

CMS AND OSHA COVID-19 VACCINATION AND TESTING UPDATES

November 10, 2021

On Thursday, November 4, 2021, the Centers for Medicare and Medicaid Service (“CMS”) [announced](#) the issuance of emergency regulations that will require many healthcare providers who participate in Medicare and Medicaid to ensure that their staff is fully vaccinated against COVID-19. These regulations went into effect on November 5, 2021.

CMS UPDATES

CMS expects the [regulations](#) to cover approximately 76,000 providers and over 17 million health care workers throughout the country. Specifically, the regulations will apply to the following facilities that are regulated under Medicare health and safety standards known as Conditions of Participation (“CoPs”), Conditions for Coverage (“CfCs”), or Requirements:

- Ambulatory Surgical Centers;
- Hospices;
- Programs of All-Inclusive Care for the Elderly;
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children’s hospitals, transplant center, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities);
- Long Term Care facilities, including Skilled Nursing Facilities and Nursing Facilities;
- Psychiatric Residential Treatment Facilities;
- Intermediate Care Facilities for Individuals with Intellectual Disabilities;
- Home Health Agencies;
- Comprehensive Outpatient Rehabilitation Facilities;
- Critical Access Hospitals;
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services;
- Community Mental Health Centers;
- Home Infusion Therapy suppliers;
- Rural Health Clinics/Federally Qualified Health Centers; and
- End-Stage Renal Disease Facilities.

The regulations do not apply to Religious Nonmedical Health Care Institutions, Organ Procurement Organizations (“OPOs”), or Portable X-Ray Suppliers. However, CMS notes that individuals employed with OPOs and Portable X-Ray Suppliers may still be subject to vaccination requirements under their arrangements with hospitals, Long Term Care facilities, and other providers and suppliers or be covered by other state or federal vaccination requirements.

Covered facilities must ensure that all “staff” are fully vaccinated for COVID-19. Staff is broadly defined to include employees; licensed practitioners (including physicians with admitting privileges in a facility subject to CMS health and safety regulations); students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the entity and/or its patients, under contract or by other arrangements. However, CMS’s new policies and procedures do not apply to staff who exclusively provide telehealth or telemedicine outside of the facility and do not have any direct contact with patients, patient families and caregivers, or other staff; nor do CMS’s requirements apply to staff who provide support services outside of the entity and do not have any direct contact with patients, patient families and caregivers, or other staff. Staff members are considered “fully vaccinated” two weeks after they have received “a primary vaccination series” consisting of a single-dose vaccine or all doses of a multi-dose vaccine. CMS is not currently considering additional vaccine doses or booster shots for the purposes of determining full vaccination status.

CMS vaccination requirements will be implemented in two phases. Phase I requires that covered individuals receive their first vaccination and that covered facilities have developed policies and procedures regarding COVID-19 vaccinations by **December 6, 2021**. Phase II, which goes into effect on **January 4, 2022**, requires that covered individuals have completed a full vaccination series. For the purposes of this deadline, CMS does not require that individuals have completed their 14-day post-vaccination period necessary to be considered fully vaccinated. CMS notes that covered staff members may be exempt from these deadlines under the following circumstances:

- They have received a medical exemption. To obtain a medical exemption, individuals must provide certification from a licensed practitioner, other than the person requesting the exemption, acting within their scope of practice that a) identifies the recognized clinical reasons for contraindications to the vaccine and b) includes a statement recommending the staff member be exempted from the COVID-19 vaccination requirement because of these clinical contraindications.
- They have received an exemption under the ADA or Title VII that requires employers to provide reasonable accommodations for employees based on a disability or sincerely held religious belief, practice, or observance, unless providing an accommodation would impose an undue hardship on the employer’s business. A discussion of the EEOC’s recent guidance on COVID-19 vaccination religious accommodations can be found [here](#).
- They are subject to a temporary delay in vaccination, as recommended by the CDC, because of clinical precautions and considerations, including acute illness secondary to COVID-19, and individuals who recently received monoclonal antibodies or convalescent plasma for COVID-10 treatment.

Covered facilities must include, at a minimum, the following policies and procedures:

- A process for ensuring that all staff, except those with pending or granted exemptions, or those for whom vaccination must be temporarily delayed, as recommended by the CDC, because of clinical precautions and considerations, have received at least a single-dose COVID-19 vaccine or the first dose of a multi-dose vaccine before providing any services;
- A process for ensuring that all staff are fully vaccinated, except those who have been granted an exemption or those for whom vaccination must be temporarily delayed, as recommended by the CDC, because of clinical precautions and considerations;
- A process for ensuring the implementation of additional precautions to mitigate the transmission of COVID-19 for all staff who are not fully vaccinated;
- A process for tracking and securely documenting the COVID-19 vaccination status of all staff;
- A process for tracking and securely documenting the COVID-19 vaccination status of all staff who have obtained booster doses as recommended by the CDC;
- A process by which staff may request an exemption from the COVID-19 vaccination requirements based on federal law;
- A process for tracking and securely documenting the information provided by staff who have requested and been granted an exemption to the COVID-19 vaccination requirements;
- A process for ensuring that all documentation supporting clinical contraindications to COVID-19 vaccinations and requests for medical exemptions from vaccination has been signed and dated by a licensed practitioner, other than the individual requesting the exemption, who is acting within their scope of practice, and contains:
 - All information specifying which of the COVID-19 vaccinations are clinically contraindicated for the staff member and the recognized clinical reasons for the contraindications; and
 - A statement from the authenticating practitioner recommending that the staff member be exempted from the COVID-19 vaccination requirement based on the recognized clinical contraindications;
- A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom the COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations; and
- Contingency plans for staff who are not fully vaccinated for COVID-19.

CMS intends to monitor compliance with these regulations through a survey and enforcement process. State survey agencies will assess all facilities for these requirements during the standard recertification survey and will assess the vaccination status of staff on all complaint surveys. While onsite at facilities, surveyors will review the facilities' COVID-19

vaccination policies and procedures, the number of COVID-19 cases among residents and staff over the last four (4) weeks, and lists of all staff and their vaccination status. Surveyors will also conduct interviews with staff members to verify their vaccination status. CMS notes that it will cite facilities not in compliance with these COVID-19 vaccination requirements, but those facilities will generally be given an opportunity to come into compliance before termination from Medicare and Medicaid programs. As [stated](#) by a White House Senior Administrative Official, “CMS’s goal is to bring health care providers into compliance; it is not to punish workers or health care facilities. However, we will not hesitate to use our full enforcement authority to protect the health and safety of patients.”

OSHA UPDATES

In conjunction with CMS’s new regulations, the Department of Occupational Safety and Health (“OSHA”) also simultaneously released an [emergency temporary standard](#) (“ETS”)—a form of regulation that takes effect immediately to address “grave dangers”—that mandates large employers require workers be vaccinated against COVID-19 or undergo testing at least once a week. It remains to be seen whether this regulation will take effect as litigation is pending to enjoin the ETS. The guidance below is provided in the event the courts allow implementation of the rules.

The OSHA rule applies to employers with a hundred (100) or more employees, including part-time workers, but not independent contractors. This rule **will not apply** to facilities that are required to comply with CMS’s new rule (or those covered by guidance for federal contractors and subcontractors).

Under this new rule, covered employers must:

- *Establish, implement, and enforce a written mandatory vaccination policy.* Employers may choose to establish a written policy that allows employees to undergo regular COVID-19 testing and wear a face covering, as described below, instead of receiving a vaccine. Additionally, employees may be exempt from vaccination under the ADA or Title VII, or because vaccination is medically contraindicated, or because medical necessity requires a delay in vaccination.
- *Determine the vaccination status of all employees.* This includes requiring vaccinated employees to provide proof of vaccination, such medical or immunization records, and maintaining records and acceptable proof of vaccination.
- *Support employee vaccination* by allowing employees reasonable time off to obtain a vaccination, including up to four hours (including travel time) of paid leave. Employers must also provide reasonable time and paid sick leave for employees to recover after each primary vaccination dose.
- *Ensure that employees who are not fully vaccinated and work in a workplace where other individuals, including coworkers or customers are present, undergo COVID-19 testing at least once every seven (7) days* and provide documentation of testing to the employer. An employee who does not report during a period of seven (7) or more days to a workplace where other individuals, such as coworkers or customers, are present must be tested within seven (7) days of returning to the workplace and provide documentation of that test result to their employer. OSHA notes that this section does not require employers to pay for testing, but that employers may be required to do so by other laws, regulations, or collectively negotiated agreements. Additionally, employers are not prohibited

from paying for the costs associated with testing. Virginia law requires employers to pay for the cost of required medical examinations. [Va. Code § 40.1-28](#).

- *Require employees to notify their employer of a positive COVID-19 test and immediately remove employees who have tested positive* until (1) the employee receives a negative nucleic acid amplification test (NAAT) following a positive COVID-19 antigen test; (2) the employee meets the return to work criteria in the CDC's "[Isolation Guidance](#);" or (3) the employee receives a recommendation to return to work from a licensed healthcare provider. This section does not require employers to provide paid time off for employees, but such time may be required by other laws, regulations, or negotiated agreements.
- *Ensure that employees who are not fully vaccinated wear a face covering when indoors and occupying a vehicle with other people for work purposes*, except: (1) when employees are alone in a room with floor to ceiling walls and a closed door; (2) for a limited time when employees are eating or drinking or for identification purposes in compliance with safety and security requirements; (3) when employees are wearing a respirator or facemask; or (4) when employers can show that the use of face coverings is infeasible or creates a hazard that would excuse compliance. OSHA notes that employers must not prevent employees from voluntarily wearing a face covering unless the employer can demonstrate that it would create a hazard of serious injury or death. Employers must also permit employees to wear a respirator instead of a facemask and must not prohibit customers or visitors from wearing face coverings. This section does not preclude employers from requiring customers or visitors to wear face coverings. Lastly, this section does not require employers to pay for face coverings, but employers may be required to do so by other laws, regulations, or collectively negotiated agreements; employers are not prohibited from paying for such costs.
- *Inform employees in a language and at a literacy level the employees understand about*: (1) the requirements of OSHA's ETS, as well as the employer's implemented policies and procedures; (2) COVID-19 vaccination efficacy, safety, and the benefits of being vaccinated by providing the document "[Key Things to Know About COVID-19 Vaccines](#);" (3) certain employee protections, including protections against discharge and discrimination for reporting a work-related illness; and (4) prohibitions that provide for criminal penalties for knowingly supplying false statements or documentation.
- *Report COVID-19 fatalities and hospitalizations to OSHA*. Employers are required to report work-related COVID-19 fatalities within eight (8) hours of learning of them and work-related in-patient hospitalizations within twenty-four (24) hours of learning about them.
- *Make available* for examination and copying (within one (1) business day of a request) an employee's COVID-19 vaccination documentation and any COVID-19 test results to that employee or an individual who has written authorized consent from the employee. Employers must also make available the aggregate number of fully vaccinated employees in the workplace and the total number of employees in the workplace. When requested by the Assistant Secretary, employers must provide, within four hours of a request, the employer's written policy and these numbers; and, by the end of the next business day, all other records and documentation required to be maintained by this ETS.

Employers are required to [comply](#) with the majority of these provisions by **December 6, 2021**. Employers have until **January 4, 2022**, to ensure that employees who are not fully vaccinated are tested for COVID-19 at least weekly or within seven (7) days of returning to work. Employers who fail to comply with the ETS may be subject to fines of up to \$13,653 per violation and ten times that for willful or repeated violations.

Answers to frequent questions regarding this ETS can be found on OSHA's [website](#).

CONCLUSION

At this time, the Fifth Circuit has [temporarily halted](#) OSHA's vaccine mandate. However, this temporary injunction does not apply to CMS's emergency regulations. While the outcome of any challenges to these new requirements remains to be seen, we recommend that employers carefully review CMS's and OSHA's vaccine mandates to determine if they apply to the employer and to prepare to comply with the applicable requirements. Employers should note that CMS's and OSHA's requirements both preempt any contrary state or local laws.

If you have questions or need assistance regarding compliance with these vaccine requirements and other employment laws, please contact a member of Hancock Daniel's [Labor & Employment](#) team. For any other concerns arising from the pandemic, please contact a member of our COVID-19 Task Force.

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