American Society of Addiction Medicine

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Treat Addiction ● Save Lives

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Public Health Advisor/Compliance Officer
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Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road, room 7-1024
Rockville, MD 20857

RE: Draft Federal Guidelines for Opioid Treatment

Dear Ms. Smith:

The American Society of Addiction Medicine (ASAM) is pleased to have the opportunity to comment on the draft Federal Guidelines for Opioid Treatment, which will serve as a guide to accreditation organizations in developing accreditation standards for opioid treatment programs (OTPs).

Established in 1954, ASAM represents nearly 3,000 physician members who specialize in the treatment and prevention of addiction and practice in a wide range of addiction treatment settings, including OTPs. As such, we feel uniquely qualified to comment on the provisions of these draft Guidelines that have the potential to improve the quality of care for patients receiving opioid addiction treatment in an OTP.

Access to Medications

ASAM applauds the Guidelines' emphasis on increased patient access to care and retention in treatment. Recent research commissioned by ASAM revealed public and private payer policies impose significant barriers to access to medications for opioid addiction treatment despite their demonstrated clinical and cost effectiveness.[i] ASAM supports the Guideline's assertion that "physician authority over the medical aspects of treatment is essential" and agrees that physicians should "retain the autonomy to make continuing treatment decisions in accord with the clinical course and emergent research findings."[ii] ASAM agrees that each OTP must have a physician directing care of the patients; the use of physician extenders such as nurse practitioners and physician assistants who are supervised by physicians in OTPS can help better leverage the limited addiction physician resources

Further, decisions about the appropriate type, modality and duration of treatment should indeed remain the purview of the treatment provider and the patient, working in collaboration to achieve shared treatment goals. To this end, ASAM applauds the Guidelines' explicit recognition

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that long-term treatment may be required for an "indefinite period" and that "there are no limits on the duration or the dosage level of medications, unless clinically indicated."

Overall, ASAM is very supportive of the language and constructs in the areas of Treatment Considerations Related to the Natural History of the Disease, Intensity and Duration of Treatment, Recovery Oriented Systems of Care, and Retention in treatment. ASAM is similarly pleased at the strength and clarity of guidance on treatment of pregnant patients with medication assisted treatment (MAT), which should dispel many myths and improve the medical care of pregnant opioid addicted women. These sections are fully aligned with the clinical data and best practices.

Access to Psychosocial Services

ASAM also commends the recognition that "it is essential to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of psychiatric comorbid conditions, medical complications, and communicable diseases that may be a part of a patient's problem list." This imperative aligns both with NIDA's Principles of Drug Addiction Treatment[iii] and ASAM's belief that pharmacological therapy is best accompanied by and provided in conjunction with evidence based psychosocial treatments and recovery support interventions as described in the ASAM Patient Placement Criteria.[iv]

Admission Requirements

ASAM agrees with language of 42 CFR 8.12 (e) which states that "An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria *such as* those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug" and with the definition of opiate addiction included in 42 CFR 8.2 (page 15). However, ASAM opposes the contradictory language under Evidence of Current Physiological Dependence and Opioid Addiction that "criteria for admission should be based on the American Psychiatric Association's definition of opioid dependence in the most current edition of the Diagnostic and Statistical Manual for Mental Disorders." ASAM's concern with this statement is twofold: (1) the most current edition of the DSM (DSM-V) does *not* contain a definition of "opioid dependence"; more importantly, other appropriate definitions, such as the one listed in 42 CFR 8.2 and ASAM's definition of addiction[v], are appropriate. Opioid addiction, not physiological dependence, should be the criterion for methadone maintenance.

Recommended Tests and Assessments

ASAM commends the comprehensiveness of the list of recommended tests and assessments, but recommends that the qualifier "as indicated" be used for item v. Electrocardiogram (EKD), chest x ray, Pap smear, and screening for sickle cell disease as it is in items ix. pregnancy test and x. neurological and psychological testing. As the Guidelines currently read, it appears that all patients should have all of these tests, which is not clinically appropriate.

Guidance for Therapeutic Dosage

It is our understanding that section b under General Dosage Principles (page 49) means to ensure that the dosage of a medication is only changed as specified for an individual patient by a physician's orders, which ASAM recognizes as a cornerstone of good treatment. However, some may wrongly interpret this section as implying that all standing orders are unacceptable. A standing order that patients should undergo a specific drug screen and not be dosed when they present with objective evidence of impairment, for example, is a clinically appropriate use of a standing order. A physician may not be reachable at the moment where those medical interventions are required, and obtaining the screen and holding the dosing is an appropriate standing practice which improves, not worsens, the quality of care. ASAM suggests a clarification which notes the example on page 63 of an appropriate standing order ("It is recommended that if standing orders are issued, that they be individualized, reasonable, time limited, and reviewed and signed within a 72-hour period"), as opposed to PRN ("as needed") dosage changes which are inappropriate.

Section d under Maintenance Therapy (page 51) correctly notes that because of its pharmacokinetics, it may take at least 5 days to reach steady state with any dose of methadone. However, deaths can occur at a dosage under 60 mg and anecdotal evidence indicates some physicians currently utilize an induction regimen of increasing by 10 mg daily to 60 mg. ASAM suggests that this item should be altered to state "As a suggestion, it may be medically indicated to maintain a stable dosage amount for 3-5 days before increasing the dosage, depending on the patient's clinical status and symptoms."

Use of Extended-Release Naltrexone in OTPs

While the Guidelines detail General Dosage Principles and Maintenance Therapy for agonist treatment medications approved by the Food and Drug Administration (FDA) for use in the treatment of opioid addiction, they do not give analogous instructions for treating patients with antagonist treatment medications carrying the same indication. According to the Winter 2012 SAMHSA Advisory, extended-release injectable naltrexone can be administered in OTP clinics.[vi] Including a section in the Guidelines addressing the accreditation standards for administering this medication in OTPs could help increase the appropriate use of this treatment option for patients for whom it is clinically indicated.

In closing, the American Society of Addiction Medicine wants to emphasize its gratitude for the opportunity to submit comments regarding this important document. We look forward to a continued collaboration on ways to advance and promote the best care for patients at risk of and suffering from substance use disorders.

Sincerely,

Stuart Gitlow, MD, MBA, MPH, FAPA

President, American Society of Addiction Medicine

[i] Rinaldo, SG and Rinaldo DW. State Medicaid Coverage And Authorization Requirements For Opioid Dependence Medications. June 2013. Available at: http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment and Chalk M, Alanis-Hirsch K, Woodworth A, et al. Report of Commercial Health Plan Medication Coverage and Benefits Survey.2013. Available at: http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment

[ii] ASAM Public Policy Statement on Phamacological Therapies for Opioid Use Disorders. April 24, 2013. Available at: http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2013/04/25/pharmacological-therapies-for-opioid-use-disorders

[iii] National Institute on Drug Abuse. Principles of Drug Addiction Treatment. December 2012. Available at: http://www.drugabuse.gov/sites/default/files/podat_1.pdf

[iv] ASAM Public Policy Statement on Phamacological Therapies for Opioid Use Disorders. April 24, 2013. Available at: http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2013/04/25/pharmacological-therapies-for-opioid-use-disorders

[v] American Society of Addiction Medicine. Definition of Addiction. Available at: http://asam.org/for-the-public/definition-of-addiction

[vi] SAMHSA. An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence. *SAMHSA Advisory*. Winter 2012. Available at: http://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf