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SAMHSA/CSAT Division of Pharmacologic Therapies
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road, room 7-1024
Rockville, MD 20857

Dear Ms. Smith,

The National Council for Behavioral Health (National Council) welcomes the opportunity to comment on the revised 2007 SAMHSA Guidelines for the Accreditation of Opioid Treatment Programs (herein after Guidelines).. The National Council is a non-profit association representing more than 2,100 community-based mental health and addiction treatment providers. Along with our member organizations, we are dedicated to fostering clinical and operational innovation and promoting policies that ensure that the more than 8 million low-income children, adults, and families our members serve have access to high quality services. Our community mental health and substance use organizations have experience and expertise in providing a range of services and supports recovery for millions of individuals with multiple chronic conditions.

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. 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 injectable naltrexone; 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".

Patient Admission Criteria

Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e) (1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge). 42 CFR 8.12 (e) (3).

The Guidelines provide the appropriate guidance regarding maintenance treatment admission exceptions but we suggest also including the following language, "if clinically appropriate, the program physician may advise the patient of the option of being treated with extended-release injectable naltrexone.

Screening, Assessment, and Evaluation

Evaluation

The National Council supports the guidance with regard to assessing the impact of induction onto the treatment drug which is referenced on page 20 of the proposed Guidelines. Each program "assesses the impact of induction onto the treatment drug. Methadone has well-documented impacts on the organ systems and, in particular, the lungs, liver, and heart. Therefore, when conducting the medical exam, consideration should be given as to whether the treatment drug will be methadone, buprenorphine, or another medication, or whether the treatment indicated is induction, detoxification, or maintenance." We recommend also including extended-release injectable naltrexone in the list of treatment drugs.

Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment

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 and other policymaking bodies in different countries. 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."

The National Council is grateful for the inclusion of such concepts in the SAMHSA draft Guidelines and we believe that it needs to be incorporated more throughout the final guidelines. We believe that this method is one of the unifying principles for recovery and helps promote a healthy and meaningful life for those struggling with addiction. This method also requires OTPs to have adequate infrastructure to meet all of the needs of its patients – physical health, mental health, housing, etc. 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.

Relapse Prevention

The draft Guidelines also provide an important reference with regard to relapse prevention. "Psychosocial treatment continues for patients electing to discontinue pharmacotherapy." As we know, upon discontinuation of maintenance therapy, patients are at an increased risk of relapse. To support gains made during treatment and to help prevent relapse, we suggest that psychosocial treatment is continued. Given the chronic nature of opioid dependence, an ongoing therapeutic relationship with the OTP should occur even after maintenance therapy is discontinued.

The National Council believes that while naltrexone in depot formulation is a viable tool in relapse prevention, we must also note that treating addiction is part of a multi-pronged approach and should also include things such as support groups, counseling and education. We also recommend using the term extended-release injectable naltrexone rather than naltrexone in depot formulation.

Detoxification, Tapering, or Medically Supervised Withdrawal

The National Council supports the guidance with regard to detoxification treatment. "An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in 1 year." 42 CFR 8.12 (e) (4)

The Guidelines provide the appropriate guidance regarding detoxification treatment but we suggest also including the following language in regards to other forms of treatment – such as a combination of psychosocial counseling coupled with monthly treatment with extended-release injectable naltrexone.

Continuing Care

Under the section of "Continuing Care" on page 32, the National Council recommends adding additional guidance stating that prior to discontinuation of maintenance therapy, the option of continuing treatment

with counseling combined and opioid antagonist medication (extended release injectable naltrexone) may be discussed with the patient.

Additional Treatment Planning Considerations

The National Council recommends including language regarding the need for health screening for common health conditions such as diabetes, high blood pressure, etc. These conditions could affect the patients overall health and wellness, compliance with treatment protocols, as well as their long term treatment and recovery prognosis. Awareness of these conditions will allow clinical staff to develop a more comprehensive patient centered treatment plan that gives the client a greater likelihood of sustained recovery.

Alcohol and Other Drug Abuse

Under the section of "Alcohol and Other Drug Abuse" on page 33, we recommend replacing "Polydrug abusing patients may benefit from treatment with other FDA-approved medications" with "patients with ongoing concurrent alcohol dependence and opioid dependence may be considered for treatment with extended-release injectable naltrexone, plus psychosocial therapy as this medication is FDA approved for the treatment of both conditions."

Care of Patients with Mental Health Needs

The National Council is grateful that these Guidelines recognizes that patients with mental health needs need to be identified through the assessment process and referred to appropriate treatment. We recommend including language that endorses that staff in these settings are trained in Mental Health First Aid in order to better help communities understand mental illnesses, seek timely intervention, and save lives.

Trauma-Informed Care

The National Council is pleased that the Guidelines recognize the relationship between substance use and trauma-related mental health problems and believes that this should be included under the "Screening, Assessment, and Evaluation" section and that such screening should be required during the initial treatment stage.

Thank you for your consideration of these comments.

Sincerely,

Linda Rosenberg, MSW
President & CEO