

APA-1
6/93

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

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

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 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.

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 Reference Service.

Signature of certifying officer 

Date: January 22, 2015

APA-2
6/93

**ALABAMA STATE BOARD
OF MEDICAL EXAMINERS**

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State 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

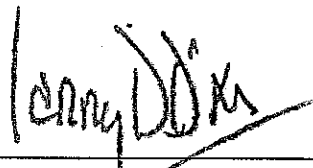
INTENDED ACTION: To add a new Chapter

SUBSTANCE OF PROPOSED ACTION: To add a new Chapter of Rules regulating the treatment of opioid addiction in the medical office

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: Patricia E. Shaner, Office of General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 848 Washington Avenue (36104), 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 Monday, March 9, 2015. Persons wishing to obtain copies of the text of this rule should contact Patricia E. Shaner, Office of General Counsel, (334-242-4116), PO Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946. Copies of the proposed rules may also be downloaded from the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: March 9, 2015

CONTACT PERSON AT AGENCY: Patricia E. Shaner, Office of General Counsel, 334-242-4116; PO Box 946, Montgomery, AL 36101-0946; 848 Washington Avenue, Montgomery, AL 36104



Larry D. Dixon, Executive Director

NEW
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 OFFICE¹

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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

¹These 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

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 SAMHSA². To qualify for such a waiver, 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

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

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 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

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 waived 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 [not mentioned/defined elsewhere, spell out?] 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 state 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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