



CMS VACCINE MANDATES

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WRITTEN MATERIALS

- CMS Rules, 86 FR 61555 (11/5/21), <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf>
- CMS Health Care Staff Vaccination Interim Final Rule FAQs, <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>
- Stanger, *CMS Vaccine Mandate for Healthcare Workers: Resources for Preparing Your Policies*, <https://www.hollandhart.com/cms-vaccine-mandate-for-healthcare-workers-resources-for-preparing-your-policies>

PRELIMINARIES

- If you did not receive .ppts or written materials, please e-mail MRVarga@hollandhart.com.
- Submit questions using the “chat” feature or send e-mail to MRVarga@hollandhart.com or any of the presenters.
- This is an overview of the requirements.
 - Application and requirements depend on the facility type and circumstances.
 - Additional requirements may apply to certain facilities (e.g., Nursing Facilities per 9/20 regulation)
 - Facilities should review the specific regulations applicable to their facility type.

COVERED FACILITIES

Medicare/Medicaid certified facilities regulated by Medicare health and safety standards (CoPs, CoCs, Requirements)

- Hospitals and CAHs
- Ambulatory surgery centers
- Nursing facilities
- Rural health centers
- Federally qualified health centers
- Community mental health centers
- Hospices
- Home health agencies
- Home infusion therapy
- End-stage renal disease facilities
- Intermediate care facilities for individuals with intellectual disabilities
- Psychiatric residential treatment facilities
- Comprehensive outpatient rehab facilities
- Programs for all-inclusive care for the elderly
- Clinics, rehab agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services

COVERED FACILITIES

42 CFR	Facility Type	Regulatory Section
416.51	Ambulatory Surgery Services (ASC)	Infection control
418.60	Hospice Care	Infection control
441.151	Psychiatric residential treatment facilities (PRTF)	General requirements
460.74	Programs of All-Inclusive Care for the Elderly (PACE)	Infection control
482.42	Hospitals	Infection control
483.80; 483.430	Long Term Care Facilities (SNF and NF); Intermediate Care Facilities for Disabilities (ICFs-IID)	Infection control; facility staffing
484.70	Home Health Agencies (HHA)	Infection control
485.58, .70, .640, .725, 904	CAH, CORF, CMHC, Clinics and certain other providers of outpatient PT and speech-language pathology	Infection control; personnel qualifications
486.525	Home Infusion Therapy (HIT)	Required services
491.8	Rural Health Center (RHC), Federally Qualified Health Center (FQHC)	Staffing
494.30	End-Stage Renal Disease Facilities (ESRD)	Infection control

NOT COVERED

- Providers and facilities that are not subject to Medicare health and safety regulations.
 - Conditions of participation
 - Conditions of coverage
- Provider practices.
- Assisted living facilities or group homes.
- Medicaid home care services.
- Others

(<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)

But...

- CMS mandate may apply indirectly if they render services at covered facility
- May be subject to other mandate, e.g.,
 - OSHA (100+ employees)
 - Federal contractors
 - State mandates

WHAT MUST FACILITIES DO?

- **By December 6, 2021***
 - Implement policies and procedures to vaccinate covered staff.
 - Covered staff must receive the J&J vaccine or the first dose of the Pfizer or Moderna vaccine before they provide any care, treatment or other services for the facility or its patients unless exempted or person's vaccination is delayed due to contraindications.
- **By January 4, 2022**
 - Covered staff must be fully vaccinated unless exempted or person's vaccination is delayed due to contraindications.
 - "Fully vaccinated" generally means receiving final dose + 14 days.
 - For purposes of January 4, 2022 deadline, staff who have received the final dose are deemed to be "fully vaccinated" without the 14 days.

(86 FR 61555)

➤ *No testing alternative.*

COVERED STAFF

- Policies and procedures for vaccine mandate must cover the following personnel (“covered staff”) regardless of clinical responsibility or patient contact:
 - Facility employees
 - Licensed practitioners
 - Students, trainees, and volunteers
 - Individuals who provide care, treatment, or other services for the facility and/or its patients under contract or by other arrangement
 - *Consider frequency of presence, services provided, and proximity to patients and staff*

NON-COVERED STAFF

- Policies and procedures for vaccine mandate do not need to cover:
 - Staff who provide telehealth exclusively:
 - Outside facility setting, and
 - Do not have any direct contact with patients or other covered staff.
 - Staff who provide support services for the facility
 - Performed exclusively outside the facility setting, and
 - Do not have any direct contact with patients or other covered staff.
- *Must be 100% remote and 0% direct contact with patients or other covered staff.*

APPROVED VACCINES

- Licensed or authorized for emergency use by the FDA.
 - Pfizer-BioNTech COVID-19 Vaccine (multi-dose)
 - Moderna COVID-19 Vaccine (multi-dose)
 - Janssen (Johnson & Johnson) COVID-19 Vaccine (single dose)
- Listed by the World Health Organization (“WHO”) for emergency use even if not approved or authorized by the FDA.
- Vaccines administered through participation in a clinical trial.
(<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)

BOOSTERS

- The current rules do not require boosters to be “fully vaccinated”.
- But the science is changing rapidly and this may change...
- Boosters or third doses of certain vaccines are recommended by the CDC, but not required by the CMS Rule.

(<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)

POLICIES AND PROCEDURES MUST ADDRESS

- Process to ensure covered staff are fully vaccinated unless exempted.
- Process for staff to request exemption based on applicable federal law (e.g., Title VII and ADA).
 - Disability or medical condition + required documentation.
 - Sincerely held religious belief
- Additional precautions to mitigate spread of COVID-19 for staff who are not fully vaccinated.
- Track and document:
 - Vaccination status of covered staff.
 - Vaccination status of booster doses recommended by CDC.
 - Vaccination status of those whose vaccination was delayed due to contraindications recognized by CDC.
 - Information from those who have been granted exemption.
- Contingency plans for staff who are not fully vaccinated.

DELAY DUE TO CONTRAINDICATIONS

- May temporarily delay a person's vaccination if CDC recommends delay due to clinical precautions and considerations, e.g.,
 - Acute illness secondary to COVID-19
 - Received monoclonal antibodies or convalescent plasma for COVID-19 treatment.
 - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine.
 - Others?

See <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

PROCESS FOR REQUESTING EXEMPTION

- Employees may request exemption; facility should establish process for considering exception, including:
 - Written request with appropriate supporting documentation.
 - Knowledgeable persons authorized to review, approve or disprove the exemption.
 - Accommodations if exemptions granted.
 - Documentation.
- See EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

MEDICAL EXEMPTION

- Documentation supporting exemption must:
 - Be signed and dated by another licensed practitioner.
 - Not the individual requesting the exemption.
 - Practitioner acting within scope of practice as defined by, and in accordance with, all applicable state and local laws.
 - Include information specifying:
 - Which of the authorized vaccines are clinically contraindicated.
 - Recognized clinical reasons for contraindications.
 - Practitioner's statement recommending that the staff member be exempted from the vaccination based on the recognized clinical contraindications.
- For recognized contraindications, see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

RELIGIOUS EXEMPTION

- Sincerely held religious belief, practice or observance.
 - “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.”
 - “CMS believes that exemptions could be appropriate in certain limited circumstances, but no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII of the Civil Rights Act of 1964) or who requests an exemption solely to evade vaccination.”

(CMS FAQs, <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)
- See EEOC guidance
 - *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>
 - *Compliance Manual on Religious Discrimination*, <https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>

ACCOMMODATIONS AND PRECAUTIONS FOR UNVACCINATED PERSONS

- May include:
 - Masks and face coverings
 - Personal protective equipment (“PPE”)
 - Sterilization and washing
 - Periodic testing
 - Personal distancing
 - Quarantines
 - Telework or reassignment
 - Education
 - Others?
- CDC, Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>
- OSHA, Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace, <https://www.osha.gov/coronavirus/safework>

TRACKING AND DOCUMENTING VACCINATION STATUS

- Must track and securely document vaccination status.
- Proof of vaccination may include:
 - CDC COVID-19 vaccination card
 - Documentation from a healthcare provider
 - Electronic health record*
 - Other?
- See CDC Vaccination Tracking Tool,
<https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html>

*Consider HIPAA implications discussed below.

CONFIDENTIALITY OF VACCINE INFO

- Vaccination info is protected under ADA.
 - Maintain in separate employee medical file.
 - Use and disclose consistent with ADA requirements.

See <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

- Vaccination info may be subject to HIPAA if (1) facility administered the vaccine, or (2) facility obtained info through its employee benefit plan.
 - Consider obtaining employee's authorization to access and use employee's protected health info ("PHI") for employment purposes.
 - Not clear if HIPAA exceptions would allow use or disclosure of employee's PHI without employee's authorization, e.g.,
 - Health care operations, e.g., quality assurance, qualifications of staff, and/or compliance.
 - OSHA surveillance if certain conditions are satisfied.
 - Other?

See <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html> and <https://www.hollandhart.com/employee-vaccine-information-privacy-concerns>

CONTINGENCY PLAN

- For staff that are not fully vaccinated:
 - Ensure they will soon be vaccinated, and
 - Ensure they will not provide care, treatment, or other services for the provider or its patients until they have:
 - Been fully vaccinated, or
 - At a minimum, have received the J&H vaccine or the first does of the Pfizer or Moderna vaccine.
- Address safe provision of services by staff who have:
 - Staff who have requested an exemption while their request is being considered, and
 - Staff for whom COVID-19 vaccination must be temporarily delayed due to clinical precautions and considerations per the CDC.

(86 FR 61573)

ENFORCEMENT

SNF, Hospice, HHA

- Civil monetary penalties
- Denial of payment on future admissions
- Termination of provider agreement
 - Complaint or re-certification survey
 - Attempts to bring into compliance
 - CMS to issue guidance to surveyors

Other facilities

- Termination of provider agreement
 - Complaint or re-certification survey
 - Attempts to bring into compliance
 - CMS to issue guidance to surveyors
- *Will CMS really terminate agreement of necessary providers?*

(<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)

OTHER POTENTIAL CONSIDERATIONS

If vaccinate

- Potential staff departures
- Conflict with state requirements or contracts

If fail to vaccinate

- Potential staff departures
- Loss of staff due to infection or quarantine
- Loss of business due to public concern
- Human and financial costs of continued pandemic
- Negligence claims if infection occurs due to failure to follow rules

LEGAL CHALLENGES

- Courts have consistently upheld vaccine mandates.
- CMS takes the position that its rules preempt contrary state or local laws.
 - Supremacy Clause of the Constitution
- CMS rule is a condition to participating in Medicare.
 - Courts usually uphold conditions associated with receipt of federal funds.
- CMS declared that if a Court enjoins a portion of the rules, the remaining portion of the rules should remain in effect.

CONFLICT WITH STATE LAW

“Q: What happens if State law prohibits vaccine mandates? How can CMS expect a facility to follow its requirements if its State prevents them from implementing this rule?”

“A: Under the Supremacy Clause of the U.S. Constitution, this regulation pre-empts any state law to the contrary. U.S. Const. art. VI § 2.”

(<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>)

TO DO

- ✓ Consider application of other mandates, including:
 - ✓ OSHA
 - ✓ Federal contractor
 - ✓ Others
- ✓ Educate staff.
- ✓ Consider employee benefit incentives.
- ✓ Review, update, and/or create policies by December 6.
- ✓ Establish workplace vaccination program. See CDC *Workplace Vaccination Program*, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/essentialworker/workplace-vaccination-program.html>
- ✓ Consider application to facility personnel, vendors, contractors and others coming onto facility or in contact with facility patients or personnel.

TO DO

- ✓ Review and update contracts with contractors and vendors.
 - ✓ May already incorporate compliance with facility policies
- ✓ Review and update Medical Staff Bylaws, Rules and Regulations
 - ✓ May already incorporate compliance with facility policies
- ✓ Implement the policies beginning December 6.
 - ✓ Prohibit services unless persons receive first dose or are exempt.
 - ✓ Consider requests for exemptions.
 - ✓ Implement accommodations.
 - ✓ Implement other appropriate precautions to protect staff and others.
- ✓ Require “full” vaccination by January 4, 2022.
- ✓ Track and document vaccination status, exemptions, etc.
- ✓ Watch for further developments...

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- Ambulatory surgery centers
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- Rehabilitation centers
- Extended and eldercare facilities

Webinars and Publications

THANK YOU – ANY QUESTIONS?



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