CMS Vaccine Mandate Rule Released

The Centers for Medicare and Medicaid Services (CMS) published their federal vaccine mandate interim final rule with comment period (IFC) on November 4th.

CMS also published an FAQ covering the most important aspects of the rule which can be read here: https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf

The interim final rule takes effect immediately. All staff (with some exceptions as noted below) will need to have their first shot by December 4th, 2021, and be fully vaccinated by January 4th 2022.

Notably, this vaccine mandate is created through the Medicare Conditions of Participation. This means that the rule only applies to "facilities" regulated by CMS. It does not apply to physician offices that are not subject to conditions of participation. IDTFs are also not mentioned in the rule and are also exempt (see the end of this memo for a full list of facilities subject to this rule). However, physician offices, and their staff, may be subject to the separate but related Occupational Safety and Health Administration (OSHA) rule if they have more than 100 employees.

Failure to meet the vaccination requirements in this IFC could result in monetary penalties, denial of payment for new Medicare/Medicaid admissions, or termination of the Medicare/Medicaid provider agreement depending on the level of non-compliance.

The FAQ makes it clear that this IFC pre-empts any state law to the contrary per the Supremacy Clause in the U.S. Constitution. There are active lawsuits led by certain states against the federal government on both the CMS and OSHA rule. At this time, the impact (if any) that those lawsuits might have on this mandate is unclear.

This IFC changes the conditions of participation for a wide array of healthcare facilities *permanently*. Unless these regulations are changed at some point in the future, the COVID-19 vaccine requirements will remain. In other words, the mandate does not automatically go away when Public Health Emergency ends.

Healthcare facilities will need to update their policies and procedures to account for these new conditions of participation and will have until the end of phase 1 (December 4th) to update their policies and procedures accordingly.

Staff Subject to COVID-19 Vaccination Requirements

The IFC states that:

> Each facility's COVID-19 vaccination policies and procedures must apply to the following facility staff, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff, who provide any care, treatment, or other services for the facility and/or its patients:

-facility 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 other arrangement.

These requirements are not limited to those staff who perform their duties within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities, such as home health, home infusion therapy, hospice, PACE programs, and therapy staff. Further, there may be staff that primarily provide services remotely via telework that occasionally encounter fellow staff, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities. Thus, we believe it is necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care. **Individuals who provide services 100 percent remotely, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements of this IFC.**

Facilities are expected to create policies on contracted workers as well. CMS writes:

When determining whether to require COVID-19 vaccination of an individual who does not fall into the categories established by this IFC, facilities should consider frequency of presence, services provided, and proximity to patients and staff. For example, a plumber who makes an emergency repair in an empty restroom or service area and correctly wears a mask for the entirety of the visit may not be an appropriate candidate for mandatory vaccination. On the other hand, a crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks would be subject to these requirements due to the fact that they are using the same common areas used by staff, patients, and visitors. Again, we strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination of all individuals who provide services infrequently and are not otherwise subject to the requirements of this IFC.

Definition of "Fully Vaccinated"

CMS defines fully vaccinated as "being 2 weeks or more since completion of a primary vaccination series."

However, "staff who have completed the primary series for the vaccine received by the Phase 2 implementation date (January 4th, 2022) are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination."

Booster shots, while encouraged, are not required for staff to be considered "fully vaccinated."

Infection Prevention and Control

CMS will require that facilities have additional precautions for staff that are not fully vaccinated:

> We require through this IFC that all applicable providers and suppliers have 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 [presumably because of one of the exemptions listed below] for COVID-19…
> This process must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19. For the providers and suppliers included in this IFC that are already subject to meeting specific infection prevention and control requirements on an ongoing basis, we require that they have 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.

The rule does not provide any detail as to what "additional precautions" for unvaccinated (due to an exemption) staff means. For instance, would COVID testing be sufficient? What frequency would that testing need to be done? This is not addressed in the IFC and is one area that may require further clarification from CMS.

Proof of Vaccination

Examples of acceptable forms of proof of vaccination include:

> -CDC COVID-19 vaccination record card (or a legible photo of the card),
> -Documentation of vaccination from a health care provider or electronic health record, or
> -State immunization information system record.

Exemptions

There are some notable exemptions to the vaccine mandate including individuals with certain allergies, recognized medical conditions, or religious beliefs, observances, or practices. Vaccination may be temporarily delayed for staff with recent COVID-19 diagnosis.

For medical exemptions, facilities should refer to the *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*.

For religious exemptions the IFC refers facilities to the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination.

All requests for exemptions must be documented according to federal law and each facility's policies and procedures.

Enforcement

CMS will issue interpretive guidelines which will include survey procedures for state surveyors and accreditors to ensure compliance. Surveyors will be instructed to conduct interviews with staff to verify vaccination status.

List of facilities subject to the interim final rule with comment period:

● Ambulatory Surgical Centers (ASCs) (§ 416.51)
● Hospices (§ 418.60)
● Psychiatric residential treatment facilities (PRTFs) (§ 441.151)
● Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74)
● Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42)
● Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80)
● Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (§ 483.430)
● Home Health Agencies (HHAs) (§ 484.70)
● Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70)
● Critical Access Hospitals (CAHs) (§ 485.640)
● Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725)
● Community Mental Health Centers (CMHCs) (§ 485.904)
● Home Infusion Therapy (HIT) suppliers (§ 486.525)
● Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8)
● End-Stage Renal Disease (ESRD) Facilities (§ 494.30)

This IFC directly applies only to the Medicare- and Medicaid-certified providers and suppliers listed above. It does not directly apply to other health care entities, such as physician offices, that are not regulated by CMS.