

Litigation Update:

On November 29, 2021, the United States District Court for the Eastern District of Missouri issued a preliminary injunction against the implementation and enforcement in ten states of Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). On November 30, 2021, the United States District Court for the Western District of Louisiana issued a nationwide preliminary injunction against the implementation and enforcement of the same rule, with the exception of the ten states covered under the first preliminary injunction. CMS has appealed both of these decisions, and has filed motions for stays of these order. While CMS remains confident in its authority to protect the health and safety of patients in facilities funded by the Medicare and Medicaid programs, it has suspended activities related to the implementation and enforcement of this rule pending future developments in the litigation. Please note that the comment period is separate from the litigation.

CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule

Basics

Q: When does this take effect?

A: The emergency regulation is effective as of November 5, 2021.

Q: Why is this rule being issued as an Interim Final Rule without going through notice and comment rulemaking?

A: Ensuring safety and protection from COVID-19 for anyone seeking care is the utmost priority. Given the rapidly evolving public health emergency, the increasing presence of the COVID-19 Delta variant, and the current instability within the health care system, CMS finds good cause to issue an emergency regulation as an Interim Final Rule allowing the agency to take immediate action to protect the health and safety of residents, clients, patients, and staff. Stakeholders will still have an opportunity to comment on the regulation.

Q: Will my feedback be considered?

A: Yes, stakeholders have 60 days to submit formal comment on the emergency regulation. It is important to note that since this is an emergency regulation, the requirements will go into effect immediately and before any additional response is provided on the comments by CMS. The comment period officially closes on January 4, 2022. At that point, CMS will consider and respond to comments as a part of potential future rulemaking, if needed.

Q: Is this a facility-specific or individual-level requirement?

A: The staff vaccination requirements apply to Medicare and Medicaid-certified provider and supplier types (collectively, “facilities”) that are regulated under the Medicare health and safety standards known as Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements. Facilities are required to have a process or policy in place ensuring that all applicable staff are vaccinated against COVID-19.

Q: What is a Condition of Participation?

A: Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation are foundational health and safety standards established by CMS to protect individuals receiving health care services from Medicare and Medicaid-certified facilities. These foundational health and safety standards cover 21 health care provider and supplier types. In order to participate in the Medicare and Medicaid programs, health care providers and suppliers must abide by these regulations.

Eligibility

Q: To which provider and supplier types does this apply?

A: The staff vaccination requirement applies to the following Medicare and Medicaid-certified provider and supplier types: Ambulatory Surgery Centers, Community Mental Health Centers, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, End-Stage Renal Disease Facilities, Home Health Agencies, Home Infusion Therapy Suppliers, Hospices, Hospitals, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities (PRTFs) Programs for All-Inclusive Care for the Elderly Organizations (PACE), Rural Health Clinics/Medicare Federally Qualified Health Centers, and Long Term Care facilities.

Q: Which staff are covered under this requirement?

A. This vaccination requirement applies to eligible staff working at almost all CMS-certified facilities that participate in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment, or other services for the facility and/or its patients. This includes facility employees, licensed practitioners, students, trainees, and volunteers. Additionally, this also includes individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements.

Q: Does this requirement apply to staff who work offsite?

A: Yes. These requirements are not limited to those staff who perform their duties solely within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities (e.g. home health, home infusion therapy, etc.). To ensure maximum patient protection, all staff who interact with other staff, patients, residents, clients, or PACE program participants in any location beyond the formal clinical setting (such as homes, clinics, other sites of care, administrative offices, off-site meetings, etc.) must be vaccinated.

Q: Does this requirement apply to full time teleworkers?

A: No. Individuals who provide services 100 percent remotely and who do not have any direct contact with patients and other staff, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements outlined in this regulation.

Q: Does this requirement apply to Indian Health Service (IHS) facilities?

A: Generally, yes. Indian Health Service facilities are regulated under the CoPs, therefore the staff vaccination requirement outlined within this regulation applies. Certain tribal FQHCs that do not participate in Medicare but only in Medicaid may not be subject to these requirements.

Q: Are any regulated provider or supplier types excluded?

A: Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs), and Portable X-Ray Suppliers are not included in these requirements. FQHCs that do not participate in Medicare are also not covered by these requirements.

RNHCIs do not furnish, on the basis of religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for their patients, but instead furnish only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing, and for whom the acceptance of medical services would be inconsistent with their religious beliefs (Note that the religious components of this type of healing services are not covered by CMS under this benefit; only nonmedical items and services provided exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients are covered).

For OPOs and Portable X-Ray Suppliers, it is important to note that the staff of these entities are indirectly included in the vaccination requirements through their service arrangements with hospitals, LTC facilities, and other providers and suppliers included under this rule. A service arrangement is when these providers have a contract with other providers to furnish services. That contract may require individuals from these organizations to be vaccinated.

Additionally, it is possible that entities not covered by this rule may still be subject to the other state or federal COVID-19 vaccination requirements, such as those being issued by the Occupational Safety and Health Administration (OSHA).

Q: Why didn't CMS include all health care settings?

A: CMS is using the authority established by Congress under the Social Security Act to regulate Medicare and Medicaid-certified health facilities. Sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services general authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged. Citations to the relevant statutory authorities for each specific type of provider and supplier are set out in the discussion of each provider- and supplier-specific provision of the regulation. This authority does not extend to certain facilities nor independent physicians/clinicians.

Scenarios

Q: Would a physician with admitting privileges in a hospital be covered under this requirement?

A: Yes, a physician admitting and/or treating patients in-person within a facility subject to the CMS health and safety regulations and included as a part of this requirement must be vaccinated so that the facility is compliant.

Q: What about Assisted Living Facilities, Group Homes, or other similar settings?

A: This regulation only applies to Medicare and Medicaid-certified facilities. CMS does not have regulatory authority over care settings such as Assisted Living Facilities or group homes. This regulation will also not apply to physician's offices because they are not subject to CMS health and safety regulations.

New as of 11/18/21 - Q: Are staff who work in Assisted Living Facilities required to be vaccinated if they also work in a nursing home?

A: Yes. While Assisted Living Facilities (ALFs) are not regulated by CMS and not directly subject to the Medicare Conditions of Participation, individuals who move between facilities (e.g. ALFs and nursing homes) and provide care, treatment, or other services for the certified nursing home and/or its residents under contract or arrangement must be vaccinated.

Q: Does this requirement apply to Medicaid home care services, such as Home and Community-based Services (HCBS), since these providers receive Medicaid funding but are not regulated as certified facilities?

A: No, this regulation only applies to those Medicare and Medicaid-certified provider and supplier types that are subject to CMS health and safety regulations. CMS's health and safety regulations do not cover providers of Home and Community-based Services.

Q: Does this requirement apply to schools receiving Medicaid funding?

A: No, this regulation only applies to those Medicare and Medicaid-certified provider and supplier types that are regulated under CMS health and safety regulations. CMS does not regulate schools.

New as of 11/18/21 - Q: Are emergency medical services (EMS) workers subject to the COVID-19 vaccination requirements?

A: EMS providers are not regulated by CMS health and safety standards; therefore, they are not directly subject to these requirements. Some EMS providers may be subject to the vaccination requirements by virtue of their professional relationship with a health care entity that is regulated by CMS. For example, a hospital may contract with EMS providers and therefore these staff would be included in the requirement. Additionally, an EMS provider may also provide non-emergency transportation for Long Term Care facility residents under contract. In that case, EMS staff would be subject to COVID-19 vaccination requirements in the IFC as applied to Long Term Care facility staff.

New as of 11/18/21 - Q: Do the new COVID-19 staff vaccination requirements apply to my therapy practice?

A: These requirements apply only to CMS-certified therapy providers, that is, an organization that operates in compliance with the Conditions of Participation as a Medicare-certified facility, not an individual therapist or group practice. [Certified provider types](#) include clinics, rehabilitation agencies, and public health agencies (referred to as providers of outpatient physical therapy and speech-language pathology services); comprehensive outpatient rehabilitation facilities (CORFs); Home Health Agencies (HHAs); hospices; an outpatient departments of hospitals; Critical Access Hospitals (CAHs); and Skilled Nursing Facilities (SNFs). These requirements do not apply to non-certified therapy providers, such as therapists in private practice or group practices (commonly referred to as Therapists in Private Practice (TPPs)).

These TPPs are treated in a manner similar to physician offices and practices. TPPs may closely resemble CMS-certified outpatient therapy providers and it is difficult to differentiate between the two without knowing how each is enrolled in Medicare. Outpatient therapy providers are certified providers that receive a survey from the State Agency (SA) or a CMS-approved Accrediting Organization (AO) as part of the enrollment process. Upon completion of enrollment, outpatient therapy providers receive a CMS Certification Number, or CCN, that the organization uses to bill Medicare for services furnished. TPPs in Medicare are not surveyed as an outpatient therapy provider and are issued a Provider Transaction Access Number (PTAN) for Medicare billing purposes. Therapists may also reassign their benefit to another professional or TPP (therapist, physician, or group practice) to allow them to bill for them and may work in a physician practice.

If you are enrolled in Medicare and the enrollment included a survey by a SA or AO because you enrolled as a CMS-certified therapy provider such as a provider of outpatient physical therapy and speech language pathology services and you have a CCN instead of a PTAN, the COVID-19 vaccination requirements apply to all applicable staff in the organization. If your Medicare enrollment resulted in a PTAN, not a CCN, you are not a certified provider and the COVID-19 vaccination requirements do not apply, although CMS encourages all individuals who work with patients to receive vaccinations, whether or not they are subject to this regulation.

New as of 11/18/21 - Q: Does this requirement apply to pharmacies that go onsite to covered facilities?

A: Yes. This vaccination requirement covers all individuals who provide care, treatment, or other services for any Medicare or Medicaid facility subject to this rule (and/or its patients) under contract or other arrangements.

New as of 11/18/21 - Q: Does this requirement apply to visitors?

A: The staff vaccination requirements apply to Medicare and Medicaid-certified facilities that are regulated under the Medicare health and safety standards known as Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements. Facilities are required to have a process or policy in place ensuring that all applicable staff are vaccinated against COVID-19. This requirement does not apply to personal visitors such as family members or friends; however, it does apply to contractors that visit the facility on a regular basis. CMS strongly encourages all individuals and families to get vaccinated now.

Requirements

Q: How quickly must staff be vaccinated in order for the facility to remain compliant with the regulation?

A: The regulation requires health care providers to establish a process or policy to fulfill the staff vaccination requirements over two phases. For Phase 1, within 30 days after the regulation is published, staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients. For Phase 2, within 60 days after the regulation is published, staff at all health care provider and supplier

types included in the regulation must complete the primary vaccination series(except for those who have been granted exemptions from the COVID-19 vaccine or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC).

Q. How does CMS define “fully vaccinated” for the purposes of this requirement?

A. For purposes of this regulation, CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, staff who have who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined in the rule as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine). Additionally, staff who receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the FDA or as a part of a clinical trial are also considered to have completed the vaccination series in accordance with CDC guidelines.

Q. Which vaccines count toward the requirement?

A. CMS expects that staff will receive a vaccine licensed or authorized for emergency use by the Food and Drug Administration (FDA), which currently includes the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty vaccine), Moderna COVID-19 Vaccine, and the Janssen (Johnson & Johnson) COVID-19 Vaccine. Facilities will also be in compliance if they allow staff to work who received a vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or who received a vaccine during their participation in a clinical trial.

Q. What if one of my staff received a vaccine outside of the United States?

A. CMS expects that vaccine administration will occur within the United States for the majority of staff and that individuals will receive a COVID-19 vaccine authorized for emergency use or licensed by the FDA, however it is permissible to receive a COVID-19 vaccine outside of the United States. Eligible COVID-19 vaccinations administered to staff outside of the United States include those that are FDA licensed or authorized for emergency use or those that are listed by the WHO for emergency use.

Q: Does “fully vaccinated” include additional doses or booster shots? For example, a third dose of mRNA vaccines is now recommended for individuals who are immunocompromised, and boosters are recommended or available for individuals who are 65 or older? Does a completed vaccine series include additional doses or boosters?

A: For purposes of this regulation, CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, staff who have who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined in the rule as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of

all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine). FDA has approved, and CDC has recommended, boosters for certain groups that previously completed a primary vaccination series. Because the science and clinical recommendations around additional doses and boosters is evolving rapidly, we refer individuals to CDC's [*Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*](#) for additional details.

Furthermore, to improve immune response for those individuals with moderately or severely compromised immune systems who received either the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine, CDC advises an additional (third) dose after completing the primary vaccination series. Additionally, and for the purposes of this rule, documented receipt of additional or booster doses is not needed for staff who have completed a COVID-19 primary vaccination series authorized or licensed by the FDA, or listed by the WHO for emergency use. Staff who have not received all manufacturer recommended doses of a vaccine listed for emergency use by the WHO may receive an FDA licensed or authorized COVID-19 vaccination series.

Q: What if one of my staff received a vaccine that is not FDA approved or authorized and is not listed by the WHO for emergency use?

A: Staff who have received a COVID-19 vaccination neither licensed or authorized by the FDA nor listed on the WHO emergency use list may receive an FDA licensed or authorized vaccination series. Per CDC guidelines, staff in this category should wait at least 28 days following the last dose of a non-FDA approved or authorized and non-WHO-listed vaccination to begin a new series. Staff should consult with their doctor or other health care provider if they have questions about their vaccination.

Q: What if one of my staff participated in a clinical trial?

A: According to the CDC, no additional doses are needed for staff who participated in a clinical trial at a site in the U.S. and received the full series of an “active” vaccine candidate (not placebo) and vaccine efficacy has been independently confirmed (by a data and safety monitoring board). Staff should consult with their doctor or other health care provider if they have questions about their vaccination.

Q: What if one of my staff received a mix of vaccines as part of their COVID-19 primary vaccination series? Does that count toward the vaccination requirement?

A: COVID-19 vaccines are not interchangeable. Therefore, individuals should generally avoid using heterologous vaccines—meaning receiving doses of different vaccines—to complete a primary COVID-19 vaccination series. Nevertheless, CDC does recognize that, in [*certain exceptional circumstances*](#) (e.g., when the vaccine product given for the first dose cannot be determined or is no longer available), a different vaccine may be used to complete the primary COVID-19 vaccination series. Accordingly, staff may be considered compliant with the requirements within this regulation if they have received any combination of two doses of a vaccine licensed or authorized by the FDA or listed on the WHO emergency use list as part of a two-dose series. Of note, the recommended interval between the first and second doses of a vaccine licensed or authorized by FDA, or listed on the WHO emergency use list, varies by

vaccine type. To be compliant with this requirement, the second dose in a two-dose mixed vaccine series must have been received no earlier than 28 days after the first dose.

Q. Will there be different requirements for existing staff versus new staff?

A. No. Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by the regulatory deadline, or prior to providing any care, treatment, or other services for the facility and/or its patients.

***New as of 11/18/21* - Q: What are the documentation requirements for staff vaccinations? Are these the same for vendors?**

A: As noted in the rule, this vaccination requirement generally applies to eligible staff working at a CMS-certified facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment, or other services for the covered facility and/or its patients. This also includes facility employees, licensed practitioners, students, trainees, and volunteers. Additionally, individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements must be vaccinated.

Regulated facilities included within this requirement must have a process or plan in place for documenting and tracking staff vaccinations. All COVID-19 vaccinations must be appropriately documented by the facility, which could be in a facility's immunization record, health information files, or other relevant documents. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files. Acceptable forms of proof of vaccinations include: 1) CDC COVID-19 vaccination record card (or legible photo of the card), 2) documentation of vaccination form a health care provider or electronic health record, or 3) state immunization information system record. Ultimately, it is up to the facility to ensure that it has a process or plan in place for capturing COVID-19 vaccination status for all staff, including individuals who provide services under contract or other arrangements. Of note, facilities are not required to ensure vaccination of vendors, volunteers, or professionals who infrequently provide ad hoc, non-health care services (e.g. annual elevator inspection) or services that are performed exclusively offsite and not at or adjacent to any site of patient care (such as accounting services).

Q: Does the regulation include testing requirements for unvaccinated staff?

A: No, this regulation requires staff vaccination only. While CMS considered requiring daily or weekly testing of unvaccinated individuals, scientific evidence on testing found that vaccination is a more effective infection control measure. CMS will continue to review the evidence and stakeholder feedback on this issue. However, facilities may voluntarily utilize testing alongside other infection prevention measures, such as physical distancing and source control. Of note, CMS published an emergency regulation in September 2020 that established new requirements for Long Term Care (LTC) facilities (nursing homes) to test facility residents and staff for COVID-19. CMS requires continued compliance with this requirement. Additionally, CMS encourages facilities not covered under this regulation to review the OSHA Emergency Temporary Standard for separate vaccination and testing requirements.

Q: Does this regulation establish any new data reporting requirements?

A: No, this regulation does not establish any new data reporting requirements. However, hospitals and LTC facilities (nursing homes) are expected to continue complying with their facility-specific data reporting requirements set forth in the emergency regulations issued by CMS in May 2020, August 2020, and May 2021, respectively. Additionally, facilities participating in the Inpatient, PPS-Exempt Cancer, Long Term Care Hospital, Inpatient Rehabilitation, and Inpatient Psychiatric Quality Reporting Programs must collect data on the new COVID-19 Vaccination Coverage among Health Care Professionals measure from October 1, 2021 to December 31, 2021 and quarterly thereafter.

Exemptions

Q: Are exemptions allowed?

A: CMS requires facilities to allow for exemptions to staff with (as a reasonable accommodation for a disability or a sincerely held religious belief, observance, or practice and for medical reasons. Providers and suppliers should establish exceptions as a part of its policies and procedures and in alignment with Federal law. CMS believes that exemptions could be appropriate in certain limited circumstances, but no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII of the Civil Rights Act of 1964) or who requests an exemption solely to evade vaccination.

Q: Is there provision for certain individuals for whom a vaccination should be delayed, for example, because of a recent COVID-19 diagnosis?

A: Yes. The regulation addresses staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations,

Q: Does the regulation include exemptions for staff that show they have COVID-19 antibodies?

A: No. Staff who have previously had COVID-19 are not exempt from these vaccination requirements. Available evidence indicates that COVID-19 vaccines offer better protection than natural immunity alone and that vaccines, even after prior infection, help prevent reinfections. CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.

Q: How will facilities determine if an individual's request for a religious exemption is valid?

A: CMS encourages facilities to review the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination for more information on religious exemptions.

Q: What is the process for staff to seek a religious exemption?

A: Facilities have the flexibility to establish their own processes that permit staff to request a religious exemption from the COVID-19 vaccination requirements. CMS requires facilities to ensure that requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of a facility's policies and procedures.

Q: What is the process for staff to seek a medical exemption?

A: Similar to religious exemptions, facilities have the flexibility to establish their own processes that permit staff to request a medical exemption from the COVID-19 vaccination requirements. Facilities must ensure that all documentation confirming recognized clinical contraindications to COVID-19 vaccinations for staff seeking a medical exemption are signed and dated by a licensed practitioner, who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. This documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications. Additionally, a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements is also expected.

Q. How do accommodations work for staff members who meet the requirements for an exemption and are not vaccinated?

A. The regulation requires that facilities develop a process for implementing additional precautions for any staff who are not vaccinated, in order to mitigate the transmission and spread of COVID-19. Under federal law, including the ADA and Title VII of the Civil Rights Act of 1964, individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practice, or observance may be entitled to an accommodation. CMS encourages facilities to review the Equal Employment Opportunity Commission's website for additional information about situations that may warrant accommodations. In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients.

Enforcement

Q: How will this new requirement be enforced on facilities?

A: CMS works directly with the state survey agencies to regularly review compliance with Medicare/Medicaid regulations across multiple health care settings.

CMS expects state survey agencies to conduct onsite compliance reviews of these requirements in two ways:

- State survey agencies would assess all facilities for these requirements during the standard recertification survey.
- State survey agencies would assess vaccination status of staff on all complaint surveys.

While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last 4 weeks, and a list of all staff and their vaccination status. This information, in addition to interviews and observations, will be used to determine the compliance of the provider or supplier with these requirements.

Additionally, Accrediting Organizations will be required to update their survey processes to assess facilities they accredit for compliance with vaccination regulations.

Q: How do the penalties work/are providers immediately denied payment?

A: Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure. The remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination; however, CMS’s goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

Q. What opportunities are available to return to compliance for hospitals and other acute and continuing care providers?

A. CMS surveyors cite hospitals and other facilities based on the severity of deficiency, classified among three levels, from most to least severe: “Immediate Jeopardy”, “Condition”, and “Standard.” In all cases, health care facilities have an opportunity to return to compliance before termination.

- “Immediate Jeopardy” citations indicate a serious scope of non-compliance, failure of the provider to address deficiencies, and close interaction with patients of unvaccinated staff. Termination of the provider type will occur within 23-days following the citation if not immediately addressed.
- “Condition” level citations indicate substantial non-compliance that needs to be addressed to avoid termination.
- “Standard” level citations indicate minor non-compliance where (with respect to this rule) almost all staff are vaccinated, the provider has a reasonable policy in place to educate staff on the vaccinations, and the provider has procedures for tracking and monitoring vaccination rates. CMS generally allows for continued operation subject to the facility’s agreement to a CMS-approved plan of correction.

Q: Is CMS planning to use the new COVID-19 Vaccination Coverage among Health Care Personnel (HCP) quality measure to monitor compliance?

A: No. Providers participating in the Inpatient, PPS-Exempt Cancer Hospital, Long Term Care Hospital, Inpatient Psychiatric, and Inpatient Rehabilitation Quality Reporting Programs are expected to report on the new COVID-19 Vaccination Coverage among Health Care Personnel quality measure from October 1, 2021 to December 31, 2021 as established in the various Fiscal Year 2022 payment rules. While this quality measure will provide valuable insight into the number of staff vaccinated over the course of a three-month period, CMS will continue to ensure compliance with the new staff vaccination requirement through the established survey process. As data become available, CMS will continue to evaluate opportunities to inform the survey process.

Alignment with OSHA Emergency Temporary Standard

Q: How does the CMS staff vaccination requirement interact with OSHA requirements on this issue?

A: On June 21, 2021, the Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) to protect health care and health care support service

workers from occupational exposure to COVID-19. Under OSHA regulations at 29 CFR Subpart U (86 FR 32376), covered health care employers must develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace and implement requirements to reduce transmission of COVID-19 in their workplaces related to the following: patient screening and management, standard and transmission-based precautions, personal protective equipment (facemasks, respirators), controls for aerosol-generating procedures, physical distancing of at least six feet when feasible, physical barriers, cleaning and disinfection, ventilation, health screening and medical management, training, anti-retaliation, recordkeeping, and reporting. The OSHA ETS encourages vaccination by requiring employers to provide reasonable time and paid leave for employee vaccinations and any side effects. The OSHA ETS exempts certain settings including, but limited to (1) non-hospital ambulatory care settings where all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are prohibited from entry, (2) well-defined hospital ambulatory care settings where all employees are fully vaccinated and individuals with possible COVID-19 are prohibited from entry, and (3) home health care settings where all employees are fully vaccinated and there is no reasonable expectation that individuals with COVID-19 will be present.

In early November, OSHA issued a second emergency temporary standard requiring worker vaccinations for any employers with 100 or more employees or weekly testing for those who remain unvaccinated without an eligible exemption. CMS worked closely with OSHA to ensure that both regulations were complementary, ensured maximum coverage of staff/workers across a multitude of settings, and were not overly duplicative.

Interaction with State Law

Q: What happens if State law prohibits vaccine mandates? How can CMS expect a facility to follow its requirements if its State prevents them from implementing this rule?

A: Under the Supremacy Clause of the U.S. Constitution, this regulation pre-empts any state law to the contrary. U.S. Const. art. VI § 2.

Q: Which rule is a given health care facility expected to follow – the CMS Omnibus Staff Vaccination Rule, the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors, the OSHA COVID-19 Healthcare Emergency Temporary Standard, or the upcoming (or new) OSHA Emergency Temporary Standard?

A: If a Medicare- or Medicaid-certified provider or supplier falls under the requirements of CMS's Omnibus Staff Vaccination Rule, it should look to those requirements first. Health care facilities are generally subject to new federal vaccination requirements based on primacy.

If facilities participate in and are certified under the Medicare and Medicaid programs and are regulated by the CMS health and safety standards known as the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation, then they are expected to abide by the requirements established in the CMS Omnibus Staff Vaccination Rule. This rule takes priority above other federal vaccination requirements. CMS's oversight and enforcement will exclusively monitor and address compliance for the provisions outlined in the CMS Omnibus Staff Vaccination Rule, while also continuing to monitor for proper infection control procedures as established under previous regulations.

There are rare situations where the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or the OSHA COVID-19 Healthcare Emergency Temporary Standard may also apply to staff who are not subject to the vaccination requirements outlined in the CMS Omnibus Staff Vaccination Rule. Facilities should review these regulations and comply with any other federal requirements as necessary.

If facilities are not certified under the Medicare and Medicaid programs and therefore not regulated by the CoPs, **then** the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or OSHA COVID-19 Healthcare Emergency Temporary Standard apply.

The OSHA COVID-19 Employer Emergency Temporary Standard (for facilities with greater than 100 employees) applies to employers that are not subject to the preceding two regulations. Facilities should review the inclusion criterion for these regulations and comply with all applicable requirements.

It's important to understand that all federal entities, including CMS, OSHA, and others, worked closely together to ensure that all requirements were complementary, ensure maximum coverage of staff across settings, and were not overly duplicative.