



## Federal Vaccine Mandates

### What Doctors of Optometry Need to Know Now

#### What do these new regulations do?

Two rules were released on November 4, 2021 which carry out an Executive Order issued by President Biden in September 2021.

1. One rule issued by the Department of Health and Human Services outlines a vaccine mandate for Medicare and Medicaid enrolled providers and suppliers. As AOA had anticipated, these rules DO NOT impact physician offices. If you are a Medicare or Medicaid enrolled physician and you provide care to Medicare and Medicaid patients outside of a physician's office (e.g. Ambulatory Surgical Center, Hospital) please review the information below in Section 1 for further details.
2. One rule issued by the Occupational Safety and Health Administration (OSHA) outlines a vaccine mandate for certain employers who have more than 100 employees. If you are an employer who has more than 100 employees, review the information below in Section 2 for further details.

#### MAJOR TAKE AWAYS

- If you are a Medicare or Medicaid enrolled doctor of optometry who only provides care to these patients in a physician's office, this mandate from HHS **does not** impact you.
- If you are a doctor of optometry who has fewer than 100 employees, this mandate from OSHA **does not** impact you.

### Section 1

#### HHS RULE: Medicare and Medicaid Enrolled Providers and Suppliers Vaccine Mandate

#### Who do these new regulations impact?

This mandate impacts Medicare and Medicaid enrolled providers, such as doctors of optometry who work in these settings:

- 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

**Are there exemptions for the mandate?**

Yes, this rule defers to other federal employment laws which allow for employees to request and receive exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance.

HHS notes that employers must also follow Federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status. For more information about these situations, employers can consult the Equal Employment Opportunity Commission's website at <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

HHS refers to the following recognized clinical contraindications to receiving a COVID-19 vaccine: <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>.

**What is considered "fully vaccinated"**

Individuals are considered fully vaccinated for COVID-19 14 days after receipt of either a single-dose vaccine (Janssen/Johnson & Johnson) or the second dose of a two-dose primary vaccination series (Pfizer-BioNTech/Comirnaty or Moderna).

**Does this mandate require individuals to have received a booster shot?**

No. Neither additional (third) doses nor booster doses are required by this rule.

**Does this mandate apply to staff working at one of the health care settings covered by the rule?**

Yes. This rule indicates that facilities impacted by the rule must develop and implement policies and procedures under which all staff are vaccinated for COVID-19, regardless of clinical responsibility or patient contact. The rule delineates individuals anticipated to be covered by the mandate: 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.

**Does the mandate impact individuals who work for an impacted health care setting, but work remotely?**

No.

**What about people who work at an impacted health setting but only go there infrequently?**

This rule would not impact those individuals. HHS indicates, "Providers and suppliers are not required to ensure the vaccination of individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. Other individuals who may infrequently enter a facility or site of care for specific limited purposes and for a limited amount of time, but do not provide services by contract or under arrangement, may include delivery and repair personnel. We believe it would be overly burdensome to mandate that each provider and supplier ensure COVID-19 vaccination for all individuals who enter the facility. However, while facilities are not required to ensure vaccination of every individual, they may choose to extend COVID-19 vaccination requirements beyond those persons that we consider to be staff as defined in this rulemaking."

**If an individual has already had COVID-19 are they required to follow this mandate?**

HHS has recognized that a significant number of health care staff have already had COVID-19, but notes that evidence indicates their infection-induced immunity, also called "natural immunity," is not equivalent to receiving the COVID-19 vaccine.

**When do the mandates take effect?**

The specific implementation dates were not published in the November 4 rule. There are two phases of implementation-Phase 1 and Phase 2.

It is anticipated that Phase 1 will be effective on January 4, 2022.

Phase 1: The rule indicates that, effective 30 days after publication of the rule, individuals must receive the first dose, or only dose as applicable, of a COVID-19 vaccine, or have requested or been granted an exemption to the vaccination requirements.

Phase 2: the rule indicates that, effective 60 days after publication of the rule, individuals must ensure that the primary vaccination series has been completed and that staff are fully vaccinated, except for those staff have been granted exemptions, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations.

**What kind of documentation must be retained to show vaccination status**

HHS is requiring that providers and suppliers track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Vaccine exemption requests and outcomes must also be documented

**What are examples of acceptable forms of proof of vaccination?**

- 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
- State immunization information system record.

**Will this mandate go away after the public health emergency ends?**

HHS expects this mandate to remain relevant for some time beyond the end of the formal PHE.

**What if one of the impacted health care settings does not follow this mandate?**

HHS is planning to advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers. Those who do not comply may be subject to enforcement remedies imposed by HHS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement). HHS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, resident, client, and PACE program participant health and safety.

**Does this rule require weekly testing for those who are unvaccinated?**

No. HHS considered requiring daily or weekly testing of unvaccinated individuals. The agency believes vaccination is a more effective infection control measure but will continue to take comments on this issue.

## Section 2

### OSHA Rule: Employers with Over 100 Employees

#### Are health care employers impacted by this rule?

OSHA has indicated that healthcare employers subject to the OSHA previously released health care standards are not covered by these rules. Doctors of optometry should review the AOA's resource on the OSHA standards for health care workers [here](#). If you are adhering to the OSHA standard outline in the AOA resource, you are not impacted by these new rules.

However, a doctor of optometry with more than 100 employees that was exempt from the previous OSHA standard because they are in a non-hospital ambulatory care setting where all non-employees are screened prior to entry would be subject to this rule.

#### What employers are impacted by these new regulations?

This rule impacts "large employers" which are defined as having 100 or more employees. If the employer has 100 or more employees on the effective date, this rule applies for the duration of the standard.

If the employer has fewer than 100 employees on the effective date of the standard, the standard would not apply to that employer as of the effective date. However, if that same employer subsequently hires more workers and hits the 100-employee threshold for coverage, the employer would then be expected to come into compliance with the standard's requirements. Once an employer has come within the scope of the rules, the standard continues to apply for the remainder of the time the standard is in effect, regardless of fluctuations in the size of the employer's workforce.

#### What are employers with more than 100 employees required to do?

Employers must develop and implement COVID-19 vaccination policy. A policy must be created to require COVID testing for all unvaccinated employees.

#### Can employees seek an exemption from the vaccine?

Yes, employees can seek an exemption for several reasons:

- (1) if the vaccine is medically contraindicated
- (2) if medical necessity requires a delay in vaccination
- (3) if the employee is legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely-held religious beliefs, practices, or observances that conflict with the vaccination requirement.

#### If an individual has had COVID-19 is that considered equivalent to being vaccinated?

No.

**Does this rule preempt state law?**

Yes, this rule will preempt what OSHA calls, “inconsistent state and local requirements, including requirements that ban or limit employers’ authority to require vaccination.”

**Are impacted employers required to pay for time off for employees to receive a vaccination?**

Yes, the rule requires all covered employers to support vaccination by providing employees with reasonable time, including up to four hours of paid time, to receive each vaccination dose, and reasonable time and paid sick leave to recover from vaccination side effects.

**For those employees who are not vaccinated, how often must the employee be tested for COVID?**

OSHA has set the minimum frequency of testing at 7 days.

**What kinds of tests are acceptable for weekly testing of unvaccinated employees?**

A “COVID-19 test” means a test for SARS-CoV-2 that is: (1) cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the U.S. Food and Drug Administration (FDA) to detect current infection with the SARS-CoV-2 virus (e.g., a viral test); (2) administered in accordance with the authorized instructions; and (3) not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. Examples of tests that satisfy this requirement include tests with specimens that are processed by a laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection and processing is either done or observed by an employer.

Employers have the flexibility to select the testing scenario that is most appropriate for their workplace.

**Is the employer required to pay for the costs associated with regular COVID-19 testing or the use of face coverings?**

In some cases, employers may be required to pay testing and/or face covering costs under other federal or state laws or collective bargaining obligations, and some may choose to do so even without such a mandate, but otherwise employees will be required to bear the costs if they choose to be regularly tested and wear a face covering in lieu of vaccination.

**What happens if an employee tests positive?**

All employers must remove from the workplace any employee who receives a positive COVID-19 test, or a COVID-19 diagnosis. The COVID-19-positive employee will be isolated from the workplace until it is safe for the employee to return.

**Do unvaccinated individuals need to wear masks?**

Yes, unvaccinated workers must wear face coverings when they are working near others.

**When is this rule effective?**

By December 6 create a vaccination policy.

By January 4 employers must begin testing for those who are not vaccinated.

### **What documentation needs to be retained to track vaccination status?**

The standard requires employers to determine the vaccination status of each employee and also to maintain records of each employee's vaccination status, preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated, and maintain a roster of each employee's vaccination status. It is important to ensure compliance with requirements for confidentiality of medical information.

### **What are acceptable proof of vaccination status documents?**

- (i) the record of immunization from a health care provider or pharmacy;
- (ii) a copy of the U.S. CDC COVID-19 Vaccination Record Card (CDC Form MLS-319813\_r, published on September 3, 2020) (CDC, October 5, 2021);
- (iii) a copy of medical records documenting the vaccination;
- (iv) a copy of immunization records from a public health, state, or tribal immunization information system; or
- (v) 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(s) or clinic site(s) administering the vaccination

### **Additional Resources**

[HHS Rule](#)

[OSHA Rule](#)

[OSHA FAQs](#)

**Please note:** This information is not considered legal advice. This information was drafted on the date of release of the rules and additional guidance and clarification will be provided on an ongoing basis.