January 3, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Re: CMS Omnibus Final Rule with Comment, CMS-3415-IFC

Dear Dr. Brooks-LaSure:

On behalf of the CMS Tribal Technical Advisory Group (TTAG), I write to you to express concern over the new CMS Omnibus Final Rule with Comment, CMS-3415-IFC, released on November 4\textsuperscript{th}, 2021. While this new rule mandates COVID-19 vaccination requirements for Medicare and Medicaid-certified facilities, CMS has not been clear about its applicability or impact on Indian Country. This ambiguity conflicts with the responsibility of the federal government to consult with Tribal Nations when such an action has an impact on Indian Country.

Tribal leaders were hopeful when President Biden affirmed his administration’s commitment to nation-to-nation dialogue in his Executive Order mandating agencies to engage in regular, meaningful, and robust consultation with Tribal Nations.\textsuperscript{2} The president acknowledged that honoring the commitments the United States has made to Tribal Nations for more than two centuries is particularly vital now, as our nation faces crises in health, the economy, racial justice, and climate change – all of which disproportionately harm American Indian and Alaska Native peoples. However, the rollout of this regulation has demonstrated a clear disconnect between the words spoken and the actions taken in this regard. This reflects a larger, long-standing, cultural disconnect between the federal government and Tribal Nations.

We understand that the current and ongoing litigation in the federal district courts in Missouri and Louisiana have caused CMS to suspend the implementation and enforcement of this rule. Nevertheless, we request that implementation and enforcement action not be taken against Tribal health care facilities until formal Tribal Consultation has occurred. CMS must do better. Without robust, meaningful consultation, rules and regulations will continue to disrespect Tribal sovereignty and bring inadvertent harm to Tribal communities.

1. Lack of Tribal Consultation

Tribal leaders are concerned over the lack of government-to-government consultation and dialogue on this rule. The minimum requirements for formal consultation between Tribal Nations and the
federal government were not met here. This was one more example of Tribal Consultation being wholly neglected in an emergency – a growing trend we have witnessed from this administration. During an All-Tribes call on November 18th, an administration official even suggested that the call was “consultation” when it was not. Such a call does not meet the standards of a formal Tribal Consultation. The way CMS handled the implementation of this rule is a disappointing reminder of the failure of the administration to create consistency across departments and agencies for proper engagement with Indian Country.

As an example of a successful consultation process, the Occupational Safety and Health Administration (OSHA) upheld its commitment by requiring Tribal Consultation in the creation and implementation of its vaccine mandate regulation, proving that this process works when it is made a priority. OSHA’s mandate specified that the agency would not engage in enforcement on Tribal facilities until after due consultation with Tribes. CMS could have followed a similar process; however, it instead published the rule without proper consultation, leaving as an afterthought the implications of the rule for Indian Country. The resulting confusion – both in interpreting the regulation and applying it in Indian Country – has demonstrated the need for consultation prior to issuance of these regulations.

During the All-Tribes call that CMS held on this regulation on November 18th, CMS gave the same presentation it had given to the general population twice already. Many Tribal leaders and representatives on the call were disappointed to see CMS had not tailored the presentation to the Tribal community to focus on the special implications this regulation has for Indian Country. As a result, the presentation did not provide the information Tribal leaders needed. We appreciate that a separate call was held for the Tribal community, and we believe this shows an intention to recognize the special government-to-government relationship between Tribal Nations and the federal government. Unfortunately, the call fell well short of this intention. This was another example of the disconnect in what the agency says it will do and the actions it takes.

It is not enough for CMS to simply provide the same presentation it provides to other stakeholders to a Tribal audience. That is NOT Tribal Consultation. Tribal Nations are not just another stakeholder group. They are sovereign nations to whom the United States owes specific treaty, trust, and statutory obligations. Any presentation by CMS must address how the proposal will specifically affect Tribal Nations, and the officials giving the presentation must understand the Tribal implications of the policy. Presentations that ignore federal law or Tribal sovereign rights that affect the scope and applicability of a proposal to sovereign Tribal Nations provide misleading information and do not constitute Tribal Consultation.

During the call, members of the Division of Tribal Affairs (DTA) suggested that Tribes could invoke consultation under CMS’s Tribal Consultation policy, but this is not sufficient to ensure that the agency is accounting for the impact of such regulations on Tribes. CMS must involve Tribal Leaders in the process before such regulations go into effect. This rule went into effect immediately upon publication and did not allow for meaningful consultation on an issue that greatly impacts Indian Country, as COVID-19 has disproportionately harmed Tribal Communities.

This is just another example of the neglect this administration has shown for its own stated commitment to meaningful Tribal Consultation. If this disconnect between intention and follow-through is due to a lack of expertise in this area, then the administration should respond to calls from Indian Country that ask for a seat at the table. Tribal leaders and organizations have been
calling for improved Tribal representation in agencies and in the Office of the Secretary at the U.S. Department of Health and Human Services (HHS). With a Tribal representative at hand, agencies will have the needed expertise to understand the special needs of Indian Country and adhere to meaningful consultation. CMS must uphold the trust responsibility it owes – as an arm of the administration – and work with Tribes as sovereign equals as it continues to implement policies that impact Indian Country.

**Trust Responsibility**

Inherent in the government-to-government relationship between Tribal Nations and the federal government is that the United States work directly with Tribes as sovereign equals in all governmental functions, including emergency preparedness and response. Tribes are sovereign nations with the authority and responsibility to exercise the right to protect their citizens and Tribal lands.

As you know, 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 have been repeatedly re-affirmed by the Supreme Court, legislation, executive orders and regulations.\(^3\) 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 provide services for American Indians and Alaska Natives based on these individuals’ relationship to Tribal governments.\(^4\)

The trust responsibility establishes a clear relationship between the Tribes and the federal government.\(^5\) The Constitution's Indian Commerce clause, Treaty Clause and Supremacy clause, among others provide 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.

In recognition of this responsibility, Congress has passed numerous Indian-specific laws to provide for Indian health care, including laws establishing the Indian health care system and those providing structure and detail to the delivery of care, such as the Indian Health Care Improvement Act (IHCIA).\(^6\) In the IHCIA, Congress reiterated that “federal health services to maintain and improve the health 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.”\(^7\) When the federal government is providing Medicare and Medicaid reimbursement to Tribes, they are doing so in furtherance of the promises that they made our ancestors. Any enforcement action related to noncompliance with this rule would interfere with that promise.

### 2. Scope of Rule Must be Clarified for Tribal Nations

The lack of clarity on the Tribal call led CMS TTAG to ask for a follow up call with CMS Tribal Affairs. While the regulation states that it applies to all Medicare and Medicaid certified providers on the list of covered provider types, the rule appears to be rooted in CMS’s Medicare authority
and appears to apply only to entities that are certified as one of the Medicare provider types listed in the rule. During the call, it was suggested that entities that are only enrolled in Medicaid, not Medicare, would not be covered by the requirement. CMS staff indicated that was the case, and further that if a provider did not have a CCN number and was not listed as one of the covered provider types in the CMS qcor.cms.gov database, then they would not be covered. In the chat during the call, CMS staff provided the following information:

- How do I know if I’m a certified facility?
- You have gone through the Medicare enrollment process
- Have received a survey by State Survey Agency or CMS approved Accrediting Organization
- Received a National Provider Identifier (NPI) and CMS Certification Number (CCN)
- Can bill Medicare for services
- Medicare pays for services
- You can also look up your provider type to see if you're certified here: https://qcor.cms.gov/main.jsp.

CMS staff further clarified that providers that show up on the qcor website just for their labs do not qualify.

The TTAG appreciates that CMS updated its FAQs to state that it may not apply to certain Tribal Medicaid FQHCs who are only enrolled in Medicaid. However, that statement is insufficient. Per CMS staff, the rule would not apply to providers who are only enrolled in Medicaid. If that is the case, CMS should so state, and not say it “may” not apply. Moreover, it is not just Tribal Medicaid FQHCs who are only enrolled in Medicaid. There are other Tribal provider types who only bill Medicaid, not Medicare. The FAQs should be revised to state that it does not apply to Tribal providers who are only enrolled in Medicaid. They should also include the information CMS staff provided in the chat quoted above.

Tribal Nations need to know whether this federal mandate applies to them or not. Tribal Nations implementing their own vaccine mandate requirements need to know whether they must rely on their inherent sovereign authority to support a mandate or whether they can rely on the CMS rule for authority to impose the mandate.

3. Tribal Sovereignty Must be Recognized in Establishing Vaccine Protocol

Tribes, as sovereign nations, should be permitted to address vaccine requirements in whatever way they see fit. Tribal Nations have proven time and time again that they have succeeded in battling COVID-19. They have done so by implementing safety measures tailored to the unique nature of their communities and encouraging members to get vaccinated. Various reservations have been relatively successful in limiting community spread by limiting access to their reservations. For example, the Blackfeet Tribe, whose reservation encompasses areas also identified as the Glacier National Park, closed roads entering their reservation through this past summer. The Tribe’s priority was protecting its elders and stemming the spread of COVID-19 and it worked. These closures and the Tribe’s strictly enforced stay-at-home orders and mask mandate led to a low daily case rate held up as an example by federal health officials. The reservation also boasts one of the highest vaccination rates in the nation. This is just one example of how unique some Tribal communities are, and how different approaches can be successful in combatting the spread of COVID-19.
Another unique characteristic of Tribal lands is the geographic demographics of some reservations and Tribal communities. Many Tribes are located in rural areas. Not only does this limit staff pools, but it also places many Tribes in geographic areas that are surrounded by communities generally opposed to mandates. The higher rates of vaccine hesitancy that exist in these areas can and does bleed over into the workforce in IHS and Tribal health facilities. This has been proven true with the experience in and around the Choctaw Nation in Durant, Oklahoma, a city of less than 20,000 people. The Choctaw Nation health system has offered incentives and has tailored its policies in order to encourage vaccination, as it has realized that enforcing a vaccine mandate like this CMS mandate would have various negative impacts on its workforce.

While we understand that vaccination has been shown to be the most effective way to combat COVID-19, health care staff shortage concerns must be considered in granting alternative methods of protecting staff and patients, such as testing. It takes years for some of these rural facilities to hire and effectively onboard staff, and it takes work to retain these staff. Facilities in Health Professional Shortage Areas (HPSAs) are at a higher risk of facing detrimental impacts from this federal mandate, and therefore must be free to make decisions based on the specific needs of their community. Permitting the flexibility for Tribal Nations to establish their own vaccine mandates and procedures would allow for continued protection for staff and patients while respecting Tribal sovereignty.

Tribes must be able to establish policies that include any measures they see fit to protect their communities. This could include policies such as testing options for those who cannot or will not get vaccinated, flexibilities for staff that do not interact directly with patients, and increased flexibilities for other departments housed within the same building as these health care facilities. If forced to implement the federal mandate requirements, Tribal facilities are at risk of losing staff. Smaller facilities, and those in more rural areas, have limited access to replacement staff. If a small facility loses even one staff member, they could run the risk of losing an entire department. The unique nature of these facilities warrants these flexibilities. Tribes have proven that they know how best to protect their communities, by their response thus far during the pandemic, and they should be permitted to continue this work as they see fit.

4. Exemption Laws Inapplicable to Tribal Nations

This rule includes the requirement for facilities to develop a policy to accommodate any medical and religious objections by its staff required by “applicable law.” These accommodations are based on federal law such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964. However, Tribes are not included in the definition of employer in the ADA and Title VII of the Civil Rights Act of 1964. Indian health care facilities are thus not required to comply with the accommodations set out in the ADA and Title VII if they do not elect to do so.

The ADA requires employers to provide "reasonable accommodation" to otherwise qualified disabled employees, unless doing so would impose an undue hardship. The ADA specifically excludes Indian Tribes from definitions of "employers" subject to the Act. Tribes are also specifically excluded from the definition of "employer[s]" who may not discriminate for above reasons in Title VII. Title VII states the term "employer" does not include "... the United States, a corporation wholly owned by the government of the United States, Indian Tribe, or any department or agency of the District of Columbia. ...". While the recent CMS rule indicates there is flexibility
allowed in creating these policies, the rule should clarify the specific exceptions for Tribal facilities regarding how these laws are applied in this rule.

5. Support Needed in Indian Country

Due to resource limitations, whether funding or staff, some smaller Tribal facilities face significant challenges in complying with the regulation’s requirements. CMS should provide these facilities with additional support to limit any harm caused by the regulation. For example, many facilities across Indian Country already face severe provider shortages. The regulation could further exacerbate this crisis if any staff resign due to the vaccine requirement. Funding is therefore not only needed for the actual implementation efforts required by the rule – like creating a compliant policy – but for the implications of the mandate itself. As we have seen throughout the country already, there are employees who will not comply with the mandate, who do not qualify for an acceptable exemption, who will leave the workplace. In facilities that are small and often shorthanded, as is common in Indian Country, this could have a catastrophic impact on the quality of care available to AI/AN people.

Conclusion

The implementation of this regulation thus far demonstrates a disconnect within the agency: the stated intention to respect Tribal sovereignty is not being realized in the actions and choices of the agency. This reflects a larger, long-standing, cultural disconnect between the federal government and Tribal Nations. We request that enforcement action not be taken against Tribal health care facilities until formal consultation has occurred regarding this emergency rule. CMS must do better. Without regular, meaningful, and robust consultation, regulations such as this one will continue to overlook the nature of Tribal health programs, the unique needs of Indian Country, and the responsibilities owed to Tribal Nations by the federal government. We urge you to take this into account as we move forward and work together to improve the health of American Indians and Alaska Natives.

Sincerely,

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