



Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services



c/o National Indian Health Board | 910 Pennsylvania Avenue, SE | Washington, DC 20003 | (202) 507-4070 | (202) 507-4071 fax

March 31, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

Submitted via regulations.gov

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407)

Dear Administrator Milgram:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to respond to the Drug Enforcement Administration (DEA) proposed rule, “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” (DEA-407). While the TTAG typically responds to rules promulgated by CMS, the TTAG is encouraged by the agency’s commitment to expanding access to medications used in treatment for those suffering from opioid use disorder (OUD), and hopes to provide its specialized input into the matter.

As you know, much of Indian Country is rural. AI/ANs are the only group that makes up a larger share of the rural population than the urban population,¹ and the use of virtual care services to serve our population has rapidly ramped up from a pre-COVID average of under 1,300 per month to a peak of nearly 42,000 per month at the height of the pandemic surge.² Therefore, the impact of telemedicine regulations on our communities cannot be overstated, as Tribal lands include some of the most remote and inaccessible in the country. For example, most villages served in the Alaska Tribal Health system have no road access. The nearest community with a pharmacist, a physician, or a psychiatrist could be an hour or more away by airplane (assuming adequate weather and available flights).

¹ Rural America at a Glance. USDA, Economic Information Bulletin 200 (November 2018). Available at: <https://www.ers.usda.gov/webdocs/publications/90556/eib-200.pdf>.

² Indian Health Service Press Release: Indian Health Service Further Expands Telehealth Services to Meet Patient Needs (October 31, 2022). Available at: https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/IHSPressReleaseRingMDTelehealthExpansion.pdf.

By necessity, health care delivery must operate differently in these locations than it may in more populated and accessible regions of the United States. Most health care and pharmacy care in these remote regions depends on village clinics' lower- or mid-level providers, connected through technology to supervising providers in other locations. These unique health care systems successfully provide essential care for hundreds of Tribes. We urge the Biden administration to carefully consider the uniqueness of the Indian health system when it is proposing regulations with the stated priority of health equity.

Throughout this rulemaking, there are exemptions for practitioners employed by the Department of Veterans Affairs (VA). **We urge the DEA to extend an exemption to practitioners operating within the Indian Health Service (IHS) and Tribal health (I/T) system.** We recommend an exemption to the requirement that the prescribing practitioner conducts a medical evaluation within a period of 30 calendar days, outside of the public health emergency (PHE) time frame, to allow an I/T practitioner to prescribe to a patient of the I/T system without such in-person exam. In many cases, a 30-day prescription could do more harm than good. This limited timeframe is risky for someone struggling with OUD. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), “patients who discontinue OUD medication generally return to illicit opioid use” and “arbitrary time limits on the duration of treatment with OUD medication are inadvisable.”³ Potential consequences of discontinued use include relapse, overdose, and death, all of which are far too common in Indian Country.

The symptoms of overdose, coupled with the distance that many AI/ANs must travel to receive care, could quickly result in life-threatening circumstances. Therefore, **we urge the DEA to increase the maximum supply permitted before an in-person visit is conducted to 180 days, or in the alternative, that the DEA not impose such a limit at all.** An essential component of a comprehensive approach to health equity recognizes that different populations have different needs, and therefore flexibility is needed to ensure groups facing inequities are not further harmed by sweeping rules lacking necessary nuance. Whatever final rule is promulgated by the DEA, flexibilities – here, in the form of an exemption – must be provided to the I/T system to provide adequate care to Indian Country.

There are many reasons why telemedicine is vital to the health of so many. There are a large number of patients that sought out psychiatric as well as other forms of telemedicine during the PHE. Over the last three years, telehealth has helped health center patients stay connected to high quality, affordable care despite the COVID-19 pandemic. In 2020, 98 percent of health centers nationwide offered telehealth services

³ Treatment Improvement Protocol 63 for guidance on medication for OUD. Medications for Opioid Use Disorder, Treatment Improvement Protocol 63, SAMHSA (2021). Available at: <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>.

compared to just 43 percent in 2019.⁴ While this uptick was primarily due to necessity due to distancing requirements and risk of infection, there were also the secondary benefits such as the distance to offices, the stigma around seeking certain kinds of care, and so much more. Being able to complete evaluations and be assessed by a practitioner from the comfort of one's own home without facing any of these barriers was an immeasurable benefit to so many folks that need care. Required in-person visits for medication is a hardship for many. Patients may discontinue greatly needed care if any one of these barriers return.

We must challenge the premise that in-person examination prevention diversion of these drugs. The TTAG supports the many comments submitted by organizations the American Telemedicine Association's affiliated trade organization, ATA Action, who have provided statistics in its comment to support the premise that the requirement that a patient see a clinician in-person is not an effective control against diversion and, instead, simply limits access to legitimate health care. ATA Action discovered a report that found that over 70 percent of providers surveyed reported that telehealth made patient continuity of care better or much better and that overall level of care provided via telehealth was better or equal to that of in-person care.⁵ **We recommend the DEA eliminate this requirement when other safeguards are in place to limit diversion.** An example of such a safeguard is the checking of a state's prescription drug monitoring program list.

We further recommend the DEA also exempt practitioners within the I/T health system from the requirement of registration that officials of the U.S. Army, Navy, Marine Corps, Air Force, Space Force, Coast Guard, Public Health Service, or Bureau of Prisons enjoy under 21 C.F.R. § 1301.23(a). While many I/T practitioners are a part of the Public Health Service, many are not. Tribal health programs operating under agreements with the Secretary of Health and Human Services under the Indian Self-Determination and Education Assistance Act (P.L. 93-638, or ISDEAA) are carrying out the federal trust responsibility for Indian health care. Their practitioners should enjoy the same registration exemption as their federal work force counterparts. In the alternative and at a minimum, we ask that DEA expressly recognize the registration fee exemption that these practitioners enjoy under the Indian Health Care Improvement Act, at 21 U.S.C. § 1616q.

Additionally, there are a number of clinically necessary treatments for psychiatry and other behavioral health needs that are classified as Schedule II stimulants. We urge that the DEA to not limit the new exception to Schedule III-V drugs. Preferably all – but certainly some – Schedule II drugs should be allowed. For example, Ritalin and other

⁴ 2021 Health Center Program Highlights Uniform Data System Trends. Data and Evaluation, Office of Quality Improvement, Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) (August 9, 2022). Available at: <https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/uds-2021-data-trends-speakers.pdf>.

⁵ Guttentag, S. The State of Telehealth, According to Healthcare Providers and Patients. GoodRx. November 15, 2021. <https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email>.

stimulants often used for psychiatric care, and morphine used for extreme pain, are important to include in this exception. There is a well-documented shortage of child and adolescent psychiatrists and psychiatric practitioners. Therefore, **we recommend the DEA allow for the short-term prescription be extended to Schedule II stimulants.**

The Indian health system and its patients will be profoundly affected by the proposed rule, given the great extent to which it relies on telemedicine to serve its beneficiaries. Given these facts, Tribal consultation on the proposed rule was clearly required under both agencies' Tribal consultation policies and Executive Order 13175. But the agencies did not consult, instead asserting without explanation that the proposal would not significantly impact Tribes.⁶

To comply with Executive Order 13175, **we recommend the DEA meaningfully consult with Tribal officials early in the process of developing its final rule.** The issue before us is a prime example of the need for Tribal consultation, in order for the DEA and other federal agencies to truly understand the unique impact its rules have on Tribal communities and to hear the innovative solutions that Tribal organizations and Tribal leaders have to offer. The Administration has committed to honoring Tribal sovereignty and including Tribal voices in policy deliberations that affect Tribal communities, such as this proposed rulemaking. The consideration of Tribal comments is crucial to honoring the unique legal and political relationship the United States has with Tribal governments and the trust responsibility it owes to ensure the health and well-being of Tribal citizens across the country.

We do not accuse the agencies of intentionally flouting their consultation duties. Rather, we surmise they mistakenly assumed that a separate statutory exception for I/T practitioners means they would never have to rely on the proposed new exception. Indeed, the proposed rule's preamble specifically mentions the I/T exception twice, explaining that the current rulemaking "would not impose any new requirements on practitioners authorized to practice telemedicine under other statutory exceptions in 21 U.S.C. § 802(54), such as U/T practitioners, who are authorized to engage in the practice of telemedicine under a different statutory paragraph."⁷

But the separate I/T provision is anything but the sweeping, system-wide exception the agencies seem to have imagined. Adopted long before the COVID-19 pandemic helped reveal the importance of safety of telemedicine practice, the exception is surprisingly limited in legal scope, and even more limited in actual practice. Today, in fact, we are reliably informed that ***there are only two I/T practitioners in the entire country who have qualified for the exception.*** The exception is limited in at least four respects.⁸

⁶ 88 Fed. Reg. 12886.

⁷ 88 Fed. Reg. at 12877; 88 Fed. Reg. at 12884.

⁸ First, it is only available on a practitioner-by-practitioner basis, to individual I/T practitioners who successfully apply for designation as an "Internet Eligible Controlled Substances Provider" by the Secretary of Health and Social Services (HHS) under 21 U.S.C. § 831(g)(2). Second, the designation is limited to practitioners serving a "sufficiently remote" location where "access to medical services is

To be sure, the Secretary and IHS could – and should – liberalize their interpretation and administration of the I/T exception. But even if they do, gaps will remain, and IHS, Tribal, and Urban programs will need to rely extensively on the proposed new exception once the COVID-19 flexibilities are no longer in place. It is thus essential that the agencies fully consider, and accommodate as much as possible, the sometimes-unique needs and circumstances of Indian people and of the Indian health system providers who strive to serve them.

Lastly, we ask that the provision on three-way conferences at proposed 21 C.F.R. § 1306.31(d)(2)(I) be revised to allow the patient to be in-person with either a DEA registered practitioner or with one who is exempt from DEA registration, similar to what the proposal allows for qualifying telemedicine referrals at proposed 21 C.F.R. § 1306.31(d)(3)). We urge the DEA to allow these conferences to be conducted using audio-only modalities in all cases where audio-video is not available or not accepted by the patient, and permitted not just for mental health services. In Indian Country, many communities have extremely limited or no broadband infrastructure, making audio-only communication the only viable and reliable option. To permit this form of telemedicine would further the Administration's aim towards health equity.

Conclusion

We appreciate the seriousness of the work entrusted to the DEA. Preventing diversion of controlled substances is important to Tribal health organizations as well, but this rule as proposed limits access to legitimate health care. We appreciate your consideration of the above comments and recommendations and look forward to engaging with the agency further.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Ron Allen". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

W. Ron Allen, CMS/TTAG Chair
Jamestown S'Klallam Tribe, Chairman/CEO

limited," and thus does not address all the other barriers to in-person care that make telemedicine services essential even in urban areas. Third, the exception is only available to practitioners working for the IHS or Tribal organizations operating programs under the Indian Self-Determination and Education Assistance Act (ISDEAA), and not to those working in Urban Indian Organizations (UIOs), which are the third arm of the Indian health system. Finally, the IHS—to which the Secretary has delegated his authority – will issue designations to facilitate Medication Assisted Treatment (MAT) of substance use disorders only, and not for any other medical purpose. See Indian Health Service (IHS) Manual Chapter 38.