



APTA Practice Advisory: CMS COVID-19 Health Care Staff Vaccination Rule

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The issue: On Nov. 4, the Centers for Medicare and Medicaid Services and the Occupational Safety and Health Administration issued federal regulations on COVID-19 vaccine mandates.

Legal status update: Both vaccine mandates are facing legal challenges and are being held up in the courts. On Nov. 30, a district court in Louisiana blocked the CMS vaccine mandate nationwide. This ruling applies to all states, except for ten states (Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming) in which the CMS mandate had already been blocked in a district court in Missouri on Nov. 29. CMS is thus halted from implementing and enforcing the rule pending further action from the courts.

On Nov. 6, the Fifth Circuit Court of Appeals froze the OSHA vaccine mandate, and OSHA announced that it was suspending implementation and enforcement of the rule. Legal challenges to the OSHA vaccine mandate have since been consolidated in the Sixth Circuit Court of Appeals. APTA will monitor the legal proceedings of both vaccine mandates.

What you need to know: The CMS interim final rule applies to employees regardless of whether their positions are clinical or nonclinical and includes employees, students, trainees, and volunteers who work at a covered facility that receives federal funding from Medicare or Medicaid. It also includes individuals who provide treatment or other services for the facility under contract or other arrangements. Among the facility types covered by the rule are hospitals; ambulatory surgery centers; dialysis facilities; home health agencies; long-term care facilities; and clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services.

Suggested next steps: Physical therapists, physical therapist assistants, and their employers should review both the CMS and OSHA mandates to determine if they are subject to one, both, or neither. If the rule is applicable to you based on your setting, review the information to avoid potential penalties or other consequences for noncompliance, which could include civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement.

About APTA Practice Advisories

APTA issues practice advisories to assist the physical therapy community in providing quality care that follows best available evidence and practice management principles. Practice advisories are not formal association guidelines, policies, positions, procedures, or standards. They are not clinical practice guidelines and do not establish a standard of care.

Physical therapists, physical therapist assistants, and students of physical therapy are responsible for clinical practice that is consistent with their scope of practice, and for complying with licensure laws and other regulations, all of which vary by state. The information provided is not meant as a substitute for legal or professional advice on any subject matter.

Practice advisories may be updated after their original publication. Use of practice advisories is voluntary.

Who Does This Impact?

Facilities subject to COVID-19 vaccination requirements: The staff vaccination requirements apply to Medicare and Medicaid provider and supplier types that are certified under the Medicare health and safety standards known as [Conditions of Participation](#), [Conditions for Coverage](#), or Requirements. Physical therapists in private practice or group practices — commonly called therapists in private practice, or TPPs — are not subject to certification under these regulations, and as CMS states in its [FAQ](#) on the rule, the staff vaccination requirements don't apply to non-certified private practice therapy providers.

To explain further, TPPs may resemble CMS-certified outpatient therapy providers, and it might be hard to distinguish between the two without knowing how each is enrolled in Medicare. Certified outpatient therapy providers complete a survey from the state agency or a CMS-approved accrediting organization as part of the enrollment process. Once enrolled, they receive a CMS certification number for billing Medicare services. TPPs in Medicare are not surveyed, and they are issued a provider transaction access number for Medicare billing.

If you're enrolled in Medicare as a CMS-certified therapy provider — your enrollment included one of the surveys and you have a CMS certification number, the COVID-19 vaccination requirements apply to all applicable staff in your organization.

If your Medicare enrollment didn't involve one of the surveys and resulted in a provider transaction access number, you are not a certified provider and the COVID-19 vaccination requirements do not apply to the staff in your organization. Even so, CMS encourages all individuals who work with patients to receive vaccinations, whether or not they are subject to the regulation.

Additionally, the rule does not apply to providers of home and community-based services, group homes, assisted living facilities, or physician's offices.

The rule covers approximately 76,000 health care facilities and more than 17 million health care workers, including:

- Ambulatory surgical centers.
- Hospices.
- Psychiatric residential treatment facilities.
- Programs of all-inclusive care for the elderly.
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long-term care hospitals, children's hospitals, transplant centers, cancer hospitals, rehabilitation hospitals, inpatient rehabilitation facilities).
- Long-term care facilities, including skilled nursing facilities and nursing facilities, generally referred to as nursing homes.
- Intermediate care facilities for individuals with intellectual disabilities.
- Home health agencies.
- Comprehensive outpatient rehabilitation facilities.
- Critical access hospitals.
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services.
- Community mental health centers.
- Home infusion therapy suppliers.
- Rural health clinics and federally qualified health centers.
- End-stage renal disease facilities.

Staff subject to COVID-19 vaccination requirements: Providers and suppliers subject to the mandate must develop and implement policies and procedures under which all staff are vaccinated for COVID-19.

This vaccination requirement applies to eligible staff working at a facility that participates in the Medicare and Medicaid programs. Each facility's COVID-19 vaccination policies and procedures must apply to the following facility staff, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff who provide any care, treatment, or other services for the facility and/or its patients. These requirements encompass 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.

These requirements are not limited to staff who perform their duties solely within a formal clinical setting, as many health care staff routinely care for patients and clients outside the facility, such as home health and home infusion therapy. All staff who interact with other staff, patients, residents, clients, or PACE program participants in any location beyond the formal clinical setting — such as homes, clinics, other sites of care, administrative offices, and off-site meetings — must be vaccinated.

Documentation: Affected facilities must have a process or plan in place for tracking and securely documenting the vaccination status of each staff member, as well as individuals who provide services under contract or other arrangements. This includes staff for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Documentation could be in a facility's immunization record, health information files, or other relevant documents. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files. Acceptable forms of proof of vaccinations include: (1) CDC COVID-19 vaccination record card (or legible photo of the card); (2) documentation of vaccination from a health care provider or electronic health record; and (3) state immunization information system record.

NOTE: Even if you aren't subject to this mandate you may still be required to comply with state or local requirements. In addition, you may be subject to the [recent rule released by the Occupational Safety and Health Administration](#). The OSHA rule requires employers with 100 or more employees to get their employees vaccinated by Jan. 4, 2022, or require unvaccinated employees to produce a negative test on at least a weekly basis. [Visit the OSHA website for more details.](#)

Exceptions to the Mandate

Under the CMS rule, individuals who provide services 100% remotely, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements.

Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices may provide grounds for exemption. With regard to 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](#).

Facilities may establish their own processes that permit staff to request a religious exemption from the COVID-19 vaccination requirements. CMS requires facilities to ensure that requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of a facility's policies and procedures.

As with religious exemptions, facilities may establish their own processes that permit staff to request a medical exemption from the COVID-19 vaccination requirements. Facilities must ensure that all documentation confirming recognized clinical contraindications to COVID-19 vaccinations for staff seeking a medical

exemption are signed and dated by a licensed practitioner, who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. This documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications. Additionally, a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements is also expected.

The regulation requires that facilities implement additional precautions for any staff who are not vaccinated, in order to mitigate the transmission and spread of COVID-19. Under federal law, including the Americans with Disabilities Act and Title VII 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 entitled to an accommodation. CMS encourages facilities to review the [Equal Employment Opportunity Commission's website](#) for additional information about situations that may warrant accommodations. In granting exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients.

In some circumstances, employers may be required by law to offer accommodations for some individual staff members. Accommodations can be addressed in the provider's or supplier's policies and procedures. Requests for exemptions based on an applicable federal law must be documented and evaluated in accordance with applicable federal law and each facility's policies and procedures.

When Do the Mandates Take Effect?

The rule is effective Nov. 5, 2021, with two phase-in dates (subject to the legal challenges noted earlier):

Phase 1, effective Dec. 5, 2021, includes nearly all provisions of the rule, including the requirements that all staff have received, at a minimum, the first dose of the primary series or a single-dose COVID-19 vaccine, or requested and/or been granted a lawful exemption, prior to staff providing any care, treatment, or other services for the facility and/or its patients. Phase 1 also requires facilities to have appropriate policies and procedures developed and implemented, and requires that all staff have received a single-dose COVID-19 vaccine or the initial dose of a primary series within 30 days after publication of this rule in the Federal Register.

Phase 2, effective Jan. 4, 2022, requires that all applicable staff are fully vaccinated for COVID-19, except for those granted exemptions from COVID-19 vaccination or for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations. 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 the Phase 2 effective date are considered to have meet the individual vaccination requirements, even if they have not yet completed the 14-day waiting period. For example, an individual may receive the first dose of the Moderna mRNA COVID-19 vaccine two or three days prior to the Phase 1 deadline but must wait at least 28 days before receiving the second dose. This second dose could (and must, for purposes of the CMS rule) be administered prior to the Phase 2 effective date, but the individual still must meet additional precautions until 14 days had passed. This timing flexibility applies only to the initial implementation of the CMS ruling and has no bearing on ongoing compliance.

Impact of Noncompliance

CMS will ensure compliance with these requirements through established survey and enforcement processes. If a provider or supplier does not meet the requirements, it will be cited by a surveyor as being noncompliant and have an opportunity to return to compliance before additional actions occur.

CMS will issue interpretive guidelines, which include survey procedures.

Providers and suppliers that are cited for noncompliance may be subject to enforcement remedies imposed by CMS that depend 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). CMS 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.

CMS expects state survey agencies to conduct onsite compliance reviews of these requirements in two ways:

- State survey agencies would assess all facilities for these requirements during the standard recertification survey.
- State survey agencies would assess vaccination status of staff on all complaint surveys.

While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last four weeks, and a list of all staff and their vaccination status. This information, in addition to interviews and observations, will be used to determine provider or supplier compliance.

Additionally, accrediting organizations will be required to update their survey processes to assess facilities they accredit for compliance with vaccination regulations.

Medicare- and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure. The remedy for noncompliance among hospitals and certain other acute and continuing care providers is termination; however, CMS's goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

CMS surveyors cite hospitals and other facilities based on the severity of deficiency, classified among three levels, from most to least severe: **Immediate Jeopardy**, **Condition**, and **Standard**. In all cases, health care facilities have an opportunity to return to compliance before termination.

- **Immediate Jeopardy** citations indicate a serious scope of noncompliance, failure of the provider to address deficiencies, and close interaction with patients of unvaccinated staff. Termination of the provider type will occur within 23 days following the citation if not immediately addressed.
- **Condition**-level citations indicate substantial noncompliance that needs to be addressed to avoid termination.
- **Standard**-level citations indicate minor noncompliance in which (with respect to this rule) almost all staff are vaccinated, the provider has a reasonable policy in place to educate staff on the vaccinations, and the provider has procedures for tracking and monitoring vaccination rates. CMS generally allows for continued operation subject to the facility's agreement to a CMS-approved plan of correction.

APTA's Position on Vaccines

The APTA House of Delegates position [Support for Participation in Centers for Disease Control and Prevention Recommended Vaccination Schedules](#) (HOD P06-19-75-41) supports the [Centers for Disease Control and Prevention](#) recommendations for age-appropriate vaccinations, including the COVID-19 vaccination.

APTA recently issued a [joint statement](#) with the American Occupational Therapy Association and the American Speech-Language-Hearing Association on COVID-19 vaccination. APTA strongly encourages, recommends, and supports all health care professionals to obtain full vaccination status and to educate our peers, patients, and the public on the need for vaccinations to address the public health challenges associated with COVID-19.

CMS Resources

- [CMS interim final rule](#)
- [CMS press release](#)
- [FAQs](#)

APTA Resources

Members can reach out to advocacy@apta.org with questions and check out [APTA's Coronavirus Resources](#) and [APTA Learning Center Courses](#).

Last Updated: 12/01/2021 | **Contact:** advocacy@apta.org