

May 26, 2016

Ms. Kana Enomoto
Acting Administrator
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Medication Assisted Treatment for Opioid Use Disorders; Proposed Rule [RIN 0930-AA22]

Dear Acting Administrator Enomoto:

The National Council for Behavioral Health (National Council) is pleased to submit comments on the proposed rule to increase access to opioid use disorder treatment while reducing the opportunity for medication diversion, entitled *Medication Assisted Treatment for Opioid Use Disorders* (“Proposed Rule”) and published by the Substance Abuse and Mental Health Services Administration (“SAMHSA”) on March 30, 2016.

The National Council is the unifying voice of America’s community mental health and substance use treatment organizations. Together with our over 2,500 member organizations employing 1,000,000 staff, we serve our nation’s most vulnerable citizens – more than 10 million adults and children living with mental illnesses and addictions.

SAMHSA’s Proposed Rule is timely given the current state of the opioid epidemic in our nation today. As the President correctly stated, our country is in the midst of a “public health crisis of opioid addiction, misuse, and related morbidity and mortality.”

The National Council offers comments on the questions that SAMHSA included in its NPRM, while also noting that many of the quality and reporting requirements that it is proposing for practices seeking to serve over 100 patients would also benefit patients served by practices not seeking this waiver. For example, new requirements related to diversion control, overdose prevention and reporting on referral to treatment would benefit all patients served in OTPs.

Question 1: Evidence Supporting an Optimal Patient Prescribing Limit

The National Council supports SAMHSA’s proposal to increase the patient limit to 200 patients for certain practitioners who meet certification standards, or who are working in qualified practice settings. The National Council suggests, however, that the list of qualified practice settings explicitly include state licensed specialty behavioral health centers that have the capacity to provide the holistic treatment called for in this proposed rule.

While a condition of receiving a waiver to treat over 200 patients is tied to that practitioner working in a qualified practice setting, there is currently no requirement that the prescription be

written by the practitioner while at that qualified practice setting. It is quite common for practitioners to work part time at many locations, some of which may not meet the standard of a qualified practice setting as defined by SAMHSA. We urge the department to clarify that the prescription, if written, be confined to the qualified practice setting.

We also suggest that SAMHSA recognize that emergency situations include the death, relocation of practitioners, and sudden practice closures and that lack of access to qualified practitioners can happen in any part of the country. We suggest that SAMHSA more explicitly define “emergency situation” and do so in a broad enough way to capture the variety of challenges facing patients, families, and organizations.

In addition to recognizing state-licensed behavioral health organizations, we also suggest that SAMHSA include standards for qualified practice settings that ensure that these organizations allow patients to appropriately adapt and modify their treatment plans over time, including, when it is clinically appropriate, for the use of non-opioid alternative medications and non-pharmacologic interventions. Also, given the well-established risk for relapse and overdose within weeks following discontinuation of buprenorphine, all waived practitioners should be required to ensure that all of their patients receive relapse prevention medication and counseling prior to their patients’ cessation of treatment.

Question 2: Potential New Formulations

The National Council recognizes that additional formulations are being developed, such as subcutaneous delivery, which in their method of delivery meet SAMHSA’s standard of improving access while also minimizing diversion potential. We would suggest that the 200 patient cap not apply to any such formulations.

Question 3: Practitioner Training for 200 Patient Limit

The National Council supports SAMHSA’s proposal that the advanced waiver only be available to physicians with board certification in addiction medicine or psychiatry. We hope this proposal will lead more physicians to seek such certification.

Question 4: Alternate pathways to qualify for 200-patient prescribing limit

The National Council cannot support alternative pathways outside of SAMHSA’s proposals for physicians to seek treating more patients. SAMHSA’s proposed approach seems appropriately balanced between access and diversion control. As one of our members observed, “We have suboxone pill mills in Ohio. The pain clinics closed and suboxone clinics opened.”

Question 5: Process to request a patient limit of 200

We have no comment.

Question 6: Patient Volume Necessary

We believe that SAMHSA's proposed increase to 200 patients will work financially for most practices and practitioners. We would also suggest, however, that additionally, SAMHSA should ensure that all such practices have not only the "*ability to ensure access to patient case management services*", but, importantly, that the practices actually do, in fact, ensure such access. We note that being *able to ensure access* to such vital services is a prerequisite for providing appropriate access; but it does not, in and of itself, ensure that practices *actually* provide access.

Question 7: Frequency of Renewal Request for Patient Limit Increase to 200 Patients & Question 8: Synchronization of Renewal Request with DEA Practitioner Registration Renewal

The National Council supports SAMHSA's proposal to align the process for waiver renewal with other requirements, such as the DEA practitioner registrations renewal process, or state licensing standards. We support anything that can be done to reduce overhead and bureaucracy for providers and increases their probability to participate.

Question 9: Estimation of the Time Required to Seek Approval to Treat up to 200 Patients

The National Council suggests that the turn-around time for approving waiver requests be shortened from 45 to 30 days.

Questions 10 through 13.

We have no comment.

Question 14: Balance of Access and Safety

Overall, the National Council believes that SAMHSA has taken a sound approach that balances the need for increased access to care with appropriate controls on diversion. We would like to reiterate, however, our belief that nationally-accredited or state licensed specialty behavioral health organizations be explicitly recognized as a qualified practice setting.

We appreciate this opportunity to comment and appreciate SAMHSA's consideration of the same.

Sincerely,



Linda Rosenberg, MSW
President & Chief Executive Officer
National Council for Behavioral Health