

UPDATE ON CMS VACCINATIONS IFR: APPLICABILITY TO PHARMACIES

FEBRUARY 16, 2022

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Update on CMS Vaccinations IFR: Applicability to Pharmacies

CMS Interim Final Rule (“IFR”)

CMS issued its IFR (effective November 5, 2021) regarding mandatory COVID-19 vaccinations for all certified Medicare and Medicaid facilities. Simply receiving Medicare or Medicaid funds does not, by itself, mean that a facility is covered by this rule. Medicare and Medicaid-certified provider and supplier types (“facilities”) are regulated under the Medicare health and safety standards known as Conditions of Participation, Conditions for Coverage, or Requirements for Participation. The “Background” section of the IFR states its applicability to “21 types of providers and suppliers, ranging from hospitals and hospices to rural health clinics to long term care facilities.”

Pharmacies are not explicitly included in the list of “providers and suppliers” to which the vaccine mandate applies. Therefore, the IFR does not impact retail (customer walk-in) pharmacies that do not work with facilities that participate in Medicare or Medicaid programs.

However, CMS said this mandate potentially impacts pharmacies because the vaccination requirement covers all individuals who provide care, treatment, or other services for any Medicare or Medicaid facility subject to this rule (and/or its patients) under contract or other arrangements.¹ For such staff, the COVID-19 vaccination is required as a condition for continued provision of services for the facility or its patients. In addition to a facility’s employees, practitioners, and volunteers, the IFR broadly includes anyone who (i) provides services to the facility under a contract or an arrangement and (ii) potentially comes in contact with the facility staff or patients. Thus, **if a pharmacy delivers drugs to hospitals, SNFs and other facilities, the delivery employee will likely need to be vaccinated.**

The CMS Rule does not apply to “one off” vendors, volunteers or professionals who infrequently provide ad-hoc, non-health care services.² Examples include individuals who infrequently enter a facility for specific limited purposes and for a limited amount of time, and do not provide services by contract or under an arrangement.³ Pharmacies should check with facilities to which they deliver products. **It is likely that the facilities will require the pharmacy’s delivery employee to be vaccinated.⁴ The IFR does not prohibit facilities from extending the vaccination requirements beyond their staff.**

Verification of Vaccination Status

Applicable certified Medicare and Medicaid facilities must require staff to provide acceptable proof of vaccination, which includes: (1) a record of immunization from a health care provider or pharmacy; (2) a copy of the employee’s COVID-19 Vaccination Record card; (3) a copy of medical records documenting the vaccination; or (4) a copy of an immunization record from a public health, state, or tribal immunization system, or a copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional or clinic site that/who administered the vaccine. These records are considered “medical records” and should be stored in employees’ medical files (separate from their HR or disciplinary files). If a staff member is qualified for an exemption for medical or religious

¹ CMS: External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule, January 20, 2022. [External FAQ IFC-6 - 1.21.22 \(cms.gov\)](#)

² Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, Federal Register, November 5, 2021. <https://www.federalregister.gov/d/2021-23831/p-286>

³ Id.

⁴ Id.

reasons,⁵ then a record of the applied for and approved exemption must be documented.

Vaccination Deadlines by State

The implementation date varies depending on whether the state was affected by the Supreme Court decision.

Affected staff in the following states have until January 27, 2022 to receive their first (or only) COVID-19 vaccine dose, and February 28, 2022 to receive their second dose:

California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, and Wisconsin.

Affected staff in the following states have until February 14, 2022 to receive their first (or only) COVID-19 vaccine dose, and March 15, 2022 to receive their second dose:

Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia, and Wyoming.

Affected staff in the following states have until February 21, 2022 to receive their first (or only) COVID-19 vaccine dose, and March 21, 2022 to receive their second dose:

Texas

Compliance and Enforcement

The CMS regulation may result in a facility's expulsion from the Medicare or Medicaid program if vaccination coverage is less than 100 percent for a covered facility's staff providing services under a contract or arrangement.⁶ However, CMS has previously stated that it will pursue other enforcement steps first.⁷ CMS also said that suppliers in which 80% or more of their employees are vaccinated by the first deadline, and in which 90% or more of their employees are vaccinated by the second deadline, will be granted 30-day and 60-day grace periods.⁸ If a facility is deemed to "pose a threat to patient health and safety," the grace period may not be applied to that facility.

On the state's initial vaccination deadline, federal agencies, state agencies, accrediting organizations, and CMS-contracted surveyors will begin evaluating facilities to ensure they meet compliance standards as part of initial certification, routine recertification or reaccreditation, and complaint surveys. If it is determined that a facility is non-compliant, then surveyors will likely give the facility a chance to comply before pursuing further enforcement measures (e.g., plans of correction) so long as the facility has a plan in place to achieve a 100% staff vaccination rate.

CMS also noted that in the following instances, it will exercise enforcement discretion and will not subject

⁵ EEOC: What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, Updated on December 14, 2021, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

⁶ Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, Federal Register, November 5, 2021, <https://www.federalregister.gov/d/2021-23831/p-316>

⁷ Id.

⁸ Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, Federal Register, November 5, 2021, <https://www.federalregister.gov/d/2021-23831/p-313>

facilities to additional enforcement action for roughly 90 days following the publication of the guidance:

- (1) facilities that have met the initial vaccination deadline of 80 percent compliance and a strategy to attain 100 percent compliance within 60 days;⁹ and
- (2) facilities with a final vaccine deadline of 90 percent compliance and a plan to reach 100 percent compliance within 30 days. CMS emphasized in its facility-specific instructions for surveyors that if fines are necessary, they may be reduced for facilities that make a good-faith attempt to comply with the mandate.¹⁰ CMS noted that if facilities can show "proof that they have made active measures to get all employees vaccinated, such as advertising for new staff, conducting vaccination clinics, and so on," CMS will consider the evidence to be a good-faith effort when evaluating compliance.¹¹

A covered facility's policy (that is required to be in place by the state's initial deadline) must include

1. A process for ensuring all staff have received, at minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multidose COVID-19 vaccine, prior to the staff providing any care, treatment, or other services for the facility and/or its patients (including new hires).¹²
2. A process for ensuring that all staff are fully vaccinated (except for those with exemptions such as a sincerely held religious belief).¹³
3. 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 (i.e., those staff who fall under the exception or for those who come to the facility and are not vaccinated).¹⁴
4. A process for tracking and securely documenting the COVID-19 vaccination status of all staff covered by the rule.¹⁵
5. A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained booster doses as recommended by the CDC. Boosters are not required to be considered fully compliant with the rule at this time, but CMS is asking organizations to track it.¹⁶
6. A process by which staff may request an exemption from the COVID-19 vaccination requirements (more on this).¹⁷
7. A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the COVID-19 vaccination requirements.¹⁸
8. A process for ensuring that the documentation supporting a medical exemption is signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within his/her respective scope of practice.¹⁹ Documentation must include:
 - a. All information specifying which of the COVID vaccines are clinically contraindicated and the **recognized clinical reasons** for the contraindication; and
 - b. A statement by the practitioner recommending that the staff member be exempt from the vaccine requirement based on recognized clinical contraindications.

⁹ Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, Federal Register, November 5, 2021, <https://www.federalregister.gov/d/2021-23831/p-316>

¹⁰ Id.

¹¹ Id.

¹² Long-Term Care and Skilled Nursing Facility Attachment A, pg. 2, <https://www.cms.gov/files/document/qso-22-07-all-attachment-ltc.pdf>

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁸ Id.

¹⁹ Id.

9. A process for ensuring the tracking and documentation of the vaccination status of staff for whom vaccination must be temporarily delayed, as recommended by the CDC (acute COVID-19 illness, monoclonal antibodies, convalescent plasma).²⁰

10. Contingency plans for staff who are not fully vaccinated for COVID-19.²¹

a. Exemptions

Facilities must provide medical, disability, and religious exemptions as required under the ADA and Title VII.²² Note that in certain circumstances, receipt of the vaccine can be legally delayed (e.g., for six months following receipt of monoclonal antibodies).

BUT: No exemption should be provided to any staff for whom it is not legally required or who requests an exemption solely to evade vaccination.²³

In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligations to protect the health and safety of patients.²⁴

The EEOC has a number of documents that address accommodations, including the following:

1. Accommodations for sincerely held religious beliefs²⁵

a. The definition is broad, and the EEOC advises that employers should assume the request is based on a sincerely held religious belief, practice, or observances.

b. Religious beliefs include theistic beliefs and non-theistic beliefs as to what is right and wrong that are sincerely held with the strength of traditional religious views.

c. NOT religious beliefs: politics, concerns regarding safety of vaccines, personal preferences.

d. If an employer is aware of the facts that provide an objective basis for questioning either the religious nature or the sincerity of a particular belief, practice, or observance, the employer is justified in requesting additional information (i.e., the health care workplace has required other vaccines and the employee has not objected to any other vaccine). Additional documentation can include a note from a religious leader. An employee will likely have an answer that will qualify him/her for a valid exemption request. Please speak to an employment law attorney for additional information.

2. Accommodations for medical and disability reasons.²⁶

Medical exemption reasons can include things like an immediate allergic reaction to a previous dose or known (diagnosed) allergy to a component of the vaccine.

What should covered facilities do now (step by step process)?

Here is a four-step priority list now that the CMS rule has been upheld:

1. **Check to review if your facility is covered by the CMS mandate** – Simply receiving Medicare or Medicaid funds does not, by itself, mean that a facility is covered by this rule, which applies only to certified providers. Certification applies to Medicare and Medicaid-certified provider and supplier types (“facilities”) regulated under the Medicare health and safety standards known as Conditions of Participation, Conditions for Coverage, or Requirements for Participation.

²⁰ Id.

²¹ Id.

²² Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, Federal Register, November 5, 2021, <https://www.federalregister.gov/d/2021-23831/p-307>

²³ Id.

²⁴ Id.

²⁵ EEOC : What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, Updated on December 14, 2021, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

²⁶ Id.

Note that this is a subset of health care providers. There are many health care providers that do not fall under these categories.

The Medicare and Medicaid-certified provider and supplier types apply to the following facilities: Ambulatory Surgery Centers, Community Mental Health Centers, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, End-Stage Renal Disease Facilities, Home Health Agencies, Home Infusion Therapy Suppliers, Hospices, Hospitals, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities, Programs for All-Inclusive Care for the Elderly Organizations, Rural Health Clinics/Federally Qualified Health Centers (Medicare only), and Long Term Care facilities.

Thus, the first step is to determine whether this mandate applies to your facility.

2. **Track Vaccination Status and Create a Policy** (by the deadline, which is dictated by the state where your facility is located) – If covered, the facility should determine and continue to track the vaccination status of its staff. A covered facility should create policies detailing how it has implemented relevant tracking, compliance, recordkeeping, documentation, and training requirements. Additionally, your facility should ensure that it has developed procedures that guarantee confidential evaluations and responses to requests for accommodation. These must include additional COVID-19 precautions relevant to individuals who are granted accommodations. Facilities should begin to prepare for CMS inspections.
3. **Review State Law Deadlines** – Determine the date the CMS rule goes into effect in the state where your facility is located. Vaccination deadlines depend on where the service is being provided.
4. **Prepare for Accommodation Requests** – Employees can make requests for accommodations based on medical, disability, or religious reasons. Those requests should be documented and responded to promptly and appropriately. Documenting accommodations and accommodations requests are crucial to complying with the CMS Rule and other federal laws. Documenting this process is important to the decision that an employer ultimately makes. This process can take time and should be factored into planning for the upcoming compliance deadlines.

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