

**Purpose** To prevent transmission of Coronavirus Disease (COVID-19-virus) and provide guidance on infection control and vaccination requirements as required by Centers for Medicaid and Medicare Services (CMS).

**Responsibility** **All direct and indirect staff** of CMS-certified facilities (Covered Staff), including Clinical Manager, Charge Nurse or Team Leader, direct patient care staff (including physicians and physician extenders), and other indirect patient care staff, service providers, and certain non-clinic staff who interact with Covered Staff, are required to adhere to the guidance outlined in this policy.

**Background** Vaccination against COVID-19 is the most effective means of preventing infection with the COVID-19 virus, and subsequent transmission and outbreaks. To reduce the chance of transmission to vulnerable populations, prevention measures have been implemented by CMS for healthcare staff, which include the requirement that all direct and indirect staff of covered facilities be fully vaccinated against COVID-19.

While a significant number of healthcare staff have been infected with SARS-CoV-2, evidence indicates their infection-induced immunity, also called “natural immunity,” is not equivalent to receiving the COVID-19 vaccine. Available evidence indicates that COVID-19 vaccines offer better protection than infection-induced immunity alone and that vaccines, even after prior infection, help prevent reinfections. Consequently, CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.<sup>1</sup>

Vaccine mandates for healthcare staff currently in place at the state or local level, may remain active concurrently with the CMS vaccine mandate. In instances where the CMS vaccine mandate is more stringent than the applicable state or local requirements, the CMS vaccine mandate will control.

**Definitions** **Covered staff** includes all current staff as well as any new staff who provide any care, treatment, or other services in or for a CMS-certified facility and/or its patients. This includes facility employees, licensed practitioners, students, trainees, and volunteers. Additionally, this also includes individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements. It also includes all staff who interact

<sup>1</sup><https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicare-omnibus-covid-19-health-care-staff-vaccination>

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with the patient care staff or patients, in any location beyond the formal clinical setting (such as homes, clinics, other sites of care, administrative offices, off-site meetings, etc.) and physicians or physician extenders admitting and/or treating patients in-person within a facility.

**Fully Vaccinated** means individuals who are considered fully vaccinated for COVID-19: two weeks or more after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna or vaccine authorized by the World Health Organization), or two weeks or more after they have received a single-dose vaccine (Johnson and Johnson [J&J]/Janssen).

**Unvaccinated** means persons who have not received any doses of COVID-19 vaccine or whose status is unknown.

**Exempt from Vaccination** means persons who have been approved for an exemption from the applicable federal vaccine mandate, as described in this policy.

## Policy

All Covered Staff must be Fully Vaccinated against COVID-19. All Covered Staff must receive, at minimum, the first dose of a two-dose series of a COVID-19 vaccine by January 27, 2022, and the second dose by February 28, 2022. For Covered Staff receiving a single dose vaccine, such individual must receive that single dose by January 27, 2022. For purposes of the CMS vaccine mandate, Covered Staff will satisfy the requirements of this Policy once they have received the final dose of their vaccine, even if they have not yet completed the 14-day waiting period following that final dose.

For purposes of this Policy, individuals providing the following services will be considered Covered under the CMS vaccine mandate:

- Fresenius Kidney Care (FKC) Clinical Care Teams (i.e., Nurses, Technicians, Registered Dietitian, Social Worker, Administrative Professionals, etc.)
- FKC Shared Support Staff including FKC Clinical and Nursing Shared Services employees (i.e., Quality, Education, Regulatory, CTMs, etc.)
- FKC Kidney Care Advocates
- FKC Sub Acute Care
- FKC Insurance Coordinators
- Medical Directors, physicians, physician extenders, and other members of the Medical Staff
- Staffing agency personnel

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- Security personnel
- Students/Interns
- Volunteers
- Transport services (i.e., Ambulnz, wheelchair transportation services, etc.)
- Janitorial services (only applies to service provided onsite when there is a high potential to interact with patients or staff members)
- Practice employed personnel visiting FKC clinics
- Other vendors that participate in patient care activities (i.e., foot checks, patient education, etc.)
- Other FMCNA staff:
  - Hospital and Patient Services Manager / Sr. Manager
  - Market Development team (VP, Sr. Director, Director)
  - NxStage Home Sales team
  - NxStage Critical Care Sales and Nursing Support
  - NxStage Home/Clinical Educators/MSS team
  - NxStage Field Service Team
  - NxStage National Accounts
  - Vascular Regional Directors and Territory Managers
  - RTG Pharma Sales
  - RTG Product Sales & National Accounts
  - RTG Clinical Innovation Managers
  - RTG Water System Installation Engineers
  - RTG Senior Water System Service Specialists
  - RTG Senior Water System Educators
  - RTG Senior Manager, Water System Quality Services
  - RTG Manager, Field Service
  - RTG Field Service Technicians
  - Spectra Sales and Spectra Nephrology Clinical Educators
  - FMCNA Clinical Educators (Spectra, PD, Crit Line, Medical Support Specialists, Clinical Support Specialist, Medical Science Liaison)
  - Frenova Clinical Research team
  - Azura Sales team
  - Azura Field Operations, Integration Team and Business Development
  - Azura/NCP Clinical Team
  - FRx Account Management team
  - IT Field Service Support (FSS/FSST)
  - Ambulnz Business Development team
  - Acumen contracted vendors

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New hires must meet the vaccine requirements prior to providing any care, treatment, or other services for the facility and/or its patients, including the initiation of training either in the clinical setting or training facility. Talent Acquisition will coordinate with hiring managers to confirm that proof of vaccination or exemption status is on file and staff may begin work.

Fresenius Medical Care (FMC) employees may be approved for exemption from the vaccination requirements after submitting one of the exemption request forms referenced below. The following are the possible bases of exemption, subject to the specific criteria set out in the applicable forms.

- Religious Beliefs; or
- Medical Exemption

FMC employees who wish to request medical or religious exemption will be required to complete all documentation as outlined on the [COVID-19 Vaccine Mandate Exemption Requests](#) page located on the Employee Service Center. Employees and their direct supervisor/manager will receive notification of the approval or denial of the requested exemption.

Covered Staff who are Exempt from Vaccination must follow the Company's current policies on Coronavirus disease screening, infection control and protective personal equipment.

FMC employees who refuse to provide proof of vaccination status will be considered unvaccinated.

Refusal to provide vaccination status, seek exemption, and/or failure to initiate the vaccination process on or before January 27, 2022, or complete the vaccination series by February 28, 2022, may result in escalation to Human Resources or the facility Governing Body, and may lead to disciplinary action, up to and including termination from employment or suspension or revocation of medical staff privileges.

### **Proof of Vaccination**

Only the following modes may be used as proof of vaccination:

1. CDC COVID-19 Vaccination Record Card, OR
2. WHO COVID-19 Vaccination Record Card, OR
3. documentation of COVID-19 vaccination from a health care provider, OR
4. a print-out from the state immunization registry, OR
5. for an individual who was vaccinated outside of the United States, a reasonable equivalent of any of the above.

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It is insufficient for an employee to document information into the FMC staff tracking application without uploading Proof of Vaccination documentation (as outlined above). It is required that all COVID-19 vaccinations received at an FMC location are documented by the administrating facility in the FMC staff vaccination tracking application. Employees that receive vaccination at an FMC location are not required to upload proof of vaccination.

Employee vaccination information cannot be kept in personnel records. In instances in which hard copies of vaccine records have been received, they must be maintained separately in the employee's medical file and stored in a secure location.

All FMCNA employees, as described above, that present to a facility will be expected to be compliant with the vaccination requirements as described in this Policy. Direct supervisors will be responsible to confirm the status of their direct reports prior to these Covered Staff visiting an FKC facility.

### Covered Vendors

Contracted vendors will be responsible for maintaining the vaccination status of their employees. This will apply to Medical Directors, attending physicians, advanced practice providers and any other medical staff member who may round in an FKC dialysis clinic or program.

- Contracted vendors/consultants will complete a onetime attestation covering all employed individuals acknowledging company policy and will only send individuals that are compliant with vaccination requirements.
  - ***Third Party Company Acknowledgment of Compliance with Applicable State or Local COVID-19 Vaccine Mandate***
- Vendors/consultants/students that do not have an employing entity will be asked to sign a onetime attestation that you will comply with the vaccination requirements as described in this policy.
  - ***Acknowledgement of Compliance***
- Individual physicians and advanced practice providers will sign a onetime attestation that you will comply with the vaccination requirements as described in this policy.
  - ***Acknowledgement of Compliance***

Refusal to provide Acknowledgement of Compliance, will result in escalation to Regional Vice President (RVP).

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**Disease Screening and Infection Control Requirements for All FMCNA Staff** All employees must be screened for ongoing signs and symptoms of COVID-19 disease. Screening of all employees will be conducted at the start of each work shift. Before screening, employees must be clocked in.

All employees must follow all infection control requirements as outlined in the following policies:

- *Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care Dialysis Clinics*
- *Dialyzing and Infection Control Practices with Coronavirus Disease Positive Patients and Persons Under Investigation (PUI)*
- *COVID-19 Disease Testing and Return to Work of FKC Staff*

Personal Protective Equipment Guidance:

At a minimum, employees, depending upon their role, are required to wear the following PPE in all FKC facilities:

- Surgical mask or higher-grade respirator face mask (i.e., N95 respirator) at all times.
  - *Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care Dialysis Clinics*
  - *Dialyzing and Infection Control Practices with Coronavirus Disease Positive Patients and Persons Under Investigation (PUI)*

Employees must wear a face mask and practice social distancing (separated by 6 ft) in other common areas (e.g., breakrooms, conference rooms, restrooms).

- It is reasonable to expect **Fully Vaccinated** staff members will remove the face mask when in the breakroom to have a beverage, food, or other personal breaks.
- **Unvaccinated staff** may briefly remove the face mask while in the breakroom to have a beverage or snack while maintaining a minimum distance of 6 feet from all other staff. **Unvaccinated staff must don face mask immediately after eating/drinking. It is strongly recommended that unvaccinated staff only remove the face mask in the breakroom or other areas of the facility when no other staff are present.**
- Employees who are not fully vaccinated must also wear face mask when occupying a vehicle with another person for work purposes.

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**Disease Screening and Infection Control Requirements for Non-Clinical Service Staff**

All other persons that present to an FKC facility to provide non-clinical services (i.e., product/supply delivery persons, service repair persons, waste management) will be required to follow all screening and infection control practices. Non-clinical service staff are always required to wear, at minimum, a surgical mask when they are in an FKC facility.

- *Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care Dialysis Clinics*

Wherever possible, non-clinical service staff should be brought into the facility when there are no patients on premises and when there are limited staff members. They should be restricted to entry through the back entrance and loading dock area, or alternative door from the clinic waiting room. Limit all access and activity to necessary work areas only and avoid contact with patient and staff areas.

**References**

- [Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination](#)

**Related Documents**

- [COVID-19 Vaccine Mandate Exemption Requests](#)
- [Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care \(FKC\) Dialysis Clinics](#)
- [Dialyzing and Infection Control Practices with Coronavirus Disease Positive Patients and Persons Under Investigation \(PUI\)](#)
- [COVID-19 Disease Testing and Return to Work of Fresenius Kidney Care \(FKC\) Staff](#)
- [Acknowledgement of Compliance](#)
- [Third Party Company Acknowledgment of Compliance with Applicable COVID-19 Vaccine Mandate](#)