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Vaccine Mandate FAQs for Health Care Organizations: Understanding How the OSHA Emergency Standards and the CMS Vaccine Mandate Work Together (Updated)

Legal Update

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Update: On December 15, 2021, the nationwide injunction stopping the federal government from enforcing the CMS Vaccine Mandate was partially lifted by the Fifth Circuit Court of Appeals. While CMS could choose to enforce the CMS Vaccine Mandate in states where it is no longer enjoined, the agency has not yet revised its earlier statement that, pending further developments in the litigation, it would not enforce the mandate anywhere in the nation.

The CMS Vaccine Mandate is currently enjoined in 25 total states: in ten states (Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota and Wyoming) pursuant to a preliminary injunction issued by the U.S. District Court for the Eastern District of Missouri on November 29, 2021; in 14 states (Alabama, Arizona, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah and West Virginia) pursuant to a preliminary injunction issued by the U.S. District Court for the Western District of Louisiana on November 30, 2021; and in the state of Texas pursuant to a preliminary injunction issued by the U.S. District Court for the Northern District of Texas on December 15, 2021. The Biden administration's efforts to lift the injunction in these 25 states have been unsuccessful, and now the administration's request is pending before the U.S. Supreme Court, which will hear oral arguments on January 7, 2022.

The CMS Vaccine Mandate is not currently enjoined – i.e., it could be enforced by CMS—in California, Colorado, Connecticut, Delaware, (District of Columbia), Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington and Wisconsin.

CMS has opted to maintain its position of not enforcing the mandate anywhere in the nation. It could potentially change this determination at any time with respect to covered facilities in the 25 states that are not subject to a preliminary injunction. However, there is speculation that if CMS changes its enforcement position, the agency will set new compliance dates for affected facilities. We encourage clients in all states to continue preparing to comply with the CMS Vaccine Mandate in case

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the preliminary injunctions are reversed or CMS opts to proceed with implementation and enforcement of the mandate in states where the injunctions do not apply.

On January 7, 2022, in addition to its consideration of the CMS Vaccine Mandate, the U.S. Supreme Court will also hear oral arguments with respect to an appeal of a recent decision by the Sixth Circuit Court of Appeals lifting the nationwide injunction against enforcement of the November 2021 OSHA ETS, which requires vaccination or testing and masking for employers with 100 or more employees. For more information on the status of the November 2021 OSHA ETS, please reference the article released by our colleagues in the Employment & Labor Group.

Fredrikson & Byron is monitoring these cases and will continue to inform clients of major developments.

Update: As of November 30, 2021, implementation and enforcement of the CMS COVID-19 Vaccine Mandate has been temporarily halted in all 50 states.

On November 29, 2021, the U.S. District Court for the Eastern District of Missouri issued a preliminary injunction enjoining the federal government from implementing and enforcing the CMS Vaccine Mandate in ten states. See the court's memorandum and order. The next day, November 30, 2021, the U.S. District Court for the Western District of Louisiana issued a similar preliminary injunction that applies to the rest of the country. See the court's order and memorandum ruling.

*In other words, pending further litigation, regulators **may not** enforce the CMS Vaccine Mandate against hospitals and other covered facilities anywhere in the nation. Nonetheless, we encourage clients in all states to continue preparing to comply with the CMS Vaccine Mandate in the event the preliminary injunctions are reversed, though this is unlikely to occur before the original implementation deadline of December 6, 2021.*

Moreover, these rulings do not prohibit an employer from independently imposing vaccination requirements on its employees. In the absence of a federal mandate, employers should look to applicable state law regarding vaccination requirements and accommodations. Several courts around the country have upheld health care organizations' employee vaccine mandates, and the U.S. Supreme Court recently declined to hear a group of plaintiff employees seeking to prevent their hospital employer from imposing vaccination requirements on employees.

Fredrikson & Byron is monitoring these cases and will continue to inform clients of major developments.

You have likely heard about various vaccine mandates and OSHA's COVID-19 workplace safety precautions and may be confused as to what they are and whether they apply to your organization. These FAQs provide information about the CMS Vaccine Mandate and clarity around the overlap between it and the various OSHA

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Emergency Temporary Standards. We are also closely monitoring the legal challenges to the November OSHA ETS and the CMS Vaccine Mandate (see FAQ 10).

1. What terms/acronyms do I need to know?

- **The Centers for Medicare and Medicaid Services (CMS).**
- **The Occupational Safety and Health Administration (OSHA).**
- **June 2021 OSHA COVID-19 Healthcare Emergency Temporary Standard (June OSHA ETS).** This Emergency Temporary Standard (ETS) **does not require vaccination.** See more information from OSHA and the regulatory text.
- **November 2021 OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard (November OSHA ETS).** This ETS requires vaccination or testing and masking for employers with 100 or more employees. See more information from OSHA and the regulatory text and the agency's preamble commentary to the interim final rule.
- **CMS Omnibus COVID-19 Health Care Staff Vaccination (CMS Vaccine Mandate).** This regulation requires vaccination. See the regulatory text and the agency's preamble commentary to the interim final rule and the agency FAQs.

2. What is the background of these OSHA and CMS regulations?

In June 2021, OSHA promulgated emergency temporary regulations applying to all workplace settings where any employee provides health care services or health care support services and designed to protect workers from COVID-19. Referred to here as the June OSHA ETS, this regulation does *not* include a vaccine mandate for employees. Rather, it requires health care settings to implement a multi-layered policy and system of protections and precautions against COVID-19, including masking, social distancing, ventilation, cleaning and disinfection, physical barriers, etc. There are several exceptions to the June OSHA ETS that many health care organizations have chosen to follow to avoid having to implement the multi-layered protections.

The CMS mandate was promulgated on November 5, 2021, and requires vaccination for health care workers at certain facilities that have regulatory Conditions of Participation and Conditions of Coverage (a complete list of facilities to which the CMS mandate applies is below at FAQ 3; *note* that Medicare suppliers like freestanding physician offices do NOT have these Conditions of Participation or Conditions of Coverage and thus are not subject to the CMS Vaccine Mandate). OSHA also promulgated a vaccine-or-test mandate on November 5, 2021, referred to here as the November OSHA ETS, that requires mandatory vaccination or masking and regular testing of employees. The November OSHA ETS applies generally to employers with 100 or more employees.

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Now, many health care organizations are rightly questioning which, if any, vaccine mandate and/or OSHA COVID-19 safety standards apply to them. The two questions to ask if you are a health care organization are, first, is my organization regulated by the CMS Vaccine Mandate, and second, if my organization is not subject to the CMS Vaccine Mandate but has 100 or more employees, must it comply with the November OSHA ETS vaccine-or-test mandate, or is it excepted from the November OSHA ETS because it complies with the multi-layered safety precautions required by the June OSHA ETS (which does not mandate vaccines).

FAQ 3 lists the facilities to which the CMS Vaccine Mandate applies. As explained in further detail in FAQ 4, most health care settings are required to comply with the June OSHA ETS, but there are exceptions. *If your organization relies on an exception to the June OSHA ETS (e.g., you are a non-ambulatory care setting that screens all visitors to your building and denies entry to people who are COVID-19 suspected or confirmed), rather than requiring masking, distancing and the other safety requirements in the June OSHA ETS, and if you have 100 or more employees, then you must require employee vaccination under the November OSHA ETS.*

(NOTE: For organizations that are subject to the CMS Vaccine Mandate, the June OSHA ETS continues to apply, unless you meet an exception. In the preamble commentary to the interim final rule for the CMS Vaccine Mandate, CMS stated that “providers and suppliers may be covered by both the [June OSHA ETS] and our interim final rule. Although the requirements and purpose of each regulation text are different, they are complementary.”)

It is worth noting that there is a vaccine mandate for businesses who have certain contracts with the federal government that we will not address in these FAQs. Contact Nena Lenz at Fredrikson for specific information on the federal contractor vaccine mandate. Note that merely participating in the Medicare or Medicaid programs is NOT considered to be contracting with the federal government for purposes of the federal contractor vaccine mandate.

3. What types of health care organizations does the CMS Vaccine Mandate apply to?

The reach of the CMS Vaccine Mandate is broad, although it does *not* apply to every type of entity that participates in Medicare and Medicaid. Rather, the CMS Vaccine Mandate applies only to certain Medicare and Medicaid providers and suppliers who are subject to health and safety standards known as Conditions of Participation or Conditions of Coverage. They are listed below (referred to as Facilities):

- Hospitals (including acute care hospitals, critical access hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children’s hospitals, transplant centers, cancer hospitals and rehabilitation hospitals/inpatient rehabilitation facilities);

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- Ambulatory surgical centers;
- Long term care facilities (including skilled nursing facilities and nursing facilities, generally referred to as nursing homes);
- Home health agencies;
- Hospices;
- Intermediate care facilities for individuals with intellectual disabilities;
- Comprehensive outpatient rehabilitation facilities;
- Specialized clinics, rehabilitation agencies, and public health agencies that are certified providers of outpatient physical therapy and speech-language pathology services certified under 42 CFR Part 485;
- Community mental health centers;
- Home infusion therapy suppliers;
- Rural health clinics;
- Federally qualified health centers;
- End-stage renal disease facilities;
- Psychiatric residential treatment facilities; and
- Programs of all-inclusive care for the elderly (PACE).

Freestanding physician offices, durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, and many state-licensed Medicaid service providers, are **not** facilities subject to the CMS Vaccine Mandate. Hospital outpatient provider-based clinics ARE covered by the mandate because they are part of a hospital. Health care workers who work at or otherwise provide services to any of the listed facilities will generally be required by the facility to be fully vaccinated under the CMS Vaccine Mandate (see FAQ 7).

4. If my organization is not subject to the CMS Vaccine Mandate, is it subject to the November OSHA ETS that requires vaccination or regular testing of employees?

A health care business that has 100 or more employees is subject to the November OSHA ETS **unless** it meets all of the multi-layered protections and precautions in the June OSHA ETS. In other words, if you are covered by the June OSHA ETS and following its multiple safety requirements, you are **not** subject to the November OSHA ETS. Notably, many health care settings have tailored behavior to meet one of the exceptions to the June OSHA ETS—e.g., a physician office that screens all nonemployees prior to entry and does not permit people with suspected or confirmed COVID-19 to enter the setting. **Organizations with 100 or more employees that are using an exception to avoid compliance with the June OSHA ETS will need to either begin complying with the June OSHA ETS or they will need to meet the vaccine-or-test mandate and other terms of the**

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November OSHA ETS.

Under the June OSHA ETS, health care settings must implement multi-layered plan and protections for employees covered by its requirements, including patient screening and management, facemasks or respirators, other personal protective equipment (PPE), limiting exposure to aerosol-generating procedures, physical distancing, physical barriers, cleaning, disinfection, ventilation, health screening and medical management, access to vaccination and medical removal protection. There are several exceptions to the June OSHA ETS that permitted a health care setting to avoid implementing the multi-layered protections. Those exceptions to the June OSHA ETS include:

- The dispensing of prescriptions by pharmacists in retail settings;
- Nonhospital ambulatory care settings where all nonemployees are screened prior to entry and people with suspected or confirmed COVID 19 are not permitted to enter those settings;
- Well defined hospital ambulatory care settings where all employees are fully vaccinated and all nonemployees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter those settings;
- Home health care settings where all employees are fully vaccinated and all nonemployees are screened prior to entry and people with suspected or confirmed COVID-19 are not present;
- Health care support services not performed in a health care setting (e.g., off-site laundry, off-site medical billing); and
- Telehealth services performed outside of a setting where direct patient care occurs.

Any health care employer that is using one of the above exceptions to the June OSHA ETS and that has 100 or more employees is subject to the OSHA November ETS unless they stop using the exception and comply with the June OSHA ETS.

In addition, health care employers who are not currently subject to the November OSHA ETS because they are subject to the June OSHA ETS will become subject to the November OSHA ETS if the June OSHA ETS expires.

The June OSHA ETS was effective on June 21, 2021, and will remain effective for six months (i.e., until December 21, 2021), unless it is extended or made permanent.

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5. What does the November OSHA ETS require? Is testing an option? Are there religious and medical exemptions? What is the timeline?

The November OSHA ETS requires all employers with 100 or more employees to implement policies that ensure their employees are either fully vaccinated against COVID-19 or subject to masking in the workplace and regular testing for COVID-19. Employers must comply with all requirements other than the testing requirement by **December 6, 2021**. Employers must comply with testing requirements by **January 4, 2022**. The regulation does not require booster shots to be considered fully vaccinated.

The November OSHA ETS allows for medical and religious exemptions. For more information on the November OSHA ETS please reference the article released by our colleagues in the Employment & Labor Group.

6. What does the CMS Vaccine Mandate require? Is testing an option? Are there religious and medical exemptions? What is the timeline?

If you are subject to the CMS Vaccine Mandate, you must establish a policy to ensure that your “staff” is vaccinated with their first dose (if two doses are required) or their one-time dose by **December 6, 2021**. All eligible staff must be fully vaccinated by **January 4, 2022**. This mandate does not require booster shots to be considered fully vaccinated. **Under the CMS Vaccine Mandate, testing is *not* an alternative to vaccination.**

There are religious and medical exemptions under the CMS Vaccine Mandate. CMS has allowed for exemptions under federal law based on recognized medical conditions or for sincerely held religious beliefs. All facilities should prepare a process to allow for these types of exemptions.

7. Who are considered facility “staff” that must be vaccinated (or receive an exemption) under the CMS Vaccine Mandate?

The CMS Vaccine Mandate requires all facility “staff” to be fully vaccinated (or receive an exemption), and the term “staff” is very broad. For example, your lawyer or construction crew may be considered “staff.” Facility staff include:

- Employees;
- Licensed practitioners;
- Students, trainees and volunteers; and
- Individuals who provide care, treatment or other services for the facility and/or its patients, under contract or by other arrangement.

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Note that facility staff must be vaccinated (or receive an exemption) regardless of clinical responsibility or patient contact.

Under the regulation, there are two narrow groups of staff who are not subject to the CMS vaccine mandate:

1. staff who exclusively provide telehealth or telemedicine services outside of the facility and who do not have any direct contact with patients or other facility staff
2. staff who provide support services that are performed exclusively outside of the facility and who do not have any direct contact with patients or other staff

In the preamble language, CMS further states that the vaccination requirement does not apply to “one off vendors, volunteers and professionals” who “infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed *exclusively off-site*, not at or adjacent to any site of patient care (such as accounting services).” In other words, CMS has signaled that there is a group of “one off” individuals who do not necessarily meet the regulatory exceptions described above, but who may also not be required to be vaccinated. This preamble language is confusing, and we expect there will be many questions around what type of facility staff meet these exceptions. However, anyone who is present in the facility on a regular basis would appear to be “staff.”

8. What are the documentation requirements for the regulated facility under the CMS Vaccine Mandate?

To comply with the documentation requirements of this mandate it will be important to track and securely document the vaccination status—or documentation supporting the exemption—of every staff member. Specifically, the CMS Vaccine Mandate requires policies and procedures that include all of the following components:

- (i) A process for ensuring that all staff (except those exempted or some narrow exceptions) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment or other services for the hospital and/or its patients;
- (ii) A process for ensuring that all staff are fully vaccinated for COVID-19, except those exempted or some narrow exceptions;
- (iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

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(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospital has granted, an exemption;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner and contains information specifying which vaccines are clinically contraindicated and the recognized clinical reasons for the contraindications and a statement by the signing practitioner recommending the exemption based on the contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom the vaccination may be delayed due to clinical precautions; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

CMS has stated in the preamble commentary to the regulation that proper forms of proof of vaccination include (1) a CDC COVID-19 vaccination record card (or legible photo of the card), (2) documentation of vaccination from a health care provider or electronic health record, and (3) a state immunization information system record. If a staff member is vaccinated outside of the United States, a reasonable equivalent of any of the previous examples will suffice.

This mandate does not create any new reporting requirements for facilities. However, hospitals and long-term care facilities need to continue to comply with existing facility-specific data reporting requirements under CMS's previous interim COVID-19 emergency regulations.

9. What is the penalty/consequence of not complying with the CMS Vaccine Mandate?

CMS will use its established survey and enforcement processes to ensure compliance with the CMS vaccine mandate. If a facility fails to meet the requirements, it will be cited, which typically involves an opportunity to cure under a Plan of Correction before further actions are taken. The potential consequences if the

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facility does not cure or if there is an immediate jeopardy citation include civil monetary penalties, denial of payment for Medicare or Medicaid services, and, most seriously, termination from the Medicare and Medicaid program. CMS's stated goal is to bring health care entities into compliance. CMS has said that it will not hesitate to use its "full enforcement authority" if a facility does not comply.

10. What vaccine mandates and requirements are currently under review by a court?

The Fifth Circuit Court of Appeals has temporarily stayed implementation of the *November OSHA ETS*, which requires vaccines or regular testing, pending further litigation. In other words, while the court is reviewing the matter, the November OSHA ETS will not be effective. The petitioners are seeking a permanent injunction. Whatever the court's ruling on the permanent injunction, it is expected that an expedited review by the U.S. Supreme Court will be sought. Nevertheless, health care organizations subject to the November OSHA ETS should be prepared for the possibility that a court could permit it to go forward at any time.

Separately, 10 states have sued the federal government in an effort to halt the CMS Vaccine Mandate. However, no court has temporarily enjoined the CMS Vaccine Mandate as of the date of this alert, and facilities subject to the mandate should continue to implement its requirements.

The June OSHA ETS is not subject to a legal challenge.

Fredrikson is closely monitoring these cases and will continue to keep updating clients with relevant information.

We hope you find this information helpful. Feel free to reach out to Katie Ilten, Sean Nagle or Marielos Cabrera from our Health Law Group with questions on this article or the CMS Vaccine Mandate. You can also contact our Employment & Labor Group with OSHA specific inquiries.