



# Health Care Reform in Indian Country

Self-Governance Communication & Education

November 17, 2021

## *CMS and OSHA Vaccination Requirements*

On November 5, 2021 the Centers for Medicare and Medicaid Services (CMS) and the Occupational Safety and Health Administration (OSHA) separately released two new vaccination requirements. CMS's [interim final rule](#) with comment period applies to health care providers participating in the Medicare and Medicaid program (the CMS rule).<sup>1</sup> OSHA's [emergency temporary standard](#) requires employers with 100 or more workers to adopt and implement a vaccine or testing and masking policy.

Comments on CMS's rule are due January 4, 2022 and should include the agency's name and file code CMS-3415-IFC. Comments on the OSHA rule are due December 6, 2021 and must include the agency's name and Docket Number OSHA-2021-0007. Comments may be submitted at [www.regulations.gov](http://www.regulations.gov).

CMS is hosting an all tribes webinar on the CMS rule this Thursday, November 18, 2021 from 2-330 pm. The registration link is here:  
[https://kauffmaninc.zoom.us/webinar/register/WN\\_ZffvUz69R8aIIBYpZzTCWA](https://kauffmaninc.zoom.us/webinar/register/WN_ZffvUz69R8aIIBYpZzTCWA)

Both rules are facing legal challenges. Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming asked the U.S. District Court for the Eastern District of Missouri to preliminarily and permanently enjoin CMS from enforcing its rule.<sup>2</sup> Because the district court has not decided the issue, the CMS rule remains in effect.

Meanwhile, suits challenging the OSHA rule have been filed in every U.S. Circuit Court of Appeals except the Federal Circuit. Missouri, Arizona, Nebraska, Montana, Arkansas, Iowa, North Dakota, South Dakota, Alaska, New Hampshire, Wyoming filed in the Eighth Circuit. Texas, Louisiana, Mississippi, South Carolina, and Utah filed in the Fifth Circuit. Florida, Alabama, and Georgia filed in the Eleventh Circuit. Kentucky, Idaho, Kansas, Ohio, Oklahoma, Tennessee, and West Virginia filed in the Sixth Circuit.

On November 6, 2021, the Fifth Circuit issued a temporary stay delaying the implementation of the rule—a decision it reaffirmed and made permanent on November

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<sup>1</sup> We note that the interim final rule discussed in this memorandum is also referred to as the “Omnibus COVID-19 Health Care Staff Vaccination.” See 86 Fed. Reg. 61555 (2021).

<sup>2</sup> *Missouri v. Biden*, No. 4:21-cv-01329 (E.D. Mo. 2021).

12, 2021.<sup>3</sup> On November 16, 2021, the Judicial Panel on Multidistrict Litigation consolidated the lawsuits and selected U.S. Court of Appeals for the Sixth Circuit to hear the legal challenges.<sup>4</sup> Ultimately, the case could end up in the Supreme Court.

Because these lawsuits are unlikely to be resolved before employers must implement the rules, at this time we recommend that healthcare employers covered by these rules consult with their legal counsel in taking steps to comply with them.

### ***CMS Vaccination Requirements***

Applicability. CMS's rule applies to all Medicare- and Medicaid-certified provider and supplier types that are regulated under the Medicaid Conditions of participation, which includes Indian Health Service facilities. Compliance with the rule is a condition of participation in the Medicare and Medicaid programs. The rule contains no separate exemptions for tribal health care providers. Therefore, Tribal health care providers must comply with CMS's rule if they are enrolled in Medicare and Medicaid and are obligated to comply with the Medicare and Medicaid conditions of participation.

The rule applies to all existing and new staff who work at a facility regardless of clinical responsibility or patient contact, including volunteers, contracted staff, those who perform duties offsite (i.e., home health, home infusion therapy, etc.), and individuals who enter into a CMS regulated facility. The rule does not apply to full time telework staff. The rule preempts any state law to the contrary.

The FAQs to the Rule state that health care providers who are subject to its requirements must comply with this rule, even if they might otherwise also be subject to the OSHA rule described below or the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contracts, or the OSHA COVID-19 Healthcare Emergency Temporary Standard.

Requirements. Providers subject to the rule must establish a process or plan for 1) vaccinating all eligible staff; 2) providing exemptions and accommodations for those who are exempt; and 3) tracking and documenting staff vaccinations. Facilities must meet these requirements by December 6, 2021. The rule does not permit facilities to implement a COVID-19 testing and masking policy in lieu of a vaccine mandate.

Staff must receive their first dose or one-dose vaccine by December 6, 2021 and all shots for full vaccination by January 4, 2022. Staff who have completed their vaccination series for a two-dose vaccine are considered fully vaccinated, for the purposes of the rule, if they received their second dose by or on January 4, 2022, even if

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<sup>3</sup> See *BST Holdings, L.L.C. v. Occupational Safety and Health Admin.*, No. 21-60845 (5th Cir. Nov. 6, 2021).

<sup>4</sup> 28 U.S.C. § 2112.

they have not completed the 14-day waiting period required for full vaccination. For example, a staff person who receives a second dose of the Pfizer or Moderna vaccine on January 4, 2022 would be considered fully vaccinated for the purposes of the rule.

At this time, the only vaccines that meet the CMS rule's requirements are the Janssen (Johnson & Johnson) COVID-19 vaccine, Moderna and Pfizer BioNTech COVID-19 vaccines, and vaccines listed by the World Health Organization for emergency use (in accordance with guidelines from the Centers for Disease Control and Prevention (CDC)). The rule does not require boosters.

Exemptions and Accommodations. All facilities must allow for exemptions required by applicable federal law, including the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, which could include recognized medical conditions for which COVID-19 vaccines are contraindicated and religious beliefs, observances, or practices. Tribes are exempt from the definition of employer in both the ADA and Title VII, however, so it does not appear that they would have provide an exemption for religious beliefs, for example. However, tribes should confer with their legal counsel in developing any policy.

CMS requires facilities to develop a process for implementing additional precautions for any staff who are not vaccinated, which could include (but is not limited to) testing, physical distancing, and source control. In all cases, facilities must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals.

Enforcement. There are no new data reporting requirements with this regulation. However, CMS will routinely check for compliance with the rule. State Survey Agencies will conduct onsite compliance reviews through recertification surveys and compliant surveys. Accrediting organizations will also assess compliance. Surveyors will cite facilities based on the level of severity of the noncompliance. Non-compliant facilities will be given an opportunity to return to compliance. If facilities remain non-compliant CMS may issue civil and monetary penalties, deny payments, and terminate a facility's participation in the Medicare and Medicaid programs.

### ***OSHA Vaccination Requirements***

Applicability. The OSHA rule applies to workplaces with 100 or more employees (i.e., "covered employers"). It does not apply to tribal governments handling "government" duties (i.e., police, fire, and schools). OSHA's position is that tribal businesses are required to comply with the rule, but it also plans to consult with tribes on this issue. OSHA has said it will not enforce the rule on Tribes until it has consulted with them.

Workplaces exempt from OSHA's rule include those covered under the Safer Federal Workforce Task Force COVID-19 Workplace Safety Guidance, and settings

where any employee provides health care services or support as subject to 29 C.F.R. § 1910.502. Employees exempted from this regulation are those who do not report to a workplace where coworkers or customers are present and those who work from home or exclusively outdoors.

Like the CMS rule, the OSHA rule preempts state and local government laws, specifically those that prohibit or limit employers' authority to require employees to be vaccinated. However, the OSHA rule does not preempt state or local requirements mandating face coverings in indoor public spaces and proof of vaccination or a recent negative COVID-19 test upon entry into public spaces.

Requirements. The OSHA rule sets forth several requirements for covered employers, all of which must be met by December 5, 2021, except the employee vaccination requirement, which provides that employees must be fully vaccinated by January 4, 2021.

Unlike CMS's rule, OSHA's rule gives covered employers the option of establishing in writing and enforcing a policy that either 1) requires all new and existing employees to be fully vaccinated; 2) allows employees who are not fully vaccinated to elect to undergo weekly COVID-19 testing and wear a face covering at the workplace; or 3) allows for mandatory vaccinations for certain employees and testing and masking options for others. However, as discussed above, CMS is taking the position that a provider who is subject to both rules must comply with the CMS rule.

Any employee who tests positive or is diagnosed with COVID-19 by a licensed health care provider must be removed from the workplace. While covered employers are not required to pay for COVID-19 testing, they must provide up to four hours of paid time off for vaccinations and, if needed, a reasonable amount of paid sick leave to recover from vaccine side effects.<sup>5</sup> Covered employers must require their employees to promptly notify them if they are COVID-19 positive.

Under the OSHA rule, covered employers must also maintain a roster of each employee's vaccination status, but they are not required to reevaluate employees' vaccination status if they confirmed and retained records of such status before the OSHA rule's effective date. The OSHA rule lists acceptable proof of vaccination status. Covered employers must also provide their employees with the following information: the rule's requirements, the Center for Disease Control and Prevention's [Key Things to Know About COVID-19 Vaccines](#), protections against retaliation and discrimination, and laws that provide for criminal penalties for knowingly supplying false statements or documentation. Unlike CMS's rule, OSHA's rule imposes additional reporting

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<sup>5</sup> We note that while the CMS rule does not require Medicare and Medicaid facilities to cover paid sick leave for vaccine side effects, health care providers subject to OSHA's [June 21, 2021 Healthcare emergency temporary standard](#) must provide reasonable time and paid sick leave for employee vaccinations.

requirements as set forth under the rule, which includes reporting COVID-19 fatalities and hospitalizations to OSHA.

Exemptions and Accommodations. OSHA's rule calls for exemptions similar to those under the CMS rules, and the same considerations and potential inapplicability arise here. Tribal entities subject to OSHA's mandate should contact counsel about how to structure exemptions under the OSHA rule's language

Enforcement. As noted above, the Fifth Circuit has stayed the implementation of the OSHA rule. We, therefore, do not expect OSHA to take enforcement action until the pending litigation is resolved. In addition, we presume that, if and when the rule goes into effect, OSHA will use its standard enforcement mechanisms to enforce compliance with the rule as OSHA's rule does not discuss this issue in detail.