Tribal Technical Advisory Group
To the Centers for Medicare & Medicaid Services
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May 6, 2021

The Honorable Xavier Becerra
Secretary
United States Department of Health and Human Services
200 Independent Ave. SW
Washington, DC 20201

Re: HHS-OCR-0945-AA00

Dear Secretary Becerra:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I submit this comment in response to HHS-OCR-0945-AA00, which makes key changes to the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). We have concerns about some of the changes and how they may impact the Indian health care system. In particular, we are concerned about the administrative burden created by the requirement that providers respond to patient requests for protected health information (PHI) within fifteen days, cutting the response time in half. We are also concerned about specifically allowing verbal requests for health care providers to transmit patient information. We also support several of the revisions, such as the ones allowing good faith disclosures and the proposed change to the "serious and imminent threat" standard. We thank HHS in advance for their consideration of our comments.

Trust Responsibility

The United States owes a special duty of care to Tribal Nations, which animates and shapes every aspect of the federal government's trust responsibility to Tribes. Rooted in treaties and authorized by the United States Constitution, the federal government's unique responsibilities to Tribal Nations has been repeatedly reaffirmed by the Supreme Court, legislation, executive orders, and regulations.[1] In 1977, the Senate report of the American Indian Policy Review Commission stated that, "[t]he purpose behind the trust doctrine is and always has been to ensure the survival and welfare of Indian tribes and people." This trust responsibility is highlighted recently in the Department of Health and Human Services (HHS) Strategic Plan FY 2018–2022:

> Importantly, the Federal Government has a unique legal and political government-to-government relationship with Tribal governments and a special obligation to

[1] The Court has consistently held that the federal government has a trust responsibility to Tribes, which has formed the foundation for federal/Tribal relations. *See* Seminole Nation v. United States, 316 U.S. 286 (1942), United States v. Mitchell, 463 U.S. 206, 225 (1983), and United States v. Navajo Nation, 537 U.S. 488 (2003).

> provide services for American Indians and Alaska Natives based on these individuals' relationship to Tribal governments.[2]

The trust responsibility establishes a clear relationship between the Tribes and the federal government.[3] The Constitution's Indian Commerce clause, Treaty Clause and Supremacy clause, among others, provides the legal authority and foundation for distinct health policy and regulatory decision making by the United States when carrying out its unique trust responsibility to provide for the health and welfare of AI/ANs and support for the Indian health system that provides their care.

Comments

The Time For Responding to Patient Requests for PHI Should Not Be Shortened

The Proposed Rule would change the existing language, which currently allows a provider to respond to a patient's request for PHI within 30 days (with a 30-day extension possible), to instead require access "as soon as practicable," but in no case later than 15 calendar days after receipt of the request. The Proposed Rule would allow one 15 calendar-day extension if the entity has established a written policy to address urgent or high-priority requests.

While we support expanding access to information for patients and ensuring patients can have timely access to their PHI, we believe that shortening the time period as proposed would create a significant administrative burden on health programs throughout the Indian health care system. As we know, the Indian health care system is chronically underfunded and has minimal capacity to take on additional functions and responsibilities. Many of our facilities are small and operate with a skeleton staff. It can regularly take up to 30 days to fully process a request for PHI, particularly if legal counsel must provide assistance reviewing the request (which often occurs, for example, when parents request records of minor children, given the complexities involved). Time is also needed to pull together records from various sources within our coordinated health care systems. **Imposing a stricter time requirement for responding will create an additional administrative burden for our facilities and take additional staff time, diverting staff away from mission-critical tasks such as facilitating patient care.**

We are concerned about the ability of our Health Information Technology (Health IT) systems to quickly handle these requests. It is not necessarily the case within the Indian health care system that an electronic health record easily allows a covered entity to put together records within a short time period. Indian Health Service facilities and some Tribal programs still use the Resource and Patient Management System (RPMS) to manage patient records, though other Tribal and Urban Indian Organization (UIO) facilities have switched to other patient records record management systems.

We have serious concerns about the ability of RPMS in particular to facilitate the expeditious retrieval and availability of these records for patients and any providers that they may designate to receive the records. Indian health care providers have regularly commented on the inadequacies

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[2] Introduction, "Cross-Agency Collaborations", https://www.hhs.gov/about/strategic-plan/introduction/index.html

[3] In Worcester v. Georgia, 31 U.S. 515 (1832), the Supreme Court explicitly outlined that the relationship between the federal government and the Tribes is a relationship between sovereign nations and that the states are essentially third party actors.

of RPMS and the difficulties it creates in managing patient records. We believe that the current Health IT infrastructure in the Indian health system would make the quick retrieval of records difficult.

Additionally, not every provider uses the same technology or technology that is even interoperable with other electronic health records. If a patient requests a records transfer from a provider using an incompatible system, the solution may require additional time to navigate between providers. After all, it is not unreasonable to think that a patient transferring from an IHS facility to a Tribal or UIO facility might request a records transfer to their new provider. If the systems are not interoperable, the provider will have to print records, assemble them, and then send them to the other provider, who would likely have to key records into their own Health IT system. On a truncated timeline, the extra time needed to print and assemble the records would represent an additional concern. **We urge HHS not to change the current response timelines, or if it does, to ensure that the Indian health care system is exempt from the change.**

We Do Not Support Verbal Requests For Records

Ensuring our patients' privacy is incredibly important to us, and we want to make sure that any changes to the HIPAA standards do not unnecessarily jeopardize that. First, we have a deep concern about the decision to allow a patient to make a verbal request to a health care provider to transmit electronic PHI to a third-party. While we understand this is intended to make it easier for the individual, this particular change puts Tribal health care providers at risk: even though verbal requests can be documented, there is still a significant risk of error (*e.g.*, a disclosure of electronic PHI to a third party may be to the wrong party, or may exceed the scope of information the patient had actually intended be disclosed). A patient may think they said one thing but they actually asked for something different. We are thus concerned about the ability of our providers to ensure the accuracy of records requests. Staff at Indian health providers are stretched thin, and it is foreseeable that a verbal request may get lost, or details may be missed as the staff member is shuffled from task to task.

Our TTAG thinks having the ability to require that the request be documented in writing is imperative so that there is absolute clarity between the provider and the patient about what should be disclosed, by whom, and to whom. We do not think a verbal request can adequately meet the "clear, conspicuous, and specific" standard. **Without a paper trail, it is difficult to ensure the accuracy of these requests and it places an unfair burden on staff to expect them to keep track of these requests.**

Additionally, the federal Privacy Act does not allow federal employees to accept verbal requests, and some Tribal programs voluntarily follow Privacy Act procedures. We are concerned that allowing verbal requests under HIPAA puts such providers either at risk of violating the Privacy Act or being accused of information blocking, both of which pose risk of liability.

Furthermore, if some facilities are not able to take verbal direction but others are required to do so, that would create confusion among our patient populations, particularly those who see multiple providers and find themselves navigating different standards. It is also true even for people who see one provider, especially when a friend or family member tells them that it is possible to request their records verbally. It is not a good practice to have standards that apply to some facilities and not others. As such, **we ask that verbal requests not be specifically allowed, so that a health**

care provider can request at least some basic information be put into writing, or otherwise that the Indian health care system receive a blanket exemption.

We Support the Flexibility of "Good Faith" Beliefs By Providers

We appreciate the proposed changes throughout different portions of the Privacy Rule to replace "the exercise of professional judgment" with "good faith belief." We think this will create better flexibility for health care providers to make decisions in their patients' best interests, while also lowering the possible risk of being challenged for a violation of HIPAA, and could help to save lives. For example, we think these changes could help to allow beneficial disclosures of PHI more broadly in scenarios that involve serious mental illness, and to help combat the opioid crisis.

We Support the Change to the "Serious and Imminent Threat" Standard

The current version of the Privacy Rule allows a covered entity to use or disclose PHI when it has a good faith belief that doing so is necessary to "prevent or lessen" a "serious and imminent threat" to the health or safety of a person or the public. Many Tribal health programs have looked to this exception for sharing PHI on a case-by-case basis related to the COVID-19 pandemic, for example, and we appreciate the guidance HHS previously issued on using this exception to help respond to the opioid crisis and to assist individuals with serious mental illness, their families, and caregivers. We fully support the proposed, increased flexibility under this exception by replacing the "serious and imminent threat" standard with a "serious and reasonably foreseeable threat" standard. This would allow Tribal programs and other covered entities to use or disclose PHI without having to determine whether the threatened harm is "imminent," which can be extremely challenging to conclude and document in some cases.

Conclusion

While the TTAG approves measures to increase transparency and care coordination, this rule imposes standards that disproportionately disadvantage small providers such as Indian health care providers. Requiring a truncated timeline and changing the professional standards for making decisions on disclosing information places an unfair burden on our providers and forces them to spend extra money complying with the requests and even training staff to comply with these requests. In deciding to approve this rule, HHS must **consider the impact on Indian health care providers and adjust it accordingly.** Increased transparency and care coordination cannot come at the expense of providers that are already stretching their resources. Thank you in advance for your consideration of our comments.

Sincerely,

W. Ron Allen

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