AATOD
American Association for the Treatment of Opioid Dependence, Inc.

Expanding Access to Quality Opioid Addiction Treatment Services

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Nichole Washington Smith, MHSA
Public Health Advisor/Compliance Officer
SAMHSA/CSAT Division of Pharmacologic Therapies
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:

I am writing on behalf of the American Association for the Treatment of Opioid Dependence (AATOD), which represents over 900 Opioid Treatment Programs (OTPs) in the United States and Mexico. We are writing in response to the published Federal Register Notice of May 16, 2013, seeking public comments with regard to the revised 2007 SAMHSA Guidelines for the Accreditation of Opioid Treatment Programs (herein after Guidelines).

We believe that these updated Guidelines reflect developing trends in the field of Medication Assisted Treatment (MAT) for opioid addiction. They are forward thinking, with a view toward the implementation of Health Care Reform and its effect on patients in treatment and increased access to care. We also think that the Guidelines take into account the need to provide additional responsibility to mid-level practitioners in the OTP based on such systemic changes. The Guidelines advance the discussion on the role of telemedicine in expanding access to care in the OTPs. Finally, the updated Guidelines appropriately reference federally approved medications which are being used more frequently in the OTP setting (buprenorphine and Naltrexone/Vivitrol), a developing trend since the 2007 Guidelines were published.

These Guidelines are thoughtful, carefully constructed, and rooted in evidence-based practices. It is understood that the Guidelines elaborate upon the Federal Opioid Treatment Standards set forth under 42 CFR Part 8, in addition to being supported by the Treatment Improvement Protocol #43, "Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs".

Opioid Treatment Standards

Administrative Organization and Responsibilities

We support the opening comment in this section, "It is essential to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services with a range of psychiatric co-morbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list." This is consonant with one of the

principles of effective drug addiction treatment based on the NIDA publication (Principles of Drug Addiction Treatment) as revised during May 2009. "Effective treatment attends to multiple needs of the individual, not just his or her drug abuse. To be effective, treatment must address the individual's drug abuse and any associated medical, psychological, social, vocational, and legal problems. It is also important that treatment be appropriate to the individual's age, gender, ethnicity, and culture."

While this is a leading NIDA principle for effective treatment and has been reinforced by the publication of the SAMHSA Treatment Improvement Protocols, we also understand that there is a debate about how to treat long term chronic opioid addiction with the three federally approved medications. A number of proponents for MAT believe that it is important to provide access to the medication while not providing access to counseling or other ancillary services. In our judgment, this is a flawed approach and we believe that the proposed SAMHSA Guidelines provide effective guidance to OTPs about how to properly treat this complex disease.

Risk Management and Continuous Quality Improvement

Prescription Drug Monitoring Program (PDMP)

AATOD believes that the Guidelines provide important guidance to OTPs with regard to utilizing Prescription Drug Monitoring Programs (PDMPs) as a therapeutic tool in treating patients effectively. "Develops, maintains, and update regularly policies and procedures related to ongoing interaction with the Prescription Drug Monitoring Program (PDMP) when a PDMP exists in its state. These policies should include checking the PDMP prior to admitting a patient and periodic checking of the PDMP while patients are enrolled in treatment."

This statement expands on the correspondence that Dr. Westley Clark (CSAT Director/SAMHSA) forwarded to OTPs throughout the United States on September 27, 2011. Dr. Clark encouraged OTPs to "utilize PDMPs as an additional resource to maximize safety in patient care pursuant to applicable state guidelines." AATOD believes that PDMPs provide a critical resource to all OTPs with regard to the safe and effective care of our patients. We have advised all OTPs to utilize their respective state's PDMP databases where they exist.

AATOD published its own guidance to its member OTPs during June 2012, supporting Dr. Clark's guidance, as referenced above. We also agreed that OTPs should access information, but not provide patient data, to a PDMP database. As Dr. Clark pointed out in his correspondence of September 27, 2011, "OTPs and DATA-waived physicians should not disclose patient identifying information to PDMPs." We understand that the PDMPs have their own confidentiality requirements and standards, but they do not carry the same protections for re-

disclosure of patient identifying information, which is covered under 42 CFR Part 2.

The AATOD Board of Directors believes that it is prudent for all OTPs to access PDMP databases as a method to ensure safe and effective treatment for our patients. All OTPs have been encouraged to use PDMP data as a therapeutic tool in guiding the treatment of patients as they enter and remain in treatment.

We agree with SAMHSA's prior positions on this topic and the guidance as reflected in the updated Guidelines. This is especially important since a number of parties, including state legislatures, are attempting to remove the confidentiality protections afforded to patients in OTPs. Such parties and legislative bodies are engaged in this activity in spite of being fully aware of the existing patient confidentiality protections as stated above. AATOD supports SAMHSA's initiative in this area since it is important to remove any barriers that a patient may have to accessing critically needed medical care for chronic opioid addiction. We understand the restriction that this may create in other areas of emergency medicine and in treating the patient in other medical care settings. In our judgment, the balance of providing confidential treatment to a stigmatized patient population, better ensuring access to care and continuity of care, outweighs the related issues involved in treating patients in other medical care settings.

Continuous Quality Improvement/Retention in Treatment

We are also pleased that the Guidelines continue to reinforce the policy regarding the favorable benefit of retaining the patient in treatment under the section of Measures and Monitors for Treatment Outcomes. This evidence-based practice, which is founded on numerous NIDA funded research studies in addition to the content of TIP #43, is referenced throughout the Guidelines. It is referenced on page 28, "Programs and individual practitioners make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient." This point is also underscored in the section on Administrative Withdrawal and Discharge, "A major goal of the programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it."

The value of retaining a patient in treatment is also referenced in the section on Maintenance Therapy on page 51. "Programs continue Medication Assisted Treatment as long as the patient derives benefits from treatment and desires treatment. There should be no fixed length of time in treatment. In fact, indefinite Medication Assisted Treatment may be clinically indicated. The physician or mid-level practitioner, as appropriate, also should be prudent in considering other medications during the course of treatment, as clinically indicated."

It is useful to reference Dr. Stephan Magura's and Dr. Andrew Rosenblum's article, "Leaving Methadone Treatment: Lessons Learned, Lessons Forgotten, Lessons Ignored", which was published in the Mount Sinai Journal of Medicine during January 2001. This article conducted an extensive review of the literature in this area of medicine. Its conclusions are extremely clear. "Outcome data reported for more than 30 methadone discharge studies reviewed in this paper led to three main conclusions: (a) most patients who left methadone treatment were not identified by their clinic as therapeutically ready for discharge; (b) among patients who began a therapeutically planned discharge, most left methadone treatment before completing their detoxification; and (c) among patients who completed a therapeutically planned discharge, most relapsed to heroin use."

The article went on to draw another important conclusion. "Considerable evidence was presented, showing that patients who leave methadone treatment have a high rate of relapse to opiate use during the year after treatment, that they use opiates at much higher rates than patients who remain in treatment, and that very few discharged patients have a planned discharge and gradual detoxification for methadone."

Finally, the article makes an important point. "The detrimental consequences of leaving methadone treatment are dramatically indicated by greatly increased death rates following discharge. Until more is learned about how to improve post-detoxification outcomes for methadone patients, treatment providers and regulatory/funding agencies should be very cautious about imposing disincentives and structural barriers that discourage or impede long term opiate replacement therapy."

The rationale for referencing this influential article and supporting SAMHSA's guidance for retaining the patient in treatment, based on NIDA's research studies and evidence contained in TIP #43, is significant in current health policy. At the present time, a number of state legislatures are attempting to impose arbitrary limits on the length of time that a patient may be in treatment or receive third party public funding to continue to receive treatment. There are also Criminal Justice organizations in the Unites States which actively challenge the value of retaining patients in treatment. We know that most of the correctional facilities in the United States still prohibit the use of methadone maintenance or buprenorphine maintenance if the individual is in treatment, either at an OTP or DATA 2000 practice at the time of incarceration. We also know that there are a number of Drug Courts and Family Courts in the United States that compel patients to end their treatment of methadone or buprenorphine as a condition of participating in the Drug Court or regaining custody of their children. Once again, we believe that the SAMHSA Guidelines provide another critical source of guidance to OTPs, which should also inform other aspects of public policy, as indicated above.

Diversion Control

All OTPs must maintain current Diversion Control Plans (DCP), "as part of its Quality Assurance Program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the Diversion Control measures and functions described in the DCP." (42 CFR 8.12 (c) (2).

The Guidelines provide the appropriate guidance to OTPs in fulfilling the value of such Diversion Control Plans. "The goal of this program responsibility is to reduce the scope and significance of diversion and its impact on communities. The DCP should contain a mechanism for periodic monitoring of clinical and administrative activities to reduce the risk of medication diversion. Such monitoring may include toxicology screens/drug tests for determining patient adherence to the medical regimen or random call backs (especially for those with extended take homes). OTPs should also have a mechanism for problem identification and correction, as well as for the prevention of related diversion problems."

OTPs in the United States have developed different Diversion Control Plans as a method of being in compliance with the SAMHSA regulations. Some OTPs have conducted randomized "call back programs" where patients are asked to return to the program with the previously dispensed medication. Nurses or other designated personnel within the OTP evaluate the medication as it is returned to the OTP by the patient to determine if there has been any tampering with the medication.

AATOD discussed the value of such medication call back programs as part of compliance with the Diversion Control Plan, as stated above, in a formal response to the Drug Enforcement Administration's Federal Register Notice (Docket Number DEA-316), which was published on December 21, 2012. "These proposed regulations expand the entities to which ultimate users may transfer unused, unwanted, or expired Controlled Substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected."

AATOD proposed that the DEA should provide a specific category for the OTPs as one of DEA's registrants to be a certified collector for the return of such unused medications in order to be in compliance with the SAMHSA regulation as stated above and as is underscored in the current proposed Guidelines. The DEA makes this point in its Federal Register Notice. "DEA proposes to authorize as collectors those persons already registered as manufacturers, distributors, reverse distributors, and retail pharmacies because, as registrants, these persons are accountable, have experience handling large volumes of Controlled Substances on a routine basis, and they are subject to controls related

to their DEA registration. These pre-existing controls also protect against the diversion of Controlled Substances in the process of ultimate user collection."

We understand that the DEA is in the process of evaluating public comments to the aforementioned Federal Register Notice. It is AATOD's collective hope that the DEA provides a favorable response in designating OTPs as certified collectors for previously dispensed medications. We understand that there are several states where Boards of Pharmacy provide regulatory oversight to OTPs. This is a distinct minority since the majority of states do not have such Pharmacy Board control over OTP operations, nor should they.

AATOD has always supported SAMHSA's regulation with regard to Diversion Control Plans in addition to the prior Guidance Statement of 2007, and the updated proposed Guidelines. It is certainly our hope that SAMHSA and the DEA will reconcile their policies in this specific domain as it relates to the regulation of OTPs in the United States.

While such Diversion Control Plans have been viewed as conservative in a number of policy settings, in addition to restrictions of "take home" medication, AATOD is of the judgment that such regulations and oversight standards have helped protect and preserve the existence of OTPs and patient care in the United States. In view of the evidence with regard to methadone mortality being connected to the distribution of methadone through pharmacy or hospital channels in the United States as methadone has been used increasingly to treat chronic pain over the past 15 years, OTPs and their patients have not been significantly implicated in this policy arena.

Patient Admission Criteria/Mid-Level Practitioner

AATOD supports the guidance with regard to expanding the authority and decision making among mid-level practitioners within the OTP setting. This is referenced in page 16 of the proposed Guidelines. "The program physician or mid-level practitioner, as appropriate, diagnoses addiction or dependence, documents that diagnosis, and admits each patient to maintenance or detoxification treatment as medically necessary." The expanded use of mid-level practitioners in OTPs is forward thinking in anticipation of the implementation of Health Care Reform in 2014. AATOD is in support of this approach as expressed throughout the draft Guidelines, based on our correspondence to Dr. Peter Delany during his tenure as Acting Director of the Center for Substance Abuse Treatment in correspondence dated July 18, 2012. We had referenced a memorandum from AATOD's Policy Committee to the Board of Directors and OTPs, dated April 16, 2012, with regard to the role of mid-level practitioners in the OTP setting.

The correspondence to Dr. Delany and AATOD's policy statement contains two primary recommendations. The first is to recommend that all federal agencies

respect state licensing rules and regulations which govern the role of mid-level practitioners when such licensing standards have applicability to their role in the OTP. The second recommendation is that federal and state regulatory licensing agencies maintain continued flexibility in supporting the long standing relationship between mid-level practitioners and physicians in admitting and treating patients in the OTPs.

The Guidelines make this point once again in the section under dosing and administration decisions by a program physician or mid-level practitioner on page 65. "Nurse practitioners and physician assistants who possess the valid DEA registration permitting them to prescribe Schedule II Drugs are allowed to provide medical services in OTPs in states that, in turn, accept and recognize their credentials to prescribe scheduled medications. Following the admission of patients to the program, the OTP's program physician, nurse practitioner, or physician's assistant is empowered to provide medication services such as methadone and buprenorphine adjustments (increases/decreases), detoxification regimens, and medically supervised withdrawal."

The relationship between physician and mid-level practitioner is also referenced in the section regarding Evidence of Current Physiological Dependence and Opiate Addiction on page 17. "A physician or mid-level practitioner, as appropriate, assesses each patient before admission to treatment and they review a medical examination performed by another appropriately licensed health care professional who had face to face contact with the patient. This review may occur by phone or fax. The physician or mid-level practitioner, as appropriate, will make the required diagnosis, admit the patient, and then see the patient and review and countersign the patient record within 72 hours."

AATOD is in full support of this utilization of mid-level practitioners within the OTP. We also support the provision that includes the involvement of such mid-level practitioners "to accept patients' informed consent to treatment" (page 16). We understand that a number of OTPs execute such consents to treatment in conjunction with non-medical and experienced clinical personnel. In these circumstances, medical personnel discuss the issue of opioid pharmacotherapy and non-medical personnel discuss the more general clinical issues involved in patient care in addition to witnessing the execution of the patient consent. We would encourage SAMHSA to consider expanding its interpretation of processing such patient consents to incorporate full staff coordination as the patient is admitted to treatment in the OTP. It is hoped that these Guidelines will inform other federal agency requirements in this area in addition to state regulatory authorities where such OTPs fall under their regulatory jurisdiction.

Recovery Oriented Systems of Care

The Guidelines provide an important reference to recovery oriented systems of care. There is significant confusion in this area, especially where the term

"recovery oriented care" has implied a discontinuation of maintenance medications such as methadone and buprenorphine. This is certainly the case in parts of the U.S. Criminal Justice community. The Guidelines provide two important reference points on page 27. "Medication Assisted Treatment for opiate addiction reflects many elements of the chronic care treatment model. Instead of brief interventions, crisis-linked timing, and a focus on abstinence characterized by the acute care treatment model, Medication Assisted Treatment focuses on treatment retention, stabilization, and medication maintenance and tapering." The guidelines make a second important reference. "Within the recovery management framework, recovery from addiction is viewed as a voluntary, self-directed, ongoing process where patients access formal and informal resources; manage their care and addiction; and rebuild their lives, relationships, and health to lead full, meaningful lives. While recovery is patient-directed, recovery management is comprised of clinically based structured processes used to coordinate and facilitate the delivery of recovery support services after the acute stage of treatment."

It is useful to reference a thoughtful monograph written by William White and Lisa Mojer-Torres, "Recovery Oriented Methadone Maintenance", which was published during 2010. There are two useful points to reference. "The future of methadone maintenance in the United States rests on the collective ability of OTPs to forge a more person-centered, recovery-focused medical treatment for opioid addiction and to confront methadone related social stigma through assertive campaigns and public education and political/professional influence. It also rests on the mobilization of a grassroots advocacy movement for methadone maintenance patients and their families. An important next step in the developmental history of methadone maintenance is to define recovery within the context of methadone maintenance and within the broader pharmacotherapeutic treatment of substance abuse disorders."

Its second point reinforces the concept of recovery and methadone maintenance or buprenorphine maintenance treatment. "To stabilize methadone maintenance patients, continued methadone maintenance or completed tapering and sustained recovery without medication support represent varieties/styles of recovery experience and matters of personal choice, not the boundary between and point of passage from the status of addiction to the status of recovery."

AATOD is grateful for the inclusion of such concepts in the SAMHSA draft Guidelines. We believe that it will help clarify misunderstood concepts about the value of recovery and the personal choices that the patient makes throughout their treatment experience. A great deal of education is needed to advance this perspective in the field of Medication Assisted Treatment for opioid addiction through federal and state policy, Criminal Justice initiatives, and legislative initiatives at both the federal and state levels. The inclusion of such a perspective within the draft Guidelines underscores the value of such long term strategic educational initiatives.

Telemedicine

The draft Guidelines also provide another forward thinking policy approach in a discussion of telemedicine starting on page 41. "Telemedicine, which also is referred to as e-therapy, has the potential to revolutionize the delivery of Medication Assisted Treatment to individuals in rural and underserved areas."

The Guidelines go on to better define how telemedicine may be used. The patient is in a registered clinic in addition to the patient being in the same state where such telemedicine is provided and where there is "at least one in-person evaluation or a covering practitioner at the request of the practitioner evaluates the patient face to face, and the practitioner has seen the patient once in the last 24 months."

It is understood that the section on telemedicine does not provide comprehensive guidance on this important and changing dynamic in the delivery of healthcare services in the United States. It is also recognized that the full implementation of Health Care Reform is expected to provide access to care for millions of Americans who are currently "shut out" of the healthcare system due to lack of insurance coverage. This applies to substance abuse treatment programs in general and to OTPs as well. It is expected that SAMHSA will provide additional and future guidance on this topic, in addition to working with other appropriate federal and state agencies in this context. We certainly think it is important to make this reference, but we also urge SAMHSA to work with a number of parties in this dynamic field of medicine to provide additional guidance to OTPs as such information becomes available.

Guest Dosing

The draft Guidelines also provide an important reference with regard to patient guest dosing. "Guest dosing is recommended for patients who do not meet the criteria outlined in 42 CFR§8.12 (i) (2) (i-viii)." Guest dosing may prove helpful when a patient will remain in an area for a protracted period and it is impractical to return to his or her own program routinely to pick up a supply of take home medication. The patient, home program, and guest program should arrive at an agreement to provide the patient with clinical services, such as counseling, if the period for guest dosing exceeds 30 days."

AATOD published its guidelines to the field with regard to guest medication dosing during March 2013. "Guest medication provides a mechanism for patients who are not eligible for take home medication to travel from their home clinic for business, pleasure, or family emergencies. It also provides an option for patients who need to travel for a period of time that exceeds the amount of eligible take home doses to do so within regulatory requirements. While AATOD acknowledges there may be state and program variations, AATOD

believes that guest medication should be patient-centered, respectful, and compassionate."

We agree with the guidance that is contained in the draft Guidelines in this area and have encouraged OTPs to stabilize such inter-facility patient referral when guest medication is of value to the patient's continuity of care.

Summary

We believe that SAMHSA has done an excellent job of working with its constituent groups in creating these Guidelines. We believe that they advance the principles of the SAMHSA regulations in addition to the prior 2007 Guidelines.

We also believe that the Guidelines have been well crafted by the individuals who have worked on the panel to provide such forward thinking guidance to the field. We did not comment on all of the Guidelines, nor did we think it appropriate to do so. What is important is to note that AATOD supports the development of these Guidelines and thinks that they provide valuable guidance to Opioid Treatment Programs in the United States and abroad in addition to helping to inform health policy in a number of arenas, as stated throughout this correspondence. AATOD also thinks that it is important use all three federally approved medications to treat chronic opioid addiction in the OTP (methadone, buprenorphine, and Naltrexone/Vivitrol) as Health Care Reform moves forward and as we increase our relationship with parties in the Criminal Justice System.

For the present, we believe that these Guidelines are well balanced. As noted in the introduction, they are carefully thought through and based on evidence. This is especially important at a time when legislators and organizations are crafting policies which are dangerously disconnected from what we have learned over the course of so many years in treating chronic opioid addiction in the United States.

Thank you for producing a very thoughtful document. We look forward to working with SAMHSA as this document moves to its final approval.

Sincerely yours,

Mark W. Parrino
President

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