VACCINE MANDATE: THE RULE IS OUT AND THE DETAILS ARE HERE AS CMS REQUIRES COVID-19 VACCINATIONS FOR STAFF OF MOST MEDICARE AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

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In Response To Lawsuits Filed By 24 States Following Publication Of The Health Care Vaccination Mandate In The 5 November Interim Final Rule With Comment Period (IFC), Two Courts Have Issued Preliminary Injunctions On The Implementation Of The IFC That Together Cover The Entire Nation.

On Monday, 29 November, The U.S. District Court For The Eastern District Of Missouri Granted A Preliminary Injunction On The Implementation And Enforcement Of The IFC In Ten States, Pending Further Review By This Court Or An Appellate Action. Pursuant To The Order, "Defendants Shall Immediately Cease All Implementation Or Enforcement Of The Interim Final Rule With Comment Period As To Any Medicare- And Medicaid-Certified Providers And Suppliers Within The States Of Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming."

On Tuesday, 30 November, a federal judge in Louisiana issued a nationwide preliminary injunction on the Centers for Medicare & Medicaid Services (CMS) mandate (excluding the ten states already addressed in Monday's ruling). The plaintiff states were Louisiana, Montana, Arizona, Alabama, Idaho, Georgia, Indiana, Mississippi, Oklahoma, South Carolina, Utah, West Virginia, Kentucky, and Ohio. In this ruling, the Court enjoins and restrains the U.S. Department of Health and Human Services and CMS, along with their directors, employees, Administrators and Secretaries from implementing the IFC not just as to the plaintiff states, but "as to all healthcare providers, suppliers, owners, employees, and all others covered by said CMS Mandate."

Today, the CMS published an interim final rule with comment titled "Omnibus COVID-19 Health Care Staff Vaccination" (the IFC).[1] The IFC establishes COVID-19 vaccination requirements for staff at fifteen (15) types of Medicare- and Medicaid-certified providers and suppliers, including but not limited to hospitals, critical access hospitals, ambulatory surgical centers, hospices, and skilled nursing facilities/nursing facilities. The requirements will be enforced through the existing survey process that applies to certified providers and suppliers, including the potential for imposition of penalties through that existing process.

While the IFC is effective today, implementation of the requirements of the IFC is divided into two phases - Phase 1 and Phase 2. Phase 1 requires that, by 5 December, 2021, each provider and supplier subject to the IFC

develop and implement policies and procedures containing the elements described in the IFC and ensure that all staff have either: (i) received at least the first dose of a two dose COVID-19 vaccine or the dose of a single dose COVID-19 vaccine, or (ii) have requested a medical or religious exemption or approval of a temporary delay of vaccination for clinical reasons in accordance with CDC recommendations, prior to providing any care, treatment, or other services. Phase 2 requires that, by 4 January 2022, all applicable staff are fully vaccinated for COVID-19, unless granted an exemption or a temporary delay of vaccination. To meet the requirements of Phase 2, it is sufficient that staff have received the final dose by 4 January 2022, even though an individual is not considered fully vaccinated until 14 days after the final dose. CMS has indicated that the requirements of the IFC preempt inconsistent state and local laws, such as those that purport to prohibit vaccine mandates or offer broader exemptions than under the IFC.[2]

Contemporaneous with this IFC, OSHA issued an emergency temporary standard (ETS) requiring worker vaccinations for employers with 100 or more employees or, alternatively, weekly testing for those who remain unvaccinated without an eligible exemption. (see client alert found here). Similarly, the Safer Federal Workforce Task Force recently released vaccine requirements for federal contractors (see client alert here). The agencies worked closely to devise complementary regulations to ensure that the various regulations were consistent and not overly duplicative.[3] The ETS only applies to employers who are not otherwise obligated to be in compliance with federal contractor vaccination mandates.

This alert provides an overview of the requirements of this IFC. Anticipating questions from Providers and Suppliers, CMS also published responses to frequently asked questions[4] and held a National Stakeholder call yesterday.

While the IFC is effective, CMS is providing stakeholders with an opportunity to submit comments on the IFC. Comments are due by 4 January 2022.

COVERED PROVIDERS AND SUPPLIERS

The IFC applies to a specified subset of providers and suppliers that are regulated by Conditions of Participation (CoPs), conditions for coverage, or requirements for participation (i.e., Medicare- and Medicaid-certified providers and suppliers). The IFC sets forth common requirements for each provider and supplier type through amending its applicable certification requirements, such as those related to infection control, services, personnel, and/or staffing, depending on the provider and supplier type. CMS lists the following fifteen (15) types of providers and suppliers (Providers and Suppliers) that are subject to the Rule[5]:

- Ambulatory Surgical Centers (ASCs)
- Hospices
- Psychiatric Residential Treatment Facilities (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)
- 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)

- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- Clinics, Rehabilitation Agencies, and Public Health Agencies as providers of outpatient physical therapy and speech-language pathology services
- Community Mental Health Centers (CMHCs)
- Home Infusion Therapy (HIT) suppliers
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities

The IFC does not apply to any provider or supplier type not expressly listed above, such as:[6]

- Religious Nonmedical Health Care Institutions
- Organ Procurement Organizations
- Portable x-ray suppliers
- Assisted Living Facilities
- Group Homes
- Home and Community Based Services
- Physicians' offices

Some of these excluded entities may, however, be subject to other Federal or state laws, such as state licensing requirements, that mandate vaccinations. Additionally, if these entities provide services under contract to other health care entities that are subject to the IFC, they could be indirectly subject to the rule as further described below.[7]

REQUIREMENTS OF IFC

In short, the IFC requires that the Providers and Suppliers ensure that staff are fully vaccinated for COVID-19 by 4 January 2022, unless the individual is exempted for medical or religious reasons or vaccination is temporarily delayed.

More specifically, Providers and Suppliers must develop and implement policies and procedures containing the specific components required by regulation covering the following areas[8]:

1. Vaccination of required staff,

2. Providing eligible exemptions and accommodating same,
3. Tracking and documenting staff vaccination status and exemptions, and
4. Contingency plans and additional precautions.

The policies and procedures must be developed by 5 December 2021. Required components of the policies and procedures include as follows.

Vaccination of Required Staff

- A process for ensuring that by 5 December 2021, required staff have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the Provider and Supplier and/or its patients, except staff who have pending requests for, or who have been granted, exemptions, or for whom COVID-19 vaccination must be temporarily delayed for clinical reasons, as recommended by the CDC.
- A process for ensuring that by 4 January 2022, all staff are fully vaccinated for COVID-19, except for those staff who have been granted exemptions or those staff for whom COVID-19 vaccination must be temporarily delayed for clinical reasons, as recommended by the CDC.
  - An individual is considered to be fully vaccinated if they have had their second dose of a two-dose COVID-19 vaccinate by 4 January, even if they have not completed the 14 day waiting period normally associated with full vaccination status.
  - At this time, boosters are not required in order to be considered fully vaccinated. However, CMS strongly encourages following compliance with CDC guidance on boosters (Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the U.S.)[9]
  - 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. If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples would suffice.

Providing Eligible Exemptions and Accommodating Same

- Processes for documenting requests for an exemption due to recognized medical conditions for which vaccines are contraindicated. Such documentation must include:
  - Signature and date by a licensed practitioner who is not the individual requesting the exemption and who is acting within their respective scope of practice, as defined by state and local laws;
  - All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated[10] for the requesting staff member;
  - Recognized clinical reasons for the contraindications, such as severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or Immediate (within 4

hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine, and

- A statement by the authenticating practitioner recommending the exemption based on the recognized clinical contraindications.
- Processes for documenting requests for a religious exemption which shall be evaluated in accordance with law.[11]

Tracking and Documenting Staff Vaccination Status and Exemptions

- A process for tracking[12] and securely documenting:
  - COVID-19 vaccination status of all staff.
  - COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC.
  - Information provided by those staff who have requested, and for whom the hospital has granted, an exemption from the staff COVID-19 vaccination requirements.
  - Vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment.

Contingency Plans and Additional Precautions[13]

- Contingency plans for staff who are not vaccinated.
- A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for staff who are not fully vaccinated for COVID-19.

STAFF SUBJECT TO IFC

Any staff who provide any care, treatment, or other services for the Provider and Supplier and/or its patients are subject to the IFC, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff.[14] This includes:

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

This requirement does not apply to the following individuals:[15]

- Staff who exclusively provide telehealth or telemedicine services outside of the Provider and Supplier setting and who do not have any direct contact with patients and other staff subject to the IFC.

- Staff who provide support services that are performed exclusively outside of the Provider and Supplier setting and who do not have any direct contact with patients and other staff subject to the IFC.

EXEMPTIONS

CMS recognizes the need, and requires Providers and Suppliers to allow, for two types of exemptions from the vaccination requirements. Those exemptions are for individuals with: (i) recognized medical conditions for which vaccines are contraindicated (as a *reasonable accommodation* under the Americans with Disabilities Act (ADA)), or (ii) sincerely held religious beliefs, observances or practices (established under Title VI of the Civil Rights Act of 1964). Individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practices, or observances may be eligible for an accommodation. In granting exemptions or accommodations, 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. Vaccination is the only option under this IFC absent a recognized exemption. Natural immunity is not an exemption and CMS does not permit a testing option as an acceptable alternative in lieu of vaccination.[16]

Providers and Suppliers covered by the IFC must include the required exceptions, and a process for requesting an exception, as a part of their policies and procedures; however, CMS has advised that no exemption should be provided to any staff for whom it is not legally required or where a request for an exemption is solely to evade vaccination.[17] Furthermore, certain individuals may qualify for a temporary delay of vaccination when doing so is consistent with recommendations by the CDC that are due to clinical precautions and considerations, but such individuals are not exempted from vaccination.

Policies and procedures, established by Providers and Suppliers, for exemptions must include, at a minimum, the components described above.

In order to grant an exemption and make accommodations, for either medical reasons or religious beliefs, Providers and Suppliers must ensure that they minimize the risk of transmission of COVID- 19 to at-risk individuals. Where vaccination must be temporarily delayed for a staff member, a Provider and Supplier must establish a process to ensure, track and secure documentation of the vaccination status of such individuals. Temporary delays should be implemented, as recommended by the by the CDC, due to clinical precautions and considerations, such as individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment.

ENFORCEMENT AND PENALTIES

CMS will enforce the IFC through its existing survey processes and penalties. Specifically, state survey agencies or accrediting organizations for Providers and Suppliers with deemed status will include reviewing compliance with the IFC as part of complaint surveys and during the regular course of recertification surveys at Providers and Suppliers.

CMS expects state survey agencies and accrediting organizations to conduct onsite compliance reviews of IFC compliance two ways:

- Assess compliance with these requirements during the standard recertification survey; and

- Assess vaccination status of staff on all surveys including reviewing vaccination policies and procedures, the number of COVID-19 cases over the last four (4) weeks, and use interviews and observations to assess the Provider and Supplier's compliance with the IFC requirements.

Providers and Suppliers that are out of compliance with the IFC will be cited based on level and severity of noncompliance and provided an opportunity to return to compliance. Failure to return to compliance may result in the application of existing enforcement remedies. Depending on the Provider and Supplier type, this may include civil monetary penalties, denial of payment of new admissions for facilities, and termination from Medicare and Medicaid participation, and referral to a state enforcement agency for application of its other enforcement remedies.

CMS has indicated its intention to work with affected Providers and Suppliers to bring them into compliance as quickly as possible. Although termination is a last resort, and would generally occur only after providing an opportunity to make corrections and come into compliance, CMS states that it will not hesitate to use its full enforcement authority to protect patients.

Note that CMS is not, at this time, planning to use the new COVID-19 Vaccination Coverage among Health Care Personnel (HCP) quality measure to monitor the compliance of Providers participating in the Inpatient, PPS-Exempt Cancer Hospital, Long Term Care Hospital, Inpatient Psychiatric, and Inpatient Rehabilitation Quality Reporting Programs. Pursuant to this quality measure, such Providers are expected to report on the new COVID-19 Vaccination Coverage among Health Care Personnel quality measure from 1 October 2021 to 31 December 2021 as established in the various Fiscal Year 2022 payment rules. While CMS expects the quality measure to provide valuable insight into the number of staff vaccinated over the course of a three-month period, CMS will ensure compliance with the IFC via the established survey process for now.

INTERSECTION WITH STATE LAWS

Recognizing that some states and local governments have enacted laws that would purport to prohibit Providers and Suppliers from complying with the IFC, CMS expressly states its view that, consistent with the Supremacy Clause of the United States Constitution, its regulation preempts inconsistent State and local laws. According to CMS, this preemption extends to laws that would appear to prohibit a vaccine mandate and those that offer broader exemptions than under the IFC. CMS does, however, invite State and local comments on the IFC, including “how we can fulfill the statutory requirements for health and safety protections of patients if we were to exempt any providers or suppliers based on State or local opposition to this rule.”[18]

CONCLUSION

In light of the short timeline for compliance with the requirements of the IFC, Providers and Suppliers should immediately begin developing and implementing the policies, procedures, and processes required by the IFC. K&L Gates' Health Care practice has been advising a wide range of health care Providers and Suppliers with matters related to the COVID-19 public health emergency, including vaccination requirements. For assistance in further understanding the requirements of the IFC, its intersection with other federal rules related to COVID-19 vaccination, or in developing policies and procedures, contact the authors of this article or another K&L Gates lawyer for assistance.

FOOTNOTES

[1] Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021). The pre-publication version of the IFC was issued yesterday.

[2] 86 Fed. Reg at 61, 613

[3] Nov. 4, 2021 CMS National Stakeholder call

[4] CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule; FAQs (Nov. 4, 2021)

[5] 86 Fed. Reg. at 61,556.

[6] CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule; FAQs (Nov. 4, 2021)

[7] 86 Fed. Reg. at 61,556.

[8] 86 Fed. Reg. at 61,568, 61571-61573

[9] 86 Fed. Reg. at 61,609

[10] See recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

[11] While Providers/Suppliers have the flexibility to establish their own policies and procedures, for further guidance on evaluating and responding to such requests, CMS refers Providers/Suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination. See The Safer Federal Workforce Task Force's "request for a religious exception to the COVID-19 vaccination requirement" for a template for a religious exemption request as an example.

[12] Providers and suppliers have the flexibility to use the appropriate tracking tools of their choice. For those who would like to use it, CDC provides a staff vaccination tracking tool that is available on the NHSN website (https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html). This is a generic Excel-based tool available for free to anyone, not just NHSN participants, that facilities can use to track COVID-19 vaccinations for staff members. 86 Fed. Reg. at 61572

[13] *See* 86 Fed. Reg. at 61,573 and 61,616 - 27 (codifying changes in regulations).

[14] *See* 86 Fed. Reg. at 61,570-71.

[15] 86 Fed. Reg. at 61,571 ("Facilities that employ or contract for services by staff who telework full-time (that is, 100 percent of their time is remote from sites of patient care, and remote from staff who do work at sites of care) should identify and monitor these individuals as a part of implementing the policies and procedures of this IFC, documenting and tracking overall vaccination status, but those individuals need not be subject to the vaccination requirements of this IFC. Note, however, that these individuals may be subject to other Federal requirements for COVID-19 vaccination.")

[16] *See* COVID-19/Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace

[17] CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule; FAQs Exemptions, (Nov. 4, 2021)

[18] 86 Fed. Reg. at 61,613

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