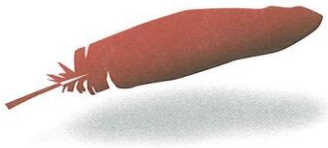
National Indian Health Board



February 14, 2023

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary
Substance Abuse and Mental Health Services Administration
5600 Fisher Lane
Rockville, MD 20857

Re: Medications for the Treatment of Opioid Use Disorder Proposed Rule

Dear Dr. Delphin-Rittmon:

On behalf of the National Indian Health Board and the 574+ federally recognized American Indian and Alaska Native (AI/AN) Tribes we serve, thank you for the opportunity to provide feedback and recommendations on the proposed rule to update 42 C.F.R. Part 8 for the Substance Abuse and Mental Health Services Administration (SAMHSA).

NIHB strongly supports the changes to expand access to opioid treatment, especially for patients in rural or remote areas. We also appreciate the movement towards rules that support practitioner discretion and patient-centered treatment. We recommend modifications to the rule to be more inclusive of Tribes and recognize Tribal sovereignty and Tribal law throughout the rule's provisions so that the proposed rule will be more successful in achieving these goals.

I. Tribal Nations Need Special Considerations Under Opioid Treatment Rules

As SAMHSA recognizes in the proposed rule, the opioid epidemic has hit Indian Country especially hard. The death toll in Tribal communities due to opioids has been devastating and has only worsened since the onset of the COVID-19 pandemic. More than ever, Tribes need the resources and flexibility to provide the services needed to protect their people and avert needless deaths. Tribes know best what their people need and how to deliver services in a way that will be most effective and culturally appropriate.

In light of both the disproportionate harm to Tribal communities from opioids and the trust responsibility the federal government owes to AI/ANs to protect their health and well-being, SAMHSA has a responsibility to take extra measures to ensure the rule will be effective for supporting the health of AI/ANs and consider the special circumstances of Indian Country. SAMSHA should recognize Tribal sovereignty and Tribal law; ensure access to care in remote areas and Tribal lands; expand access to care in a way that will be effective within the Indian health system; and support Indian health care providers in providing robust, culturally appropriate opioid treatment services that center the unique needs of AI/AN patients.

II. The Rule Must Recognize Tribal Sovereignty

To make the rule relevant and meaningful for Indian Country, it must recognize Tribal sovereignty and Tribal law throughout its provisions. NIHB appreciates and supports the change to include Indian Tribes as accreditation bodies; this is a meaningful step to recognizing Tribal sovereignty in opioid treatment. As history has shown, if the opioid crisis is to be remedied and abated in Indian Country, it will be through empowering Tribes to control and direct resources as they deem appropriate and to implement solutions that respond to the specific needs of their citizens and communities. The proposed rule must also take additional steps to recognize Tribal sovereignty and support Tribal self-determination.

Notably, the Supreme Court has held that, due to Tribal sovereignty, Tribes "could not be subjected to the laws of the State."[1] Tribal nations are sovereign governments with the authority to promulgate their own laws and responsible for protecting the health of their citizens. Tribes are not subsumed within, nor are they political subdivisions of, any state or of the United States federal government, with which Tribes have historically complex relationships. Tribal health programs are not governed by states, and the proposed rule should not attempt to give states authority over Tribal opioid treatment providers (OTPs). For example, Section 8.12(e)(1) states, "OTPs shall comply with all pertinent State laws and regulations…The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States." However, OTPs operated by Indian Tribes should also be included in the list of exceptions, alongside those operated by the Indian Health Service. Neglecting to include Tribes in the list of exceptions leaves Tribal OTPs subject to the will of states, which does not accord with Tribal sovereignty.

Likewise, in places where the proposed rule refers to following applicable "state laws", it should instead refer to "state or Tribal laws," which would recognize that Tribal law operates independently of states. Tribal law, not state law, applies for opioid treatment providers (OTPs) operating in Tribal jurisdictions. For example, Section 8.12(e)(2) discusses comprehensive treatment for persons under 18. We support and appreciate that this proposed rule increases access to treatment for minors. However, we encourage SAMHSA to amend the second sentence of this section to acknowledge that Tribes, like states, also have the authority to enact their own laws addressing the age of majority and capacity for health decisions. We ask that SAMHSA amend this section to the following: "Except in States or Tribes where State or Tribal law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State or Tribal authority consents in writing to such treatment." Such changes to include references to Tribal laws alongside state laws should be made throughout the regulation to clarify that Tribal OTPs are not subject to state laws. These changes would make the rule more consistent with other laws governing the operation of Tribal health programs, which function independently of states.

The rule will be more effective if SAMHSA ensures the sovereignty and self-determination of Tribes are both respected and reflected throughout its provisions.

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[1] *United States v. Kagama*, 118 U.S. 375, 384 (1886).

III. Protecting Access to Telehealth Services

We support the inclusion of telehealth as an alternative means for admission assessment, and we appreciate the inclusion of an audio-only option for the evaluation. Access to visual-capable devices may be impossible for patients in remote areas, with low incomes, or experiencing homelessness. Audio-only is critical to ensure equitable access to opioid treatment.

However, we ask that SAMHSA modify the types of providers allowed to monitor the patient on the in-person side of an audio-only telehealth evaluation. Section 8.12(f)(2)(v)(A) states, "In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications."

It should not be necessary that these practitioners are registered to prescribe and dispense controlled medications; lower-level providers have sufficient training to make the observations needed for the physical side of the evaluation. Expanding the provider types allowed to support these telehealth visits will protect access to care for patients in rural and remote locations that may lack any higher-level providers. For example, much of the health system serving Alaska Natives depends on certified Community Health Aides Practitioners who connect patients to higher-level providers via audio-only telehealth to receive needed care. To protect access to care for Alaska Natives and others in remote areas, this section should be revised to say "a licensed or certified practitioner who is registered to prescribe (including dispense) controlled medications or supervised by someone so registered." This revision will support health equity by expanding access to care for underserved patients in remote locations.

IV. Expanding Access to Care

We appreciate the rule changes intended to promote focus on patient needs and improve accessibility for opioid treatment. We support the removal of a one-year history of Opioid Use Disorder (OUD) requirement for admission to treatment. We also appreciate the clarification that an examination by an outside practitioner can be accepted in lieu of an on-site examination. The new inclusion of mid-level practitioners (nurse practitioners and physician assistants) is also a welcome change, to expand access to care in light of widespread healthcare workforce shortages. These changes will reduce barriers to care and make it easier for AI/ANs with OUD to find and access needed opioid treatment.

V. Supporting Practitioner Discretion & Integrated Care

We support the efforts of the proposed rule to allow more practitioner discretion in treatment decisions and the movement towards more integrated care. When it comes to addressing the special needs and circumstances of Tribal citizens, the rule must allow providers to use their judgement and discretion and to recognize the provider-patient relationship. In addition, the changes to improve treatment integration with evidence-based practices are beneficial, especially since addiction medicine has changed to focus more on addiction as a chronic disease and continues to evolve. Furthermore, Indian health care providers need the flexibility to be able to integrate the mental and spiritual wellbeing of Tribal community members and provide culturally appropriate care.

In support of this movement towards more dependence on practitioner discretion, we recommend revising the wording of Section 8.12(f)(5) regarding medications for opioid use disorder (MOUD),

which currently states, "Patient refusal of counseling shall not preclude them from receiving MOUD." We recommend revising this statement to state, "Clinics are not required to mandate counseling services as a condition of receiving MOUD." Decisions about needed counseling services should be left to the care team. This embraces harm reduction as the intent but allows more flexibility than an across-the-board rule.

VI. Conclusion

Thank you for the opportunity to provide comment on SAMHSA's proposed rule to update 42 C.R.F. Part 8. We appreciate changes that support Tribal sovereignty, practitioner discretion, and expanded access to care. We ask that SAMHSA take care to ensure Tribal sovereignty is respected and recognized throughout the rule, and that the special circumstances and barriers to care experienced by AI/ANs are also sufficiently addressed.

Yours in Health,

William Smith, *Valdez Native Tribe*
Chairman
National Indian Health Board