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

Expanding Access to Quality Opioid Use Disorder Treatment Services
since 1984

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Robert Baillieu, MD, MPH,
Physician and Senior Advisor, SAMHSA/CSAT
5600 Fishers Lane, Room 13-E-30,
Rockville, MD 20857

RE: 42 CFR Part 8
RIN 0930-AA39

Dear Dr. Baillieu,

I am writing on behalf of the American Association for the Treatment of Opioid Dependence (AATOD), which represents over 1,300 Opioid Treatment Programs (OTPs) in the United States. At the outset, it is important to note our support for these thoughtful and enlightened regulatory reforms. We believe that the proposed regulatory changes are a positive move toward addressing the challenges in treating opioid use disorder in OTPs in the era of fentanyl use.

Introduction

We enthusiastically support the intent of providing greater clinical flexibility to OTP clinicians when determining the best course of treatment for our patients. The point of planning effective treatment is to work in conjunction with the patient toward the goal of recovery. To this end, we also appreciate the use of language, which removes stigmatizing references towards the patient. The following points indicate the areas of support and also identifies areas of concern and caution.

Inducting Patients with Methadone through Audio-Visual Telehealth

We support SAMHSA's intent to provide OTPs with the opportunity to induct patients with methadone through audio-visual telehealth. We have made this recommendation for the past two years because we believe this will also remove a barrier in having patients enter treatment.

Regulatory Alignment

We support SAMHSA working with State Regulatory Authorities for better regulatory alignment between federal and state standards, in addition to aligning

these new reforms with third party reimbursement. If such an alignment does not happen, the intent of the proposed regulations will be severely compromised.

Accordingly, our Association strongly recommends that SAMHSA does all that is possible to work with the state regulatory authorities, CMS Medicare and state Medicaid Directors in order to ensure that the regulations are actively promulgated once finalized. Our Association will work in cooperation with SAMHSA and State Authorities in addition to state Medicaid Directors in order to fulfill SAMHSA's vision.

Medications for the Treatment of Opioid Use Disorder

We have concerns about the elimination of Medication Assisted Treatment references since this term was coined by SAMHSA over 10 years ago to reflect the evidence of 50 years of research and clinical practice. In this case, research demonstrated that medication alone is insufficient to treat a complex disorder. The new term "medications for the treatment of opioid use disorder" does not capture the holistic care provided to patients at OTPs and the implication is certainly inconsistent with the comprehensive nature of OTPs, the main focus of these regulations. What is odd about the title is that medication-assisted references are made throughout the document. Illustratively, the rule indicates the following:

> The proposed rule expands the definition of 'counseling services' to include psychoeducational services, harm reduction and recovery-oriented services, and counseling and linkage to treatment for anyone with positive test results on human immunodeficiency virus (HIV), viral hepatitis, and other sexually transmitted infection (STI) panels, or from OTP-provided medical examinations. Language about services that must be provided directly or through referral is revised to promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters shared decision- making for all care plans.

We recognize that there is an increasing movement toward this new terminology, which is stated in the proposed rule, but we also think that this is more of a political approach rather than an evidence-based clinical approach. We are suggesting that SAMHSA maintain references to Medication-Assisted Treatment when SAMHSA is referring to services that are provided by OTPs. The basis for this suggestion is rooted in requiring OTPs to provide additional clinical services when OTPs are writing medical orders for the use of federally approved medications to treat opioid use disorder.

Definition of Practitioner

Our Association agrees with the expanded definition of "practitioner" to include nurse practitioners, physician assistants and other specialists (as appropriately licensed by their state authority in their respective states or territories) as noted in the proposed regulations. From our Association's point of view, such professionals have been used to provide care to the patients in the OTPs and it successfully expands our workforce opportunities. Additionally, we recommend that this definition be applied to the use of non-affiliated OTP practitioners, when audio-visual telehealth services are used to induct new patients with methadone maintenance.

Accreditation Surveys

We agree with the policy to incorporate additional communication between approved accreditation bodies and SAMHSA. However, from our point of view, the current accreditation approach needs to be reevaluated. As we have noted in recent communications, accreditation oversight has moved away from clinical guidance in support of SAMHSA's regulations and more towards administrative oversight, which has become increasingly burdensome and expensive to the OTPs and may not result in improved program quality and treatment outcomes.

We are recommending that SAMHSA work with all approved accreditation agencies and other entities/organizations that have jurisdictional interest in this area to review exactly what accreditation organizations are doing to provide oversight of the OTPs to better support clinical standards of care and at what cost. This is especially true given the proposed regulations in their currently enlightened state.

Now we turn to a part of the regulatory reform that appears counter to the overarching theme of what SAMHSA is recommending. There is an odd section with regard to accreditation that may inadvertently create greater expense and burden to accreditation oversight. We are gravely concerned with the requirement that any accreditation body's recommendations automatically results in a maximum one-year accreditation status or no accreditation status if an OTP fails to meet any component of the accreditation standard. A small percentage of accreditation surveys have zero recommendations. Thus, this proposed rule will exponentially increase accreditation costs and staff resources with little improvement in quality of care or patient safety. We strongly request that this rule is altered to permit greater flexibility with respect to surveyor recommendations and their impact on OTPs.

Certification as an OTP

Certification as an OTP under section [8.11(h)(3)] "will not be required for the continuous medication treatment or withdrawal management of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than OUD and who requires medication continuity or withdrawal management during the period of their stay in that long-term care facility when such treatment is permitted under applicable Federal law." We are asking SAMHSA to consider adding correctional facilities as part of this reference.

Interim Treatment

We understand the point of expanding the time of interim treatment from 120 days to 180 days. This will give treatment programs a greater opportunity to place the patient in a more comprehensive model of care when interim care is used. We also support having the State Opioid Treatment Authorities rather than the State Chief Medical Officers, work to approve the use of interim care.

It is important to keep in mind that interim care would be implemented only if OTPs in the state do not have the capacity to admit patients to more comprehensive treatment. In this case, the OTPs work directly in conjunction with the State Opioid Treatment Authorities to ensure that this is the case.

It is also important to consider having interim care applied to all operating OTPs in the United States whether they are nonprofit or for-profit entities. If the goal is to provide increased access to care, SAMHSA cannot bypass 60% of the OTPs operating in the United States. This is especially important since there are approximately 2,000 operating programs currently approved by SAMHSA.

Individuals Under the Age of 18 Being Considered for Treatment

Our Association supports removing the requirement that individuals under the age of 18 must provide documentation of two unsuccessful attempts at treatment within one year prior to being eligible for OTP admission.

Given the reality of opioid use in the United States, currently driven by fentanyl, it is important to consider patients under the age of 18 for admission to OTPs. Clearly, the OTP also needs to provide the appropriate level of clinical support for such patients when they are being considered for care. It is important to keep in mind from past experience that adolescents tend not to want to be treated with adults in the same therapeutic environment. Accordingly, SAMHSA needs to take this consideration into account, drawing upon the experiences of the adolescent OTP units, although very few, in the United States.

Eliminating the Word Detoxification

We completely support SAMHSA's interest in removing stigmatizing language from prior regulatory requirements. The use of the term "detoxification" has never been helpful and has been deeply stigmatizing. Many OTP clinical staff would need to explain this very issue to patients and "withdrawal management" is more respectful and certainly more clinically appropriate.

Take-Home Medication

We also support SAMHSA's approach in determining take-home medication schedules. "SAMHSA recommends that the best interest of each patient and the public's health be taken into consideration, and clinical judgment, not rigid rules, determine if the therapeutic benefits of take-home medication outweighs the risk to the patient and public's health".

Certainly, we learned a great deal about patients' capacity to responsibly manage take-home medications during the period of COVID-19 when SAMHSA approved its emergency ruling during March 2020. On the other hand, we are still getting information about methadone related overdoses during the period of COVID-19. Two recently published articles provide additional references. The first "Examination of Methadone Involved Overdoses During the COVID-19 Pandemic" as authored by Daniel E. Kaufman, Amy L. Kennalley, Kenneth L. McCall and Brian J. Piper. It is important to point out their findings.

> The key finding from this report was that methadone overdoses significantly increased by 48.1% in 2020 relative to 2019. This increase is consistent with but also much larger than the 5.3% elevation in calls involving methadone reported nationally to poison control centers in the year following the March 16, 2020 relaxation of methadone take-home regulations.

It is also important to reference "Methadone-Involved Overdose Deaths in the United States Before and During the COVID-19 Pandemic" as authored by Robert A. Kleinman and Marcos Sanches and once again, it is important to reference the findings of this study.

> Methadone-involved overdose deaths among U.S. residents increased in the 12-months after March 2020 compared with prior trends. Methadone-involved overdose deaths increased above previous trends both with and without co-involvement of synthetic opioids. In analyses with and without involvement of synthetic opioids, there was an initial spike in methadone-involved overdose deaths during March – May 2020, after which

these deaths stabilized but remained elevated above their prior trends.

It is also important to keep in mind that throughout this period of time that sound clinical judgment was supported by considerable resources provided by the multidisciplinary OTP staff, including robust diversion control mechanisms creating the ability to quickly identify misuse and diversion. That is to say, OTPs relied heavily on the comprehensive structure in determining which patients could safely manage take homes and quickly adjusted those determinations based on multiple feedback points collected in the usual course of treatment.

The general recommendation of providing up to 14 days of take-home medication to clinically unstable patients and the opportunity to provide up to 28 days to stable patients was a broad policy adjustment during a public health crisis. At no time were OTPs required to provide such medication if it went against the staff's clinical judgment or ability to swiftly adjust the take-home schedule, and this remains true at the present time.

To be clear in making this point, patient take-home medication is determined based on how well the patient is doing in treatment, based on clinical standards of care. The clinical determination is based on the benefits and risks associated with take-home medication, which was also the case during the height of COVID-19. This decision making was not based on any person's inalienable right to receive take-home medication if the risks outweighed the benefits.

Time in Treatment

We also support SAMHSA's intent of removing the "time in treatment" requirement in determining take-home medication. As stated above, providing greater flexibility to OTPs will lead to improvement in retention in care, which is one of the hallmarks of effective treatment. Two of the most important clinical determinations made by an OTP include the decision to admit and discharge the patient. We understand SAMHSA's interest in indicating that patients should not be discharged if they are not in compliance with counseling or other similar standards of care. We agree that discharging a patient from treatment has serious consequences so OTPs must be judicious in making such determinations since it is in the patient's interest to be retained in treatment, as long as they benefit from such continued care. As a matter of practical reality, there will be times when patients should be discharged from care due to clinical and/or administrative reasons. When a decision is made to discharge a patient, the OTPs should always work to provide appropriate discharge planning.

In this regard, it is important to understand that clinically unstable patients benefit from additional counseling and other clinical support services. This is especially true for patients, who present a danger to themselves or others in the absence of counseling. Once again, it is important to understand the treatment benefits of clinical care. Our Association has always held the view that clinical staff need to be informed in treating our patients in addition to being compassionate. In our judgement, OTPs will drift into dangerous clinical territory in addition to being vulnerable to liability claims if we are not responsive to the needs of patients including those individuals, who do not think that they need such care.

One Year Admission Criteria

Our Association supports SAMHSA's intent to eliminate the one-year history of opioid use disorder as a condition of being admitted to the OTPs. Once again, the SAMHSA proposed regulations provide much greater clinical flexibility for clinical personnel as patients are being admitted to treatment. This will certainly result in a greater number of patients being admitted, however, this does not reduce the program's need for sound clinical judgment in making safe determinations about who is being admitted to treatment.

Split Dosing

We support the SAMHSA proposal for greater spilt dosing among our patients, who are rapid metabolizers of methadone and have a greater opioid tolerance in the age of greater fentanyl use. This is particularly the case with patients who receive medications for co-occurring medical and psychiatric disorders that affect the rate of methadone metabolism. We recognize that split-dosing has been used for many years in treating pregnant patients and we appreciate SAMHSA's interest in expanding this opportunity as a means of providing more effective care for other patients as well.

In our judgement, broadening the use of split dosing will require more clinical training on the part of program personnel. Our Association will be pleased to be involved in such efforts.

Induction Dosages

While we understand SAMHSA's interest in maintaining the efficacy and safety of 30 milligram admission dose, we also appreciate the opportunity to employ greater flexibility in accelerating dosages during the induction period, which can be two to four weeks. For a number of patients, this induction period will be longer in duration, especially in an age of fentanyl use.

We are learning the value of ensuring that patients are engaged and retained in treatment during the induction period by carefully titrating dosages upward in an accelerated but safe manner. This induction period is a critical period for greater clinical flexibility and how OTPs induct patients. It would appear that methadone is more clinically appropriate in treating fentanyl using patients as opposed to buprenorphine based on the strength of fentanyl. Fentanyl using patients are more challenging to treat, especially during the earlier parts of treatment. This is not to suggest that buprenorphine is clinically ineffective in treating fentanyl using patients. This is determined by how the patient responds during treatment induction, whether methadone or buprenorphine are used. The point here is using medications to effectively treat the patient. Once again, this is not a political issue, but a clinical matter.

It is still too early to interpret why patients are leaving treatment at a premature rate in the age of fentanyl. That is something that needs to be studied and we urge SAMHSA to work with NIDA and other appropriate agencies in order to get a better sense of this phenomenon.

Summary

This letter provides an overview of what we consider to be the most significant changes in the proposed rulemaking. We believe that these recommendations provide a thoughtful analysis of what needs to be reevaluated and changed.

There is an important point to be made at this time. Once SAMHSA completes its evaluation of submitted comments, it is important to keep a management principle in mind. SAMHSA will need to conduct an ongoing systemic management of how the final regulations impact treatment programs and states. OTPs represent an extremely valuable treatment option, especially in an age of fentanyl use. While this system of care has always experienced challenges from the inception of the Rockefeller research in the mid 1960's as led by Drs. Vincent Dole, Marie Nyswander and Mary Jeanne Kreek, it would appear that the OTPs have been more severely criticized over the last several years.

As you know, we are just about to cross the threshold of 2,000 OTPs in the United States in treating over 600,000 patients. There are many parts to this treatment system including the State Opioid Treatment Authorities, municipal authorities, accreditation oversight and third party reimbursement authorities. As the OTP evolves through SAMHSA's proposed regulatory changes, it is also important for SAMHSA to remind other federal agencies of the value of the OTPs.

We understand that this is also the responsibility of our Association, its state chapters and individual program providers. It is also the responsibility of federal authorities, who have jurisdiction in this area, in addition to state authorities. In

order to move this system forward as we make increasing connections with the justice community and expand access to care through mobile vans to extend the reach of OTPs in rural and urban communities, we need to make sure that the OTPs have the ongoing support of policy partners in order to support our work of treating patients effectively.

It is also important for SAMHSA to consider a number of technical improvements, which will support programs in following through on these new clinical flexibilities. In this case, there are opportunities to observe patients taking their medications outside of the confines of a direct nurse/pharmacist observation at the OTPs. There are other new technologies that can be used to assist OTPs in treating patients more effectively and we encourage SAMHSA to work with State Regulatory Authorities and the OTPs in order to gain a better understanding of how these new technologies can be effectively used.

It is our hope that this communication is of help to SAMHSA as it finalizes these regulations for implementation.

Sincerely,

Mark W. Parrino, MPA
President