussions documented in the patient record.

(6) Informed Consent.

(a) Although agonist medications such as buprenorphine clearly are effective for the treatment of opioid dependence, they do entail a substitute dependence on the prescribed medication to replace the prior dependence on the misused opioid. This issue should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process. Patients and family members often are ambivalent about agonist treatment for this reason and their concerns may influence subsequent treatment choices. Possible topics of discussion include the difference between addiction and physical dependence (including an explanation of why agonist therapy is not simply "switching one addiction for another"), the likelihood of relapse with and without medication-assisted treatment, the projected duration of the treatment, the potential for successfully tapering from agonist therapy at some point in the future, and the role and importance of adjunctive therapies such as counseling and peer support. With the patient's consent, this conversation could include family members, significant other(s), or a guardian.

(b) A written *informed consent* document, discussed with and signed by the

patient, can be helpful in reinforcing this information and establishing a set of “ground rules.” The practitioner should document the informed consent in the patient’s medical record.

(7) Treatment Agreement.

(a) The terms of treatment agreements vary widely, but typical provisions include an acknowledgment of the potential benefits and risks of therapy and the goals of treatment; identification of one provider and one pharmacy from whom the patient will obtain prescriptions; authorization to communicate with all providers of care (and sometimes significant others) and to consult the PDMP; other treatments or consultations in which the patient is expected to participate, including recovery activities; avoidance of illicit substances; permission for drug screens (of blood, urine, saliva or hair/nails) and pill counts as appropriate; mechanisms for prescription renewals, including exclusion of early renewals; expected intervals between office visits; and specification of the conditions under which therapy will be continued or discontinued.

(b) The agreement also should include a statement instructing the patient to stop taking all other opioid medications unless explicitly told to continue. Such a statement reinforces the need to adhere to a single treatment regimen. Inclusion in the agreement of a pharmacy address and telephone number reinforces to the patient the importance of using one pharmacy to fill prescriptions.

(c) Finally, the treatment agreement should set forth the objectives that will be used to evaluate treatment success, such as freedom from intoxication, improved

physical and psychosocial function, and adherence to the treatment regimen.

(d) Copies of the treatment agreement and informed consent should be provided to the patient and all other care providers, and filed in the patient's medical record. The agreement should be reviewed regularly and adjusted as needed.

(8) Induction, Stabilization, and Follow-up.

(a) The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable craving for the drug of abuse.

(b) The initial induction process requires a higher degree of attention and monitoring than the later maintenance phase. Particular attention should be given to the timing of the initial doses so as to minimize untoward outcomes. Withdrawal symptoms can occur if either too much or too little buprenorphine is administered (i.e., spontaneous withdrawal if too little buprenorphine is given, precipitated withdrawal if buprenorphine is administered while the opioid receptors are substantially occupied by an opioid agonist). Undermedication or overmedication can be avoided through a flexible approach to dosing, which sometimes requires higher doses of treatment medication than expected, and by taking into account patient-reported symptoms.

(c) The stabilization phase is focused on finding the right dose for an individual patient. A patient is stabilized when the dose allows him or her to conduct activities of daily living and to be aware of his or her surroundings without intoxication and without suffering withdrawal or distressing drug craving. Although there is no

precise way to determine in advance what the optimal dose for a particular patient will be, most patients are likely to stabilize on eight to 16 mg. of buprenorphine per day, although some may need doses of up to 24 mg per day. As the dose of Buprenorphine increases, the board recognizes that the risk for diversion and abuse also increases. While the board recognizes that from time to time a patient may need a higher dose of Buprenorphine, it is expected that the clinical reasons for an increased dose be documented in the medical records, and that the clinician utilize available resources to be vigilant for risk of diversion regardless of dosage prescribed.

(d) Buprenorphine blood concentrations stabilize after approximately seven days of consistent dosing. If withdrawal symptoms subsequently emerge during any 24-hour dosing interval, the dose may be too low, or other factors may be involved. Medical factors that may cause a patient's dose requirements to change include (but are not limited to) starting, stopping. or changing the dose of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; and significant increase or decrease in weight.

(e) Dose adjustments generally can be made in increments of 2 mg/day. Because buprenorphine has a long plasma half-life and even longer duration of action at the mu opioid receptor, five days should be allowed between dose adjustments.

(f) Patient adherence to medication regimens and session appointments is associated with better treatment outcomes, and regular monitoring can help patients plan for possible obstacles and teach them ways to handle any problems that occur. Regular assessment of the patient's level of engagement in treatment and the strength

of the therapeutic alliance allows for modification of the treatment plan and level of care in response to the patient's progress or lack thereof.

(g) Early in treatment, medications should be prescribed and follow-up visits scheduled commensurate with the patient's demonstrated stability. Until patients have shown the ability to be compliant with the treatment plan and responsible with their medication supplies, and have discontinued high-risk behaviors and associated diversion risks, they should be seen more frequently and given supplies of medication only as needed until the next visit. As patients demonstrate stability and the risk declines, they can be seen less often (typically once a month) and prescribed larger supplies of medication.

(h) Patient monitoring during follow-up visits should address the following points:

1. Whether the patient continues to use alcohol or illicit drugs, or to engage in non-medical use of prescription drugs;

2. The degree of compliance with the treatment regimen, including the use of prescribed medications as directed;

3. Changes (positive or negative) in social functioning and relationships;

4. Avoidance of high-risk individuals, situations, and diversion risk;

5. Review of whether and to what degree the patient is involved in counseling and other psychosocial therapies, as well as in self-help activities through participation in mutual support meetings of groups such as Narcotics Anonymous;

6. The presence or absence of medication side effects; and

7. The presence or absence of medical sequelae of substance use and its remission.

(i) The patient's compliance with regard to use of prescribed buprenorphine and avoidance of other opioids should be monitored through patient report, regular toxicologic analyses, reports from significant others, and regular checks of the PDMP.

(j) Individuals being treated with medication-assisted treatment often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible. Reducing the frequency of monitoring visits, with their associated costs, and increasing the patient's responsibility for medications are examples of how positive, responsible behaviors can be reinforced.

(9) Adjusting the Treatment Plan.

(a) Treatment outcomes typically are positive for patients who remain in treatment with medication-assisted therapies such as buprenorphine. However, some patients struggle to discontinue their misuse of opioids or other drugs, are inconsistent in their compliance with treatment agreements, or succeed in achieving some therapeutic goals while not doing well with others.

(b) Behaviors that are not consistent with the treatment agreement should be taken seriously and used as an opportunity to further assess the patient and adapt the treatment plan as needed. In some cases, where the patient's behavior raises concerns about safety or diversion of controlled medications, there may be a need to refer the patient for treatment in a more structured environment (such as an OTP).

However, behavior that violates the treatment agreement or a relapse to nonmedical drug use do not constitute grounds for automatic termination of treatment. Rather, they should be taken as a signal to reassess the patient's status, to implement changes in the treatment plan (as by intensifying the treatment structure or intensity of services), and to document such changes in the patient's medical record.

(c) Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record.

(d) Patients with more serious or persistent problems may benefit from referral to a specialist for additional evaluation and treatment. For example, the treatment of addiction in a patient with a comorbid psychiatric disorder may be best managed through consultation with or referral to a specialist in psychiatry or addiction psychiatry. In other instances, aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling, or psychotherapies, or possibly referral to a more structured treatment setting.

(10) Preventing and Managing Relapse.

(a) Relapse always should be ruled out as a reason for loss of stability. Relapse to drug use has been described as "an unfolding process in which the resumption of substance abuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli." It rarely is caused by any single factor; rather, it is a dynamic process in which the patient's readiness to change interacts with other external and internal factors. Patients in relapse vary in the

quantity and frequency of their substance use, as well as the accompanying medical and psychosocial sequelae.

(b) Clinical strategies to prevent and address relapse generally encompass the following steps:

1. Identify environmental cues and stressors that act as relapse triggers;

2. Help patients develop skills to cope with or manage negative emotional states;

3. Help the patient work toward a more balanced lifestyle;

4. Understand and manage craving;

5. Identify and interrupt lapses and relapses. Patients should have an emergency plan to address a lapse so that a full-blown relapse can be avoided. If relapse does occur, be prepared to intervene; and

6. Develop a recovery support system. Families are likely to provide such support if they are engaged in the treatment process and have an opportunity to ask questions, share their concerns and experiences, and learn practical coping strategies and behaviors to avoid.

(c) It should be noted that lack of adherence to pharmacologic regimens occurs in a substantial portion of patients being treated for addiction, with some studies reporting that a majority of patients fail to follow the treatment plan at some point in their care. Retention in treatment is also a problem. This is no different from the challenges encountered in managing any chronic disease, such as diabetes, hypertension, epilepsy, and other potentially life-threatening disorders, and is not an

indication to terminate treatment.

(d) Patients who continue to misuse opioids after sufficient exposure to buprenorphine and ancillary psychosocial services or who experience continued symptoms of withdrawal or craving at 32 mg of buprenorphine should be considered for therapy with methadone.

(11) Duration of Treatment.

(a) Available evidence does not support routinely discontinuing medication-assisted treatment once it has been initiated and the patient stabilized. However, this possibility frequently is raised by patients or family members. When it is, the physician and patient should carefully weigh the potential benefits and risks of continuing medication-assisted treatment and determine whether buprenorphine therapy can be safely discontinued.

(b) Studies indicate that opioid-dependent patients are at high risk for relapse when medication-assisted treatment is discontinued, even after long periods of stable maintenance. Research also shows that longer duration of treatment is associated with better treatment outcomes. Such long-term treatment, which is common to many medical conditions, should not be seen as treatment failure, but rather as a cost-effective way of prolonging life and improving the quality of life by supporting the natural and long-term process of change and recovery. Therefore, the decision to discontinue treatment should be made only after serious consideration of the potential consequences.

(c) As with other disease processes, the continuation of medication-assisted

treatment should be linked directly to the patient's response (for example, his or her attainment of treatment goals). Relapse risk is highest in the first six to 12 months after initiating abstinence, then diminishes gradually over a period of years. Therefore, it is reasonable to continue treatment for at least a year if the patient responds well.

(d) If buprenorphine is discontinued, the patient should be tapered off the medication through use of a safely structured regimen, and followed closely. It may be necessary to reinstate pharmacotherapy with buprenorphine or a different medication or other treatment services if relapse appears imminent or actually occurs. Such relapse poses a significant risk of overdose, which should be carefully explained to the patient. Patients also should be assured that relapse need not occur for them to be reinstated to medication-assisted treatment.

(12) Medical Records.

(a) Accurate and up-to-date medical records protect both the physician and the patient. In the event of a legal challenge, detailed medical records that document what was done and why are essential elements of the practitioner's defense.

(b) A written informed consent and a treatment agreement articulating measurable treatment goals are key documents. The treatment agreement should be updated as new information becomes available. Both the informed consent and treatment agreement should be carefully explained to the patient and signed by both the patient (or guardian) and the treating physician. The medical record should clearly reflect the decision-making process that resulted in any given treatment regimen.

(c) The patient's chart should contain a summary of the information needed to

understand the treatment plan, even without a thorough knowledge of the patient. This includes some demographic data, the names of other practitioners caring for the patient, all diagnoses, therapies employed, and a list of all medications prescribed. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed.

(d) Other documents that should be part of the medical record, where available, include:

1. Diagnostic assessments, including the patient history, physical examination, and any laboratory tests ordered, with their results;

2. Actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;

3. The treatment plan, treatment agreement, and informed consent;

4. Authorization for release of information to other treatment providers;

5. Documentation of discussions with and consultation reports from other health care providers; and

6. Medications prescribed and the patient's response to them, including any adverse events.

(e) The medical record also must include all prescription orders, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record.

(f) Monitoring visits should be carefully documented in the medical record, along with any subsequent changes to the treatment plan. The patient's record also

should contain documentation of steps taken to prevent the diversion of treatment medications, including any communications with other treating physicians and use of the PDMP to verify that all prescribed medicines have been obtained and that no other prescriptions for controlled drugs have been dispensed without the physician's knowledge.

(g) Records (including drug logs, if buprenorphine is dispensed in the office) should be up-to-date and maintained in an accessible manner, readily available for review. Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.

(h) Physicians who treat patients for addiction must observe the special confidentiality requirements of federal law found in 42 CFR, Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR §§ 2.1 through 2.67), which addresses the confidentiality of patients being treated for alcohol or drug addiction. Title 42 CFR, Part 2, includes a prohibition against release of records or other information without the patient's consent or a valid court order, or in cases of a bona fide medical emergency, or in the course of mandatory reporting of child abuse.

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540-X-21-.04 Definitions.

(1) Accurate use of terminology is essential to understanding office-based

treatment of opioid addiction. However, terminology in this area is changing. for many years, the most commonly used terms have been “drug abuse” and “drug dependence,” with the latter indicating a severe condition considered synonymous with the term “addiction” (the chronic brain disease). The terms “abuse” and “dependence,” in use since the third edition of the *Diagnostic and Statistical Manual of Mental Disorders*, were replaced in the fifth edition by the term “substance use disorder.” Other new terms include “opioid use” for the activity of using opioids benignly or pathologically, and “opioid use disorder” for the disease associated with compulsive, out-of-control use of opioids.

(2) For the purposes of Chapter 540-X-21, the following terms are defined as shown.

(a) Abuse. The definition of “abuse” varies widely, depending on the context in which it is used and who is supplying the definition. For example, in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-T), the American Psychiatric Association defines drug abuse as “a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors.” The *Diagnostic and Statistical Manual of Mental Disorders, Fifth* Edition (DSM-V), published in May 2013, replaces the term “abuse” with “misuse.”

(b) Addiction.

1. Addiction is widely defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired

control over drug use, craving, compulsive use, and continued use despite harm. (As discussed below, physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction.)

2. A recent definition of addiction, adopted by the American Society of Addiction Medicine in 2011, reads as follows: "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death."

(c) Controlled Substance.

1. A controlled substance is a drug that is subject to special requirements under the CSA, which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for

serious violations of the statute are part of the government's drug control apparatus. Title 21, Chapter II of the Code of Federal Regulations (21 CFR. §§ 1300-1399) implements the CSA.

2. The CSA confers the responsibility for scheduling controlled substances on the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

3. Most opioids are classified as Schedule II or III drugs under the CSA, indicating that they have a high potential for abuse and a currently accepted medical use in treatment in the U.S., and that abuse of the drug may lead to psychological or physical dependence. (Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled substances have some potential for abuse.)

(d) Dependence.

1. Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist. It is important to distinguish addiction from the type of physical dependence that can and does occur

within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. The distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD-10) of the World Health Organization (WHO), and the *Diagnostic and Statistical Manual* of the American Psychiatric Association. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the DSM V, the term dependence is reestablished in its original meaning of physiological dependence; when symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings.

2. It may be important to clarify this distinction during the informed consent process, so that the patient understands that physical dependence and tolerance are likely to occur if opioids are taken regularly for a period of time, but the risk of addiction is relatively low unless the patient has additional risk factors. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid."

(e) Detoxification.

1. Detoxification (also termed "medically supervised withdrawal") refers to a gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve the elimination of tolerance and physical dependence.

2. "Detoxification" is a legal and regulatory term that has fallen into disfavor with some in the medical community; indeed, some experts view "detoxification" as a

misnomer because many abusable drugs are not toxic when administered in proper doses in a medical environment.

(f) Diversion.

1. The CSA establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA.

2. Pharmaceuticals that make their way outside this closed system are said to have been “diverted” from the system, and the individuals responsible for the diversion (including patients) are in violation of the law. The degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system.

(g) Maintenance Treatment. Maintenance treatment involves the dispensing or administration of an opioid medication (such as methadone or buprenorphine) at a stable dose and over a period of 21 days or more, for the treatment of opioid addiction. When maintenance treatment involves the use of methadone, such treatment must be delivered in an OTP. However, maintenance treatment with buprenorphine may be delivered in either an OTP or a medical office by a properly credentialed physician.

(h) Medication-Assisted Treatment (MAT). MAT is any treatment for opioid addiction that includes a medication (such as methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment. MAT

may be provided in a specialized OTP, or, for buprenorphine or naltrexone, in a physician's office or other health care setting.

(i) Misuse. The term misuse (also termed non-medical use) incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice.

(j) Opioid.

1. An opioid is any compound that binds to an opioid receptor. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides. Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader, more appropriate term because it includes the entire class of agents that act as opioid receptors in the nervous system, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for, including the most common currently used and misused prescription opioids, may well be present in the sample that was analyzed.

2. *Opioid agonists* are compounds that bind to the mu opioid receptors in the brain, producing a response that is similar in effect to the natural ligand that would

activate it. With full mu opioid agonists, increasing the dose produces a more intense opioid effect. Most opioids that are misused, such as morphine and heroin, are full mu opioid agonists, as is methadone.

3. *Opioid partial agonists* occupy and activate the opioid receptors, but the activation they produce reaches a plateau, beyond which additional opioid doses do not produce a greater effect. It should be noted that the plateau (or "ceiling effect") may limit a partial agonist's therapeutic activity as well as its toxicity. Buprenorphine is a partial mu opioid agonist.

4. *Opioid antagonists* bind to and block the opioid receptors and prevent them from being activated by an opioid agonist or partial agonist. Naltrexone and naloxone both are opioid antagonists, and both can block the effect of opioid drugs.

(k) Opioid Treatment Program (OTP). (Sometimes referred to as a "methadone clinic" or "narcotic treatment program"). An OTP is any treatment program certified by SAMHSA in conformance with 42 CFR, Part 8, Certification of Opioid Treatment Programs (42 CFR §§ 8.1 through 8.34), to provide supervised assessment and medication-assisted treatment of patients who are addicted to opioids. An OTP can exist in a number of settings, including intensive outpatient, residential, and hospital facilities. Treatments offered by OTPs include medication-assisted treatment with methadone, buprenorphine or naltrexone, as well as medically supervised withdrawal or detoxification, accompanied by varying levels of medical and psychosocial services and other types of care. Some OTPs also can provide treatment for co-occurring mental disorders.

(l) Recovery. A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. As used in the ASAM Patient Placement Criteria, “recovery” refers to the overall goal of helping a patient achieve overall health and well-being. SAMHSA’s 10 guiding principles recognize that recovery:

1. Emerges from hope;

2. Is person-driven;

3. Occurs via many pathways;

4. Is holistic;

5. Is supported by peers and allies;

6. Is supported through relationship and social networks;

7. Is culturally-based and influenced;

8. Is supported by addressing trauma;

9. Involves individual, family and community strengths and responsibility; and

10. Is based on respect.

(m) Relapse.

1. Relapse has been variously defined as “a breakdown or setback in a person’s attempt to change or modify any target behavior” and as “an unfolding process in which the resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli.” Relapse rarely is caused by any single factor and often is the result of an interaction of physiologic and environmental factors.

2. The term *lapse* (often referred to as a *slip*) refers to a brief episode of drug use after a period of abstinence. A lapse usually is unexpected, of short duration, with relatively minor consequences, and marked by the patient's desire to return to abstinence. However, a lapse can also progress to a full-blown relapse, marked by sustained loss of control.

(n) Tolerance.

1. Tolerance is a sate of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance may occur both to an opioid's analgesic effects and to its unwanted side effects, such as respiratory depression, sedation, or nausea. Most investigators agree that absolute tolerance to the analgesic effects of opioids does not occur. In general, tolerance to the side effects of opioids develops more rapidly than does tolerance to the drug's analgesic effects.

2. Tolerance may or may not be evident during treatment with opioids and is not the same as addiction.

(o) Trial Period. A period of time, which can last weeks or even months, during which the efficacy of a medication or other therapy for the treatment of addiction is tested to determine whether the treatment goals can be met. If the goals are not met, the trial should be discontinued and an alternative approach (i.e, a different medication or non-pharmacologic therapy) adopted.

(p) Waiver. A documented authorization from the Secretary of Health and Human Services, issued by SAMHSA under the DATA 2000 regulations, that exempts a

qualified physician from the rules applied to OTPs and allows him or her to use buprenorphine for the treatment of addiction in office-based practice.

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