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CMS Vaccine Mandate for Healthcare Workers: Resources for Preparing Your Policies

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Under the Centers for Medicare & Medicaid Services (CMS)'s new vaccine mandate for healthcare workers, facilities must draft and implement policies and procedures by **December 6, 2021** to ensure covered personnel are fully vaccinated or exempted by **January 4, 2022**. (86 FR 61573). That does not give facilities much time, but here are some resources that may help with compliance. (This alert supplements our summary of the CMS and OSHA mandates.)

Who Must Comply? The CMS rule applies to the following facilities to the extent they are regulated under Medicare conditions of participation or conditions for coverage:

- Hospitals
- Critical Access Hospitals
- Ambulatory Surgery Centers
- Skilled Nursing Facilities and Nursing Facilities
- Rural Health Centers
- Federally Qualified Health Centers
- Community Mental Health Centers
- Hospices
- Home Health Agencies
- Home Infusion Therapy Suppliers
- End-Stage Renal Disease Facilities
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Psychiatric Residential Treatment Facilities
- Comprehensive Outpatient Rehabilitation Facilities
- Programs of All-Inclusive Care for the Elderly
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services

The CMS rule does not apply directly to physician practices and other providers that are not regulated by Medicare, but the rules may apply indirectly to such providers if they practice at covered facilities. In addition, providers may also be subject to other mandates, including the new OSHA

rule applicable to employers with more than 100 employees; the mandate for federal contractors; or state mandates.

What Must the Policies and Procedures Address? CMS requires covered facilities to implement policies and procedures addressing the following issues:

1. Covered Staff. All employees, licensed practitioners, students, trainees, volunteers and anyone else providing treatment, care or other services for the facility or its patients must be fully vaccinated (collectively "covered staff"), including independent medical staff members with clinical privileges. The mandate applies to any personnel who may come in contact with patients or other staff members who have contact with patients regardless of the frequency of their contact or whether the contact occurs away from the facility. (86 FR 61570). It includes administrative staff, facility leadership, volunteers, board members, housekeeping, food services, etc. *(Id.)*. In its commentary, CMS confirmed that the mandate does not necessarily extend to vendors who may come to the facility on an ad-hoc, "one off" basis (*e.g.,* the plumber who comes to fix a pipe and wears a mask), but it may apply to contractors who provide services more frequently and have contact with patients or covered staff members (*e.g.,* workers on a construction project at the facility who share restrooms with covered staff). (86 FR 61571). "When determining whether to require COVID–19 vaccination of an individual who does not fall into the categories established by [the CMS rule], facilities should consider frequency of presence, services provided, and proximity to patients and staff." *(Id.)*. Facilities may want to review and/or update relevant contracts to incorporate vaccine requirements or require contractors to comply with facility policies, including the vaccine mandates.

2. Exempt Staff. The vaccination requirements do not apply to (1) staff who exclusively provide telehealth services outside of the facility setting and who do not have any direct contact with patients and/or other covered staff; (2) staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and/or other covered staff; (3) staff who have requested and/or been granted an exemptions as described below; and (4) staff whose vaccination must be temporarily delayed due to clinical precautions recommended by the CDC, including but not limited to those with acute illness secondary to COVID-19 and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment.

3. Timing of Vaccinations. Effective **December 6, 2021**, covered staff must receive, at a minimum, the first does of vaccine before they may render any care, treatment or other services for the facility and/or its patients. By **January 4, 2022**, covered staff must have received the single-dose vaccine or received the last does of a multi-dose vaccine. Thereafter, covered staff are not considered "fully vaccinated" until 14 days after receiving the last required dose for the vaccine. (86 FR 61573).

4. Process for Requesting Exemptions. The facility must comply with applicable federal anti-discrimination and civil rights laws, including the Americans with Disabilities Act ("ADA"); Section 504 of the Rehabilitation

Act; Title VII of the Civil Rights Act of 1964; the Pregnancy Discrimination Act; and the Genetic Information Nondiscrimination Act ("GINA"). (86 FR 61568). Those laws generally allow covered staff to request exemptions from vaccination, e.g., for disability, medical conditions, or sincerely held religious beliefs. Facilities likely have policies in place to address workplace discrimination; the facilities just need to extend or apply those policies to COVID-19 vaccines. The EEOC has published an extremely helpful guide for applying those laws in the COVID-19 context, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, available here ("EEOC COVID-19 Guide"). Per CMS's FAQs, "no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII …) or who request an exemption solely to evade vaccination." (Available here.)

CMS takes the position that its rule "preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this [Rule]." (86 FR 61572).

a. Medical Exemptions. All contraindications to the vaccination and support for staff requests for medical exemptions must (1) be signed and dated by a licensed practitioner who is not the individual requesting the exemption and who is acting within their scope of practice; (2) identify which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member and the recognized clinical reasons for the contraindications; and (3) include a statement by the authenticating practitioner recommending that the staff member be exempted from the vaccination based on recognized clinical contraindications. (86 FR 61572). Facilities should refer to the CDC guidance identifying clinical contraindications, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, available here. *(Id.).*

b. Religious Exemptions. Many employees have resorted to the religious exemption to avoid vaccination requirements, but that exemption is narrower than most people realize. (Click here for our earlier alert on this topic.) Facilities should refer to EEOC guidance concerning the process for evaluating and responding to such requests, including the section on *Vaccinations – Title VII and Religious Objections to COVID-19 Vaccine Mandates* in the EEOC COVID-19 Guide and its *Compliance Manual on Religious Discrimination*. A facility may establish its own forms for religious accommodation requests, but CMS points to the template on The Safer Federal Workforce Task Force's website as an appropriate sample.

5. Accommodating Unvaccinated Staff. The facility must implement precautions to mitigate the transmission of COVID-19 for all staff who are not fully vaccinated, which may include COVID-19 testing, wearing masks, isolation, and other safety measures. For guidance concerning such actions, see the CDC's *Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)*; the CDC's *Workplace Prevention Strategies*; and OSHA's *Healthcare Workers and Employers*.

6. Tracking and Documenting Staff Vaccinations. The facility must track

and securely document the vaccination status of covered personnel, including booster doses recommended by the CDC. Acceptable proof may include a CDC COVID-19 vaccination card; documentation of vaccination from a health care provider or electronic health record; or state immunization information system record. (86 FR 61572). Although CMS did not expressly address the issue, some of its commentary may be read to permit a facility to access its employee's protected health information to confirm vaccination status despite HIPAA concerns. For example, CMS noted,

> While provider and supplier staff may not have personal medical records on file with their employer, all staff COVID–19 vaccines must be appropriately documented by the provider or supplier. Examples of appropriate places for vaccine documentation include a facilities [sic] immunization record, health information files, or other relevant documents

(86 FR 61572). For more information about the HIPAA concerns and potential justifications for using employee health information to confirm vaccination status, see our article on the topic. Once obtained, the employee's health information must remain confidential and kept in a separate employee medical file pursuant to the ADA the Rehabilitation Act requirements. (86 FR 61572). Again, the EEOC COVID-19 Guide explains the requirements. The CDC has provided a simple tracking tool that facilities may use to meet the rule requirements, available here.

7. Tracking and Documenting Exemptions. The facility must track and securely document information provided by staff who have requested and/or received an exemption from vaccination.

8. Tracking and Documenting Delayed Vaccination. The facility must track and securely document the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed per CDC recommendations.

9. Contingency Plan. The facility must have contingency plans addressing staff that are not fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for the provider or its patients until such time as such staff have completed the primary vaccination series for COVID-19 and are considered fully vaccinated, or, at a minimum, have received a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID19 vaccine. This planning should also address the safe provision of services by individuals who have requested an exemption from vaccination while their request is being considered and by those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations. (86 FR 61573).

Enforcement. Because the vaccine mandates appear in the conditions of participation, CMS may use all the enforcement remedies available for a violation of the conditions. For nursing facilities, home health agencies and hospices, that may mean civil monetary penalties, denial of payment on new admissions, or termination of the participation agreement. For

hospitals and most other facilities, however, CMS's remedies are more limited: there are generally no civil monetary penalties available, so CMS is left with terminating the provider agreement. Any violation would likely be uncovered through the survey process—either a complaint survey or recertification survey. CMS is working on new guidelines for surveyors. (86 FR 61575). Even if a poor survey were to occur, CMS is not anxious to terminate certification of hospitals and other necessary providers; instead, CMS will work with the provider to come into compliance before imposing sanctions. (See CMS FAQs). The net result is that despite the rapidly approaching deadlines, it may take months before there is any real risk of an adverse action by CMS and most facilities will be given the chance to come into compliance before adverse action is taken.

Contrary State Laws and Federal Preemption. Lawsuits have already been filed challenging the vaccine mandates. In addition, several states have enacted laws that would prohibit vaccine mandates. Nevertheless, CMS takes the position that its rule preempts contrary state laws:

> We understand that some states and localities have established laws that would seem to prevent Medicare- and Medicaid-certified providers and suppliers from complying with the requirements of this IFC. We intend, consistent with the Supremacy Clause of the United States Constitution, that this nationwide regulation preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified.

(86 FR 61568; see also 86 FR at 61613). To date, courts have repeatedly upheld legal challenges to vaccine mandates, and most legal scholars believe the federal rules will preempt contrary state laws. Accordingly, until a court rules otherwise, facilities should probably more forward on implementing the CMS rule.

Loss of Employees. Many employers have pushed back against vaccine mandates out of fear that employees will quit. CMS acknowledged that the vaccine mandates might cause some healthcare workers to leave their jobs, but ultimately concluded that the risks posed by COVID-19 outweighed any losses due to employee departures. (See 86 FR 61569).

Workplace Vaccination Program. For those facilities that have not already developed a workplace vaccination program, the CDC has published helpful tools for implementing such programs. In addition, the EEOC COVID-19 Guide is an additional resource for evaluating employee incentives or penalties relating to the vaccination program.

Additional Resources. The new CMS rules are published at 86 FR 61555. CMS has also published helpful FAQs. Those providers and facilities with more than 100 employees may also be subject to the new OSHA rules. (86 FR 61562). The new OSHA rules are available here. A summary sheet is available here, and the OSHA website has a wealth of resources available.