

# National Indian Health Board



January 18, 2022

The Honorable Anne Milgram  
Administrator  
Drug Enforcement Administration  
U.S. Department of Justice  
Attn: Office of Diversion Control  
8701 Morrissette Drive  
Springfield, VA 22152

***Re: Advanced Notice of Proposed Rulemaking on the Regulation of Telepharmacy Practice***

Dear Ms. Milgram:

On behalf of the National Indian Health Board (NIHB),<sup>1</sup> I write to you to request that the Drug Enforcement Administration (DEA) engage in Tribal consultation regarding its Advanced Notice of Proposed Rulemaking (ANPR) on the practice, industry, and state regulation of telepharmacy.<sup>2</sup> Indian Country has a unique perspective and experience with telepharmacy – and telehealth, more generally – and this must be considered in the formulation of any regulations regarding telepharmacy, including the definition of the term itself. **By initiating Tribal consultation before creating any new regulations or definitions around telepharmacy, DEA can uphold the Biden Administration’s commitments to honoring the federal trust responsibility, Tribal sovereignty, and health equity.**

## **I. Trust Responsibility**

We kindly remind the agency that the United States has a unique legal and political relationship with Tribal governments, established through and confirmed by the U.S. Constitution, treaties, federal statutes, executive orders, and judicial decisions. Central to this relationship is the federal government’s trust responsibility: a legal obligation to protect the interests of Indian Tribes and communities, including the provision of health care to American Indians and Alaska Natives (AI/ANs). In recognition of the trust responsibility, Congress has passed numerous Indian-specific laws to provide for Indian health care, such as the Indian Health Care Improvement Act (IHCIA). In the IHCIA, Congress reiterated that “Federal health services to maintain and improve the health

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<sup>1</sup> Established in 1972, the National Indian Health Board (NIHB) is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a board of directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA) or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

<sup>2</sup> 86 FR 64096.

of the Indians are consonant with and required by the federal government’s historical and unique legal relationship with, and resulting responsibility to, the American Indian people.”

Adequate health care includes the provision of needed prescription drugs and pharmacist care to all AI/AN peoples in the United States, including those living in the most remote and inaccessible areas of the country. To fulfill the federal government’s trust responsibility to Tribal nations, DEA must ensure any new rules regarding telepharmacy will support and enhance the provision of health care to AI/AN peoples, whether in remote villages or urban centers. Likewise, **DEA must take special precautions – through both initiating and conducting formal Tribal consultation in an honorable, respectful, and equitable – to make every effort to affirm Tribal sovereignty and engage Tribal voices in this space.**

## **II. Tribal Sovereignty and the Nation-to-Nation Relationship**

Tribes are sovereign nations with the authority and responsibility to protect their citizens and Tribal lands, including through the provision of health care services for AI/AN peoples. As sovereign equals, the United States maintains a government-to-government relationship with all federally recognized Tribal nations. This means the United States must work directly with Tribes in all governmental functions concerning Indian Country, including in the development of rules and regulations. As telepharmacy is an essential element of care in modern medicine and this includes Tribal communities, Tribes must be closely involved in any decision-making around regulatory changes concerning the use of telepharmacy. **Honoring the government-to-government relationship requires initiating Tribal consultation before any new rules or definitions for telepharmacy are created.**

## **III. Federal Policy on Tribal Consultation**

Through Executive Order 13175, President Biden set forth as Administration priorities respect Tribal sovereignty and self-governance; fulfillment of the federal trust and treaty responsibilities to Tribes; and engagement in robust consultation with Tribes. “Honoring those commitments is particularly vital now, as our Nation faces crises related to health, the economy, racial justice, and climate change — all of which disproportionately harm Native Americans.”<sup>3</sup> The Administration has committed to honoring Tribal sovereignty and including Tribal voices in policy deliberations that affect Tribal communities, such as this DEA ANPR. To comply with this executive order, DEA must meaningfully “[consult] with [T]ribal officials early in the process of developing the proposed regulation.”

Likewise, the Department of Justice reinforced its commitment to robust, meaningful consultation on January 27, 2010, when it set forth its own Tribal consultation policy. The Department’s plan is based on the principles that (a) the Department must engage with Tribal nations on a government-to-government basis, (b) Tribal sovereignty and Indian self-determination are now, and must always be, the foundations of every policy or program, and (c) communication and coordination — with [its] Tribal partners, among federal agencies, and with [its] state and local counterparts — are essential to accountability and thus to success.

The issue at hand is a prime example of the need for robust consultation to respect Tribal sovereignty and self-determination, as alluded to in the DOJ Tribal Consultation Policy. Under the

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<sup>3</sup> Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships. Executive Order 13175 (January 26, 2021).

Indian Self-Determination and Education Assistance Act (ISDEAA), many Tribal programs are contracted or compacted to carry out and manage federal health programs on behalf of the federal government. Any regulations DEA might develop around telepharmacy have the potential to inhibit the ability of Tribal health programs to adequately fulfill this responsibility.

**The DEA must consult with Tribes and Indian Health Service programs before developing any rules and regulations regarding telepharmacy, consistent with the requirements of Executive Order 13175 and the Department of Justice Tribal Consultation Policy.**

#### **IV. Health Equity**

##### *a. The President's Commitment to Health Equity*

President Biden has set forth health equity as a major priority of this Administration. In Executive Order 13985, he stated it is “the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all.” When it comes to advancing health equity for AI/AN peoples, part of this “comprehensive approach” must include proper consultation with Tribes, across all federal agencies. In the case of telepharmacy, DEA has an opportunity to bring Tribes into the discussion early in the rulemaking process to ensure any new rules will fulfill their purpose without impeding healthcare delivery for AI/AN peoples. In this way, the DEA can meaningfully contribute towards the Biden Administration’s stated priority for health equity.

##### *b. Telehealth Use in Indian Country*

Tribal nations can provide a unique perspective and expertise in telehealth, as the remote and rural nature of many Tribes has prompted Tribal leaders and health care providers to discover innovative ways to provide health care services to their communities.

Much of Indian Country is rural. In fact, 46.1 percent of AI/ANs live in rural communities, a rate which is over twice the percentage of the overall US population.<sup>4</sup> Furthermore, AI/ANs are the only group who make up a larger share of the rural population than the urban population.<sup>5</sup> Innovations like telepharmacy promise the potential to greatly expand access to care for rural, underserved areas, and therefore have an outsized impact on Indian Country. Likewise, any regulations governing telepharmacy will also have a disproportionate impact for AI/AN peoples.

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 or physician may be an hour or more away by airplane (assuming adequate weather and available flights). By necessity, health care delivery must operate differently in these locations than it may in more populated regions of the United States. These special circumstances have driven innovation in health care delivery, like the development of the Community Health Aide Program and advances in telehealth and telepharmacy capabilities. Most healthcare and pharmacy care in these remote regions depends on lower- or mid-level providers in village clinics,

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<sup>4</sup> Janice C. Probst, Fozia Ajmal, “Social Determinants of Health among Rural American Indian and Alaska Native Populations,” Univ. of S.C. Rural and Minority Health Research Center, July 2019  
[https://www.sc.edu/study/colleges\\_schools/public\\_health/research/research\\_centers/sc\\_rural\\_health\\_research\\_center/documents/socialdeterminantsofhealthamongruralamericanindianandalaskanativepopulations.pdf](https://www.sc.edu/study/colleges_schools/public_health/research/research_centers/sc_rural_health_research_center/documents/socialdeterminantsofhealthamongruralamericanindianandalaskanativepopulations.pdf).

<sup>5</sup> Rural America at a Glance. USDA, Economic Information Bulletin 200, November 2018,  
<https://www.ers.usda.gov/webdocs/publications/90556/eib-200.pdf>.

connected through telehealth technology to supervising providers in other locations. These unique health care systems successfully provide essential health care services for hundreds of Tribes.

The current COVID-19 pandemic has only made the need for telehealth and telepharmacy capabilities more urgent. Not only is telehealth the only option in some locations due to rurality, but COVID-19 had worsened provider shortages across Indian Country (often increasing the distance to care) and heightened the importance of limiting interpersonal contact to prevent the spread of disease. Telehealth and telepharmacy have become critical modes of health care delivery in Indian Country in the current COVID-19 pandemic and will be important in future evolution of health care delivery everywhere.

*c. Flexibility is Essential to Health Equity*

An essential component of a comprehensive approach to health equity is recognizing 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. Rules that are effective in one region, or even in most of the United States, may be instead detrimental to the delivery of health care in Indian Country. Whatever rules and definitions are created by DEA, flexibilities must be provided to Tribes and the Indian Health Service to tailor the delivery of telepharmacy care to the unique needs and circumstances of each Tribal community.

**V. 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. However, our mutual objectives can best be achieved through robust, meaningful consultation prior to and throughout any development of rules and regulations by the DEA. Any other course of proceeding will almost certainly lead to disruptions in the delivery of health services to American Indian and Alaska Native (AI/AN) peoples, and further perpetuate health inequities. We look forward to working with DEA in framing the future of telepharmacy.

Yours in Health,

A handwritten signature in black ink, appearing to read "Stacy A. Bohlen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stacy A. Bohlen, *Sault Ste. Marie Chippewa*

Chief Executive Officer

National Indian Health Board