Prescribing Controlled Substances via DEA Statutory Telemedicine and The Impact on Tribal Communities
U.S. Department of Justice Consultation Framing Paper

BACKGROUND

I. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008

The *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (the "*Ryan Haight Act"*) amended the Controlled Substances Act (CSA) by, among other things, requiring all prescription drugs which are dispensed by means of the *internet* be issued as a "valid prescription." 21 U.S.C. 829(e)(1). Generally, a valid prescription requires, at a minimum, at least one "in-person medical evaluation," which is issued for a legitimate medical purpose in the usual course of professional practice. 21 U.S.C. 829(e)(2)(A)(i); 21 U.S.C. 829(e)(2)(B)(i). The *Ryan Haight Act* does, however, provide an exception to this in-person medical evaluation requirement, when the practitioner is "engaged in the practice of telemedicine." 21 U.S.C. 829(e)(3)(A).

The *Ryan Haight Act* provides seven (7) distinct categories of the *practice of telemedicine* in which a prescribing practitioner need not satisfy the *Ryan Haight Act's* in-person medical evaluation requirement, yet nonetheless may be able to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. 21 U.S.C. 802(54). In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the *practice of telemedicine* is able to conduct a *bona fide* medical evaluation of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the *Ryan Haight Act* contemplates that the practitioner will be permitted to prescribe controlled substances by means of the *internet* despite not having conducted an in-person medical evaluation.

Thus far, DEA has permitted, or promulgated regulations to permit, the practice of telemedicine pursuant to two of the seven categories of telemedicine authorized under the *Ryan Haight Act.* In March 2020, in response to the COVID-19 Public Health Emergency (COVID-19 PHE) declared by the Secretary, DEA used its authority under 21 U.S.C. 802(54)(D)[1] to grant temporary exceptions to the Ryan Haight Act and its implementing regulations, allowing authorized practitioners to generally prescribe controlled substances in Schedules II-V through telemedicine. These temporary exceptions have been extended several times, most recently on December 31, 2025 via the *Fourth Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications.* 90 FR 61301 (Dec. 2025). Additionally, in January 2025, DEA, in concert with HHS, promulgated two final rules utilizing its authority under 21 U.S.C. 802(54)(G) to permit, in limited circumstances, certain prescribing practitioners to issue prescriptions for controlled substances by telemedicine, without having personally performed an in-person medical evaluation. *See Expansion of Buprenorphine Treatment via Telemedicine Encounter,* 90 Fed. Reg. 6504 (January 2025)*; Continuity of Care via Telemedicine for Veterans Affairs Patients;* 90 Fed. Reg. 6523 (January 2025).

[1] 21 U.S.C. 802(54)(D)(i) is being conducted during a public health emergency declared by the Secretary under section 247d of Title 42; and (ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of Title 5.

It is important to note when the *Ryan Haight Act* and its implementing regulations do not apply. Specifically, the *Ryan Haight Act* applies only in limited circumstances affecting only a subset of practitioner-patient relationships, where:

1. the prescribing practitioner intends to prescribe controlled substances, and
2. the prescribing practitioner has never conducted an in-person medical evaluation of the patient prior to the issuance of the prescription.

In other words, any regulations implemented under the *Ryan Haight Act* would not be applicable to practitioner-patient relationships in which there has ever been a prior in-person medical evaluation of the patient by the prescribing practitioner.

II. The 2023 General Telemedicine Proposed Rule and Buprenorphine Proposed Rule

On January 31, 2020, the Secretary (the Secretary) of the Department of Health and Human Services (HHS) declared the COVID-19 PHE, pursuant to his authority under section 319 of the Public Health Service Act (42 U.S.C. 247). In response, in March 2020, DEA used its authority under 21 U.S.C. 802(54)(D) to grant temporary exceptions to the *Ryan Haight Act* and its implementing regulations, allowing authorized practitioners to generally prescribe controlled substances in Schedules II-V through audio/video telemedicine encounters when the patient and the practitioners have never had a previous in person consultation.

On March 1, 2023, DEA, in concert with HHS, promulgated two Notices of Proposed Rulemakings (NPRMs) (the General Telemedicine Rule and Buprenorphine Rule) pursuant to 21 U.S.C. 802(54)(G), which collectively proposed to expand patient access to prescriptions via telemedicine relative to the pre-COVID-19 PHE landscape. *See Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Evaluation,* 88 Fed. Reg. 12875 (March 2023); *Expansion of Induction of Buprenorphine via Telemedicine Encounter,* 88 Fed. Reg. 12890 (March 2023).

The General Telemedicine Rule generally proposed to allow a DEA-registered practitioner to prescribe non-narcotic Schedule III-V controlled substances to a patient via telemedicine for an initial 30-day supply. However, ongoing prescriptions for the same patient would require an in-person examination by the prescribing practitioner or a "qualifying telemedicine referral" from another practitioner who has conducted an in-person evaluation of the patient.

The Buprenorphine Rule generally proposed to allow a DEA-registered practitioner to prescribe any Schedule III-V narcotic drug approved by the Food and Drug Administration (FDA) specifically for use in the maintenance or detoxification treatment of opioid-use disorder (OUD) via telemedicine, including through audio-only telemedicine. Currently, buprenorphine is the only FDA-approved drug in this category. Buprenorphine is a Schedule III narcotic. 21 C.F.R. 1308.13 (e)(2)(i). Like the General Telemedicine Rule, controlled substance prescriptions would have been limited to a 30-day supply, and subsequent prescriptions would

require an in-person examination by the prescribing practitioner or a "qualifying telemedicine referral" from another practitioner who has conducted an in-person evaluation of the patient. As an additional safeguard, both proposed rules required Prescription Drug Monitoring Program (PDMP) checks, specific notations on the face of the prescriptions, and certain recordkeeping requirements.

In the General Telemedicine Rule NPRM, DEA asserted that the "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 Indian Health Service (IHS) and Tribal practitioners, who are authorized to engage in the practice of telemedicine under a different statutory paragraph, 802(54)(C)." 88 Fed. Reg. 12875, 12877-78. The regulatory analyses of the NPRMs of both the General Telemedicine Rule and the Buprenorphine Rule asserted that the proposed rules would not have substantial direct effects on the Tribes, on the relationship between the national government and the Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes, and therefore would require no Tribal consultation pursuant to Executive Order 13175.

However, in response to the two March 2023 NPRMs, DEA received at least six comments from Alaskan Native and American Indian (AN/AI) organizations expressing concerns about the proposed telemedicine regulations. Among their concerns was DEA's assertion that there would be no direct impact on Tribal communities, which they argued was inaccurate. They contended that despite the telemedicine exception for certain Indian Health Services and Tribal practitioners there would still be a substantial direct effect on Tribal communities given the limited practical and legal scope of the exception under 21 USC 802(54)(C). Further, they argued that DEA was obligated to engage and consult with Tribal officials as mandated by Executive Order 13175.

On May 10, 2023, to prevent the lapse of care with the expiration of the COVID-19 PHE, DEA, jointly with HHS, promulgated a rule (the First Temporary Rule) pursuant to 21 U.S.C.802(54)(G) to extend the temporary exceptions originally authorized under the COVID-19 PHE through November 11, 2023 for all telemedicine relationships, and through November 11, 2024 for such telemedicine relationships that were established on or before November 11, 2023. *See Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, 88 Fed. Reg. 30037 (May 2023).

On September 12, 2023, and September 13, 2023, DEA hosted live, in-person Telemedicine Listening Sessions to receive additional input concerning the practice of telemedicine with regards to controlled substances and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. DEA invited the public to express their views concerning the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation at all, the availability and types of data that would be useful in detecting diversion of controlled substances via telemedicine, and specific additional safeguards that could be placed around the prescribing of Schedule II controlled substances via telemedicine.

On October 10, 2023, in light of the need to further evaluate the best course of action, and given the comments received in response to the March 2023 NPRMs and the presentations at the September 2023 Telemedicine Listening Sessions, DEA, jointly with HHS, issued a second temporary rule (the Second Temporary Rule) to further extend the temporary exceptions originally authorized under the COVID-19 PHE through December 31, 2024. *See Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, 88 Fed. Reg. 69879 (October 2023).

III. 2024 Tribal Consultation on Prescribing Controlled Substances via Telemedicine and the Impact on Tribal Communities

In response to the concerns from Tribal organizations, DEA coordinated with the Office of Tribal Justice (OTJ) to host two virtual Tribal consultations in June 2024 to receive comments from and discuss the views of Tribal leaders and subject matter experts on Telemedicine and its impact on Tribal communities. While these tribal consultations arose in response to comments submitted to the 2023 Telemedicine NPRMs, they were not solely intended to focus on those proposed requirements. Rather, DEA sought to engage in a broader discussion to better understand the current practice of telemedicine and the experiences of Tribal communities, helping to guide the agency and formulate thoughtful but effective policy going forward.

Two Virtual Telehealth Tribal Consultations were held from 3 pm to 5 pm Eastern Time on June 13 (June 13 Session) and June 27, 2024 (June 27 Session). There were thirty-two registrants for the sessions, which included Tribal government leaders, Tribal health clinic providers, Tribal human service professionals, representatives from Tribal organizations, and Tribal government representatives attended the consultations. While attendees present represented Tribes or discussed Tribal communities all over the country, many attendees raised concerns over the need for flexibilities in Alaska, given the limited infrastructure faced by communities served by the Alaska Tribal Health System (ATHS).

During the June 2024 Tribal consultation sessions, commenters raised concerns about In-Person Medical Evaluation (IPME) requirements, in particular in remote and poorly accessed areas with limited transit options. Several commenters pointed out such a requirement imposes significant barriers to care for patients in remote and rural communities where inclement weather, unreliable transportation, and high travel costs can limit a patient's care options to only telemedicine.

Of particular concern to many during the consultation sessions was access to buprenorphine. Commenters contended that buprenorphine is essential for patient care of a vulnerable patient population, and that telemedicine plays a critical role in expanding access to care. Commenters noted that in small tribal communities, where stigma around addiction is prevalent, telemedicine allows for discreet treatment. One commenter also raised the point that OUD often coincides with social issues like domestic violence and abuse, and limiting buprenorphine could possibly exacerbate these issues.

Commenters highlighted the significant healthcare challenges faced by Alaska Native communities in remote areas, where, according to one commenter, the majority of federally recognized tribes are located. They emphasized the extreme remoteness of many Alaskan villages, which are often only accessible by plane, boat, or snowmachine during the winter. To address some of these challenges, the ATHS has developed a hub-and-spoke healthcare model over the past 30 years. Commenters explained that the system's regional hubs, located in more populated areas, are connected with remote sub-regional village clinics (the spokes), which provide immediate, routine, and in some cases, urgent care. The model is seen as essential for serving not only Native residents, but non-Natives and veterans as well.

However, commenters also pointed out that accessing care at these spokes can still be difficult in remote Alaska. For example, the nearest Tribal village clinic may still require hours of travel. One commenter noted that the closest Tribal village clinic was over 40 miles away and part of the journey required traveling on a dirt road. Additionally, clinics often have limited hours and appointment availability. One commenter shared that at some Tribal village clinics, patients need to schedule appointments two weeks in advance for buprenorphine treatment and are required to attend the clinic three days in a row to receive necessary medications.

Given Alaska's vast distances and limited local providers, commenters stressed the critical role telemedicine plays in delivering care in remote areas of the state. Commenters highlighted that telemedicine reduces the need for patients to travel hundreds of miles to the hubs, which can be costly, and allows patients to receive care closer to home and remain in their communities. According to one commenter, telemedicine is a particularly useful option for patients on Medicaid as there can be delays in travel approval, particularly for those with OUD or other behavioral health issues. However, telemedicine, especially for audio-visual encounters, depends on reliable internet access, which is not always available in Alaska. According to one commenter, the delivery of remote care relies on microwave satellite networks, with *Starlink* as a backup. One commenter, however, discussed recent investments in Alaska's broadband infrastructure, which they believe will significantly improve telemedicine connectivity.

During discussions regarding diversion concerns commenters highlighted the effectiveness of Tribal pharmacies in preventing diversion, comparing their internal checks and balances to those of the Veteran Affairs (VA) pharmacies. They explained that these pharmacies operate within a "closed system" under Alaska's hub-and-spoke health system, and that diversion is primarily an issue with medications originating outside the Tribal Health system.

The overall sentiment of those in attendance at the June 2024 consultations was that the current telemedicine flexibilities are vital for ensuring continued access to care in remote areas, most especially Alaska. DEA noted that many of the concerns echoed much of what was provided in submitted public comments to the March 2023 Telemedicine NPRMs, both from Tribal submitters and from the public. DEA carefully considered such insights and concerns in the 2025 NPRM development and believed that it addressed many of the concerns, in particular Tribal concerns with IPME, prescriptions limitations, and access to buprenorphine, in the formulation of the Special Registration NPRM. However, DEA also recognized that continuing

tribal consultations would occur prior to the drafting of a final telemedicine rule, in particular considering the new proposals found in the 2025 NPRM.

IV. 2025 Special Registrations for Telemedicine and Limited State Telemedicine Registrations Proposed Rule

DEA published a new Notice of Proposed Rulemaking on January 17, 2025, entitled *Special Registrations for Telemedicine and Limited State Telemedicine Registrations*. 90 FR 6541, (Jan. 2025). This NPRM introduced three types of Special Registration for Telemedicine, which would include: (1) a Telemedicine Prescribing Registration, authorizing qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine, (2) an Advanced Telemedicine Prescribing Registration, authorizing qualified, specialized clinician practitioners to prescribe Schedule II-V controlled substances via telemedicine, and (3) a Telemedicine Platform Registration, authorizing covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances. DEA would also require the special registrant to maintain a State Telemedicine Registration for every state in which a patient is treated by the special registrant, unless otherwise exempted in order to satisfy the statutory requirements under 21 U.S.C. 831(h). Further, this proposed rulemaking provided heightened prescription, recordkeeping, and reporting requirements.

In response to the January 17, 2025, NPRM, DEA received 6,475 comments during the comment period from January 17, 2025, through March 18, 2025. The comments received were both positive and negative regarding the NPRM. Many commenters supported this proposed rule as it would help ensure that telemedicine can remain as an option for prescribing controlled substances while protecting the public with numerous safeguards. However, there were also many commenters who expressed opposition to this NPRM finding the proposed rule to be administratively burdensome and complex.

DEA received comments dated March 18, 2025, from the Alaska Native Tribal Health Consortium (ANTHS), Tanana Chiefs Conference (TCC), and Alaska Native Health Board (ANHB) discussing their concerns. Some of their concerns included but were not limited to: that the proposed rule would be more restrictive than the telemedicine flexibilities allowed during the COVID-19 era; that the proposed rule would increase the administrative burden on providers and pharmacies; that access to broadband infrastructure can be limited in certain communities; that DEA's proposal to mandate the utilization of both audio and video components can restrict patient access to care; and that prescribing controlled substances based on telemedicine visits is within the current standard of practice for oncologists and pain management providers, and the lack of oncology and pain management provider special registration can negatively impact patients. The proposed rule does not include a special registration allowance for non board-certified practice providers or general medicine/family providers for the prescribing of Schedule II controlled substances, which will cause irreparable harm to patients.

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On December 31, 2025, DEA and HHS issued the *Fourth Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications* temporary rule to further extend the temporary exceptions originally authorized under the COVID-19 PHE through December 31, 2026. 90 FR 61301, (Dec. 2025).

In this second round of Tribal consultations, DEA is soliciting Tribal comments on the Special Registrations for Telemedicine and Limited State Telemedicine Registrations proposed rule, published January 17, 2026. 90 FR 6541 (Jan. 2025). This consultation is intended to provide DEA with further insight into the current telemedicine models used in Tribal health systems and to understand what aspects of those models might be able to be leveraged within DEA's legal authorities under the Controlled Substance Act and Ryan Haight Act. DEA is requesting specifically that commenters focus on what proposed regulatory guardrails of the January 2025 NPRM can be integrated into their current systems and which proposals, if any, will create an undue hardship on Tribal health systems. DEA further requests that if Tribes are able to provide any data, reports, or studies on Tribal health systems and the care provided, specifically related to controlled substances, that this data is included with comments.

QUESTIONS FOR CONSIDERATION

The following questions are not intended to limit discussion; the Department welcomes any question or topic of interest to consultation participants. The Department respectfully requests that participants refrain from submitting verbatim previously submitted comments. The Department's goal is to have a conversation with those tribal entities that could be impacted by a Special Registration for Telemedicine rule.

Tribal Health Systems

1. DEA understands that issues such as distance and travel limitations can impact a patient's ability to receive care within a tribal health system (in particular in Alaska). What additional aspects of the Tribal health systems and Tribal care should DEA consider when developing regulations and policies related to telemedicine and controlled substances?

2. In locations where providers and patients are relying heavily on telemedicine for care access, what existing regulatory frameworks or best practices from Tribal health systems have been implemented that ensure adequate oversight of telemedicine to prescribe, or otherwise dispense, controlled substances?

3. Can you provide information about the integration of telemedicine into the hub-and-spoke model[2] within Tribal health systems, including any challenges and successes encountered in this integration?

4. What are the unique issues and concerns regarding access to healthcare services for AN/AI communities residing in **rural areas**? In what ways has telemedicine affected the delivery and accessibility of healthcare within these rural areas?

5. What are the unique issues and concerns regarding access to healthcare services for AN/AI communities residing in **urban areas**? In what ways has telemedicine affected the delivery and accessibility of healthcare within these urban areas?

6. What experiences or observations can you share about telemedicine practiced *by Internet Eligible Controlled Substance Providers* designated by the Secretary of the Health and Human Services pursuant 21 USC 831(g)(2)? Have conversations occurred between tribes and IHS to address the regulations surrounding this designation? DEA heard that receiving this designation is difficult for providers, are there specific reasons this is difficult to acquire?

7. Are any of the proposed recordkeeping and recording requirements from the 2025 NPRM overburdensome to Tribal health systems? If so, how can these concerns be addressed while maintaining DEA oversight as statutorily required?

8. In the 2025 NPRM DEA utilized a specialty-based registration scheme to determine access to Schedule II controlled substances. Does the specialty-based special registration scheme cause challenges or affect the accessibility to healthcare within Tribal health systems? Under the current flexibilities, what are the frequent situations when a Schedule II controlled substance is prescribed via telemedicine and the provider is not one of the specialty providers detailed in the NPRM. If there are concerns with the specialty-based model, how do you believe these concerns are best addressed and what alternatives are available while still providing heightened oversight of Schedule II prescriptions?

9. What is the role of non-board certified advanced practice providers within the Tribal health systems, and how do these non-board certified advanced practice providers contribute to Tribal health care accessibility?

10. Beyond ease of access for patients, how else are the current telemedicine flexibilities beneficial to the Tribal health care systems?

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[2] In healthcare settings, the hub-and-spoke model organizes services with a central hub providing extensive medical resources and specialized care, while satellite spokes offer limited services closer to patients. Local, but limited, healthcare needs are met at satellite facilities, while more intensive medical interventions are referred to the main hub for treatment. Elrod JK, Fortenberry JL Jr. *The Hub-and-Spoke Organization Design Revisited: A Lifeline for Rural Hospitals*. BMC Health Serv Res. 2017 Dec 13;17(Suppl 4):795. doi: 10.1186/s12913-017-2755-5. PMID: 29297334; PMCID: PMC5751794.

11. How will the changes to telemedicine as detailed in the proposed 2025 NPRM positively and/or negatively affect tribal communities?

12. In remote locations where it is difficult for a patient to travel to a medical clinic with a practitioner (doctor or mid-level) and telemedicine is utilized as an option, is the patient seen via telemedicine from their home or from a community health center? Is there another medical provider or aid with them at the time of the telemedicine visit?

Diversion of Controlled Substances

13. What are the specific challenges or vulnerabilities related to diversion of controlled substances in telemedicine within the AN/AI communities? Are there specific controlled substances more prone to diversion? Are there specific circumstances when tribal health authorities have more concern that diversion could occur? How can these challenges be addressed?

14. DEA is required by law to detect and prevent diversion. DEA's proposed telemedicine regulations will be crafted to effectively monitor and regulate telemedicine practices to prevent and detect diversion of controlled substances. Knowing that some level of regulation, recordkeeping, and oversight will occur, what should DEA know in order to ensure access to necessary medications for remote communities?

15. After telemedicine regulations are in place, how can DEA best work with Tribal governments and healthcare organizations to establish reporting mechanisms for suspicious activities related to telemedicine and controlled substances?

DEA Registration

16. In your opinion, how can DEA ensure that registration requirements for telemedicine providers do not impede access to healthcare services for AN/AI communities?

17. What safeguards should be established to ensure that any telemedicine flexibilities specifically extended to AN/AI communities do not compromise patient safety or exacerbate risks of diversion of controlled substances? Do existing Tribal health systems already have these safeguards in place? Can you provide examples of how it is effective in preventing diversion of controlled substances?

Buprenorphine for Treatment of OUD

18. In general, what considerations should DEA consider regarding prescriptions via telemedicine for Schedule III-V controlled substances for the use in the treatment of opioid use disorder (OUD)? And specifically, what issues or limitations may arise from requiring audio-visual telemedicine versus audio-only telemedicine encounters?

19. In areas where no telemedicine services for the treatment of OUD are available, what are some of the burdens on AN/AI communities to access in-person treatment?

20. What alternatives are there to audio-video communication for patients who may lack the financial means to obtain in-person or audio-video communication and/or face other challenges such as lack of consistent access to wireless internet?

21. What other safeguards should DEA impose to allow for continued access to OUD treatment while also ensuring buprenorphine is not diverted for illicit purposes?