ALSTON & BIRD

WWW.ALSTON.COM



Labor & Employment and Health Care ADVISORY •

NOVEMBER 5, 2021

COVID-19 Vaccination Requirements for Health Care Staff

On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) released an interim final rule with comment period (IFC) to require many types of Medicare- and Medicaid-certified providers and suppliers to establish COVID-19 vaccination requirements for their staff. Under the IFC, providers must implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19, to provide medical and religious exemptions and related accommodations, and to track and document staff COVID-19 vaccinations. Comments on the IFC are due on January 4, 2022. CMS also released guidance in the form of Frequently Asked Questions (FAQs).

Which types of health care providers are covered by the rule?

Vaccination requirements under the IFC apply to the following types of health care providers and suppliers:

- 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 facilities, including skilled nursing facilities and nursing facilities, generally referred to as nursing homes
- Critical-access hospitals
- Ambulatory surgical centers
- Home health agencies
- Hospices
- Home infusion therapy suppliers
- Rural health clinics / federally qualified health centers
- Psychiatric residential treatment facilities
- End-stage renal disease facilities
- Programs of all-inclusive care for the elderly

This advisory is published by Alston & Bird LLP to provide a summary of significant developments to our clients and friends. It is intended to be informational and does not constitute legal advice regarding any specific situation. This material may also be considered attorney advertising under court rules of certain jurisdictions.

- Intermediate care facilities for individuals with intellectual disabilities
- Comprehensive outpatient rehabilitation facilities
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
- Community mental health centers

Notably, the IFC does not apply to physician offices because they are not subject to CMS health and safety regulations. Physicians who admit or treat patients on-site at an applicable facility, however, would be subject to the IFC as it applies to that facility.

Similarly, the rule does not apply to home and community-based service providers because they are not subject to CMS health and safety regulations. Further, the rule does not apply to assisted-living facilities or group homes, over which CMS does not have regulatory authority. Organ procurement organizations and portable x-ray suppliers are not directly included in the rule, but staff of these entities will be subject to vaccination requirements through their service arrangements with hospitals, nursing homes, or other covered facilities.

Which individuals are covered by the requirements?

Vaccination policies and procedures must be applied to staff who provide any care, treatment, or other services (regardless of clinical responsibility or patient contact), including: employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services under contract or other arrangement. The vaccine requirements reach all staff who interact with other staff or with patients, regardless of the frequency of patient contact, and reach all current staff as well as any new staff. At the site of care, CMS indicates that the IFC reaches administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others.

Standards differ slightly by provider type, but staff who provide support services that are performed exclusively outside of the care setting, and who do not have any direct contact with patients or covered staff, are generally excluded from the vaccination requirements.

Individuals who provide services 100 percent remotely, such as fully remote telehealth or payroll services, are also not subject to the vaccination requirements, but should be identified and monitored as part of the rule's requirements.

What are the vaccine requirements?

Providers and suppliers covered by the rule must ensure that staff are fully vaccinated for COVID-19, which for purposes of these requirements is defined as being two weeks or more since completion of a primary vaccination series. This is defined as a single-dose vaccine (such as Johnson & Johnson) or all required doses of a multidose vaccine (such as the Pfizer-BioNTech or Moderna). In accordance with Centers for Disease Control and Prevention (CDC) guidelines, staff may also receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the U.S. Food and Drug Administration (FDA) or vaccines as a part of a clinical trial.

When do the requirements go into effect?

Applicable providers and suppliers must establish a policy ensuring all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine before providing any care, treatment, or other services by **December 5, 2021.** All eligible staff must have received the necessary shots to be fully vaccinated by **January 4, 2022.** Although an individual is not considered fully vaccinated until 14 days after the final dose, staff who have received the final dose of a primary vaccination series by January 4, 2022 are considered to have met the individual vaccination requirements.

Are religious and medical exceptions allowed?

Also by December 5, 2021, providers and suppliers must implement a process for staff to request an exemption from COVID-19 vaccination requirements based on an applicable federal law. Recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. CMS guidance states that no exemption should be provided to any staff for whom it is not legally required (under the Americans with Disabilities Act or Title VII of the Civil Rights Act of 1964) or who requests an exemption solely to evade vaccination.

Is testing allowed as an alternative to vaccination? What about other accommodations?

No. Testing is not allowed as an alternative to vaccination under the IFC. For all staff who are not fully vaccinated, applicable providers and suppliers must have a process for ensuring the implementation of additional precautions intended to mitigate the transmission and spread of COVID-19.

CMS suggests testing, physical distancing, or source control as potential accommodations for exempted staff. CMS also notes that nothing prevents a provider from exercising testing precautions voluntarily in addition to vaccination.

Are there record-keeping requirements?

Yes. Applicable providers and suppliers must track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination (e.g., due to recent receipt of monoclonal antibodies or convalescent plasma). Providers and suppliers have the flexibility to use the appropriate tracking tools of their choice.

Who enforces the requirements?

CMS will enforce the requirement that facilities have the required policy in place through its survey authority. Forthcoming guidelines will instruct surveyors on how to determine if a provider or supplier is compliant with the requirements by reviewing the entity's records of staff vaccinations, such as a list of all staff and their individual vaccination status or qualifying exemption. The guidelines will also instruct surveyors to conduct interviews of staff to verify their vaccination status. Policies and procedures will be reviewed to ensure each component of these requirements have been addressed.

What are the potential consequences of noncompliance?

Providers and suppliers that are cited for noncompliance may be subject to enforcement remedies imposed by CMS depending on the level of noncompliance. The remedies available under federal law include civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement.

You can subscribe to future *Labor & Employment* and *Health Care* advisories and other Alston & Bird publications by completing our publications subscription form **publications subscription form**.

If you have any questions or would like additional information, please visit our <u>Labor & Employment</u> or <u>Health Care</u> groups or contact any of the following:

Ashley D. Brightwell 404.881.7767 ashley.brightwell@alston.com Elinor A. Hiller 202.239.3766 elinor.hiller@alston.com

asmey.ongneven@aistorn.com

elinor.hiller@alston.com

Angela T. Burnette 404.881.7665 angie.burnette@alston.com Brian Lee 202.239.3818 brian.lee@alston.com

F. Nicholas Chandler 404.881.7679 Charles H. Morgan 404.881.7187

nick.chandler@alston.com

charlie.morgan@alston.com

Brett E. Coburn 404.881.4990 Michael H. Park 202.239.3630

brett.coburn@alston.com

michael.park@alston.com

Christina Hull Eikhoff 404.881.4496 christy.eikhoff@alston.com Robert D. Stone 404.881.7270 rob.stone@alston.com

Ashley Gillihan 404.881.7390 ashley.gillihan@alston.com Kelsey K. Wong 213.576.1044

kelsey.wong@alston.com

Joyce Gresko 202.239.3628 joyce.gresko@alston.com

ALSTON & BIRD

WWW.ALSTON.COM

© ALSTON & BIRD LLP 2021