

IMPLEMENTING THE CMS VACCINE MANDATE



Brad Cave
Kim Stanger
(3-22)

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OVERVIEW

Kim Stanger

Rule requirements

- Deadlines
- Application
- Vaccination requirements
- Policy requirements
- CMS Enforcement

Brad Cave

Implementing the rules

- Handling exemptions
- Accommodations
- Adverse action for noncompliance
- Confidentiality concerns

WRITTEN MATERIALS

- Vaccine Mandate Rule, 86 FR 61555 (11/5/21), <https://www.federalregister.gov/citation/86-FR-61555>
- CMS, External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (1/22), <https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf>
- CMS, Guidance for Omnibus COVID-19 Health Care Staff Vaccination Rule, CMS QSO-22-07-ALL (12/28/21), <https://www.cms.gov/files/document/qso-22-07-all.pdf>
- CMS, Guidance for Omnibus COVID-19 Health Care Staff Vaccination Rule, CMS, QSO-22-09-ALL (1/14/22), <https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf>
- CMS, Hospital Attachment for QSO-22-07-ALL, <https://www.cms.gov/files/document/qso-22-07-all-attachment-d-hospital.pdf>



WRITTEN MATERIALS

- Annotated sample policy and forms for a hospital.
- H&H Client Alert, *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>
- H&H Client Alert, *CMS Vaccine Mandate: New Deadlines*, <https://www.hollandhart.com/cms-vaccine-mandate-new-deadlines>
- H&H Client Alert, *Evaluating Religious Exemption Requests Under the CMS COVID-19 Vaccine Mandate*, <https://www.hollandhart.com/evaluating-religious-exemption-requests-under-the-cms-covid-19-vaccine-mandate>

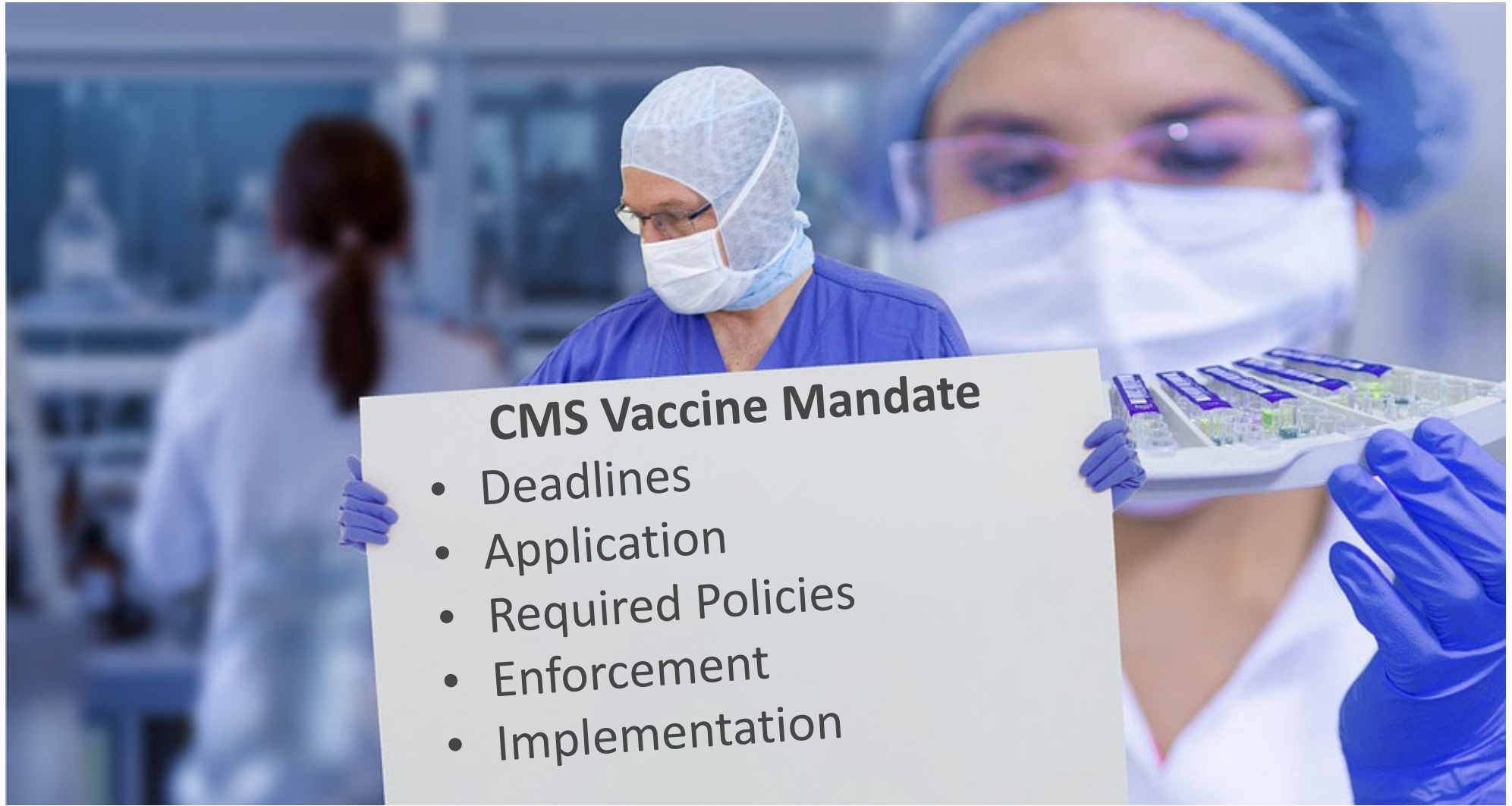
CAUTION

- We are only covering CMS vaccine mandate for healthcare workers.
- Some states, local govts, or private employers may have their own vaccine mandates.
- CMS takes the position that its rule preempts contrary state laws, e.g.,
 - Prohibitions against vaccine mandates.
 - Additional exemptions for good faith belief.
(86 FR 61572)
- Some entities may be subject to additional regulatory requirements, e.g.,
 - CMS rules for nursing facilities.
 - OSHA general duty clause.
 - Others.

CAUTION

- Mandate appears in relevant CMS life safety regulations for covered providers.
 - Usually appear in regulations governing infection control.
- In this presentation, we cite regulations applicable to hospitals, but the requirements are similar for other providers.
- Check the specific regulations applicable to your provider type.

CMS VACCINE MANDATE



BRIEF HISTORY

Date	Event
8/18/21	CMS announced vaccine mandate for nursing home staff
11/5/21	CMS issued interim final rule mandating vaccine for staff of specific CMS-certified facilities
	24 states filed lawsuits; federal court issued injunction for the 24 states in the lawsuits; injunction did not extend to remaining states
1/13/22	Supreme Court rejected primary arguments raised by states and vacated injunction
12/28/21 1/13/22	CMS issued survey guidance concerning implementing the mandate (QSO-22-7-ALL and QSO-22-9-ALL)
1/31/22	WV and VA requested waiver; CMS considering same
2/4/22	States continue to push lawsuit...
Stay tuned.	

DEADLINES

States	Phase 1: First Dose	Phase 2: Second Dose
CA, CO, CT, DE, DC, FL, HI, IL, ME, MD, MA, MI, MN, NV, NJ, NM, NY, NC, OR, PA, RI, TN, VT, VA, WA, WI	January 27, 2022	February 28, 2022
AL, AK, AZ, AR, GA, ID, IN, IA, KS, KY, LA, MS, MO, MT, NE, NH, ND, OH, OK, SC, SD, UT, WV, WY	February 14, 2022	March 15, 2022
TX	February 22, 2022	March 21, 2022

BREAKING NEWS

← → ↻ 🏠 <https://www.govexec.com/management/2022/03/senate-passes-measure-aimed-undoing-healthcare-vaccine-mandate/362668/>

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The Senate Passes a Measure Aimed at Undoing the Vaccine Mandate for Healthcare Workers

The Supreme Court allowed it to stand last month, but lawmakers say the measure punishes the health care workforce.

MARCH 2, 2022 03:50 PM ET

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The Senate voted on Wednesday to repeal President Biden's COVID-19

APPLIES TO SPECIFIED CMS-CERTIFIED FACILITIES

- Hospitals (42 CFR 482.42)
 - CAHs (485.640)
 - SNFs and NFs (483.30)
 - ASCs (416.51)
 - Hospices (418.60)
 - HHAs (484.70)
 - RHCs/FQHCs (491.8)
 - ESRDs (494.30)
 - CORFs (485.58 and .70)
 - Community Mental Health Centers (485.904)
 - Psychiatric Residential Treatment Facilities (411.151)
 - Home Infusion Therapy Suppliers (486.525)
 - Intermediate Care Facilities for Individuals with Intellectual Disabilities (483.430)
 - Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (485.725)
 - Programs for All-Inclusive Care for the Elderly (PACE) Organizations (460.74)
- (86 FR 61556; CMS FAQs)

DOES NOT APPLY DIRECTLY

- Does not apply directly to:
 - Non-CMS certified facilities.
 - Providers, facilities or suppliers that are not on the list.
 - Most physician or provider groups
 - Labs, pharmacies, imaging, etc.
 - Assisted Living Facilities
 - Religious Nonmedical Health Care Institutions
 - Organ Procurement Organizations
 - Portable X-Ray Suppliers
 - FQHCs that do not participate in Medicare

(CMS FAQs)

- CMS-certified provider may require vaccination if provide services under contract or arrangement.

REQUIRED POLICIES AND PROCEDURES

- ✓ Ensure all staff are fully vaccinated unless exempted.
- ✓ Process to request exemptions per federal law.
 - Delays due to CDC contradictions
 - Medical exemptions
 - Other exemptions
- ✓ Ensure unvaccinated staff adhere to precautions to mitigate spread of COVID-19.
- ✓ Track and securely document vaccination and booster status.
- ✓ Contingency plan for staff who have not completed primary vaccination series.

(42 CFR 482.42(g)(3))

STAFF VACCINATIONS

- Ensure all staff are fully vaccinated prior to providing any care, treatment or other services for the facility and/or its patients unless exempt.
 - CMS survey criteria expects 100% compliance.
- Exemptions
 - Vaccination temporarily delayed because is contraindicated based on CDC guidance.
 - Person granted exemption under federal law.
 - Medical condition (ADA)
 - Sincerely held religious belief (Title VII)
 - Other?

(42 CFR 482.42(g)(3))

COVERED "STAFF"

- Employees
- Licensed practitioners, including medical staff members
- Adult students
- Trainees
- Volunteers
- Others who provide care, treatment, or other services for the facility and/or its patients **under contract or other arrangements**

(42 CFR 482.42(g)(1))

- Existing and new staff.
- Clinical and non-clinical, admin duties.
- With or without patient contact.
- Inside and outside the facility.

COVERED “STAFF”

- Examples of others who provide care, treatment, or services for the facility and/or patients under arrangement:
 - Hospice and dialysis staff
 - Physical therapists
 - Occupational therapists
 - Mental health professionals
 - Social workers
 - Portable x-ray suppliers
 - Fiduciary board members
 - Vendors and vendor representatives
 - Contractors
 - Many, many others

(86 FR 61570)

COVERED “STAFF”

- “[F]acilities are not required to ensure vaccination of vendors, volunteers, or professionals who **infrequently** provide **ad hoc, non-health care** services (e.g., annual elevator inspection) or services that are performed **exclusively offsite** and not at or adjacent to any site of patient care (such as accounting services).”

(CMS FAQs; 86 FR 61571)

- Consider the frequency, services provided, and proximity to patients and staff, e.g.,
 - Plumber making emergency repair in restroom: not required to be vaccinated.
 - Construction crew using common areas: may be required to be vaccinated.

(86 FR 61570-71)

“STAFF” NOT COVERED

- Staff who:
 - Provide telehealth or support services 100% remotely, and
 - Do not have any direct contact with patients or other staff.

(42 CFR 482.42(g)(2))

- Visitors
- Persons who may be onsite or have contact with staff or patients but who do not provide services for the facility and/or its patients under contract or other arrangements (e.g., delivery personnel, repair personnel, etc.)

(86 FR 61570-71)

APPROVED VACCINES

- Approved vaccines:
 - Janssen (Johnson & Johnson)
 - Pfizer-BioNTech
 - Moderna
 - Vaccine listed by WHO for emergency use
 - Vaccine that is part of a clinical trial

(86 FR 61571)

- Vaccination ≠
 - Had COVID-19
 - Had first dose of multi-dose vaccine
 - Had dose of non-approved vaccine

“FULLY VACCINATED”

- For Phase 2 Deadline
 - Complete “primary vaccination series”, i.e.,
 - Single-dose vaccine (e.g., Janssen/Johnson and Johnson)
 - Second dose of 2-dose vaccine (e.g., Pfizer-BioNTech, Moderna)
- After Phase 2 Deadline:
 - Complete primary vaccination series + 14 days
(42 CFR 482.42(g)(1))
- Rule does not currently require boosters.
 - But still required to track booster status.

ACCEPTABLE PROOF OF VACCINATION

- CDC COVID-19 vaccination record card (or legible photo of the card).
- Documentation of vaccination from a health care provider or electronic health record.
- State immunization info system record.
- If vaccinated outside the US, a reasonable equivalent of the foregoing.
- Other?

(CMS FAQs; 86 FR 61572)

PRECAUTIONS FOR UNVACCINATED STAFF

- Ensure unvaccinated staff adhere to precautions to mitigate spread of COVID-19, e.g.,
 - Reassign staff to non-patient care areas; reassign to duties that reduce risk of infection, or remote work.
 - Physical distancing when possible
 - NIOSH-approved N95 masks or higher
 - Weekly testing
 - Other CDC precautions at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

(42 CFR 482.42(g)(3)(iii); QSO-22-07-ALL Attachment)

HTTPS://WWW.CDC.GOV/CORONAVIRUS/2019- -NCOV/HCP/INFECTION-CONTROL.HTML

CDU Infection Control Guidance for HCP x +

← → ↻ 🏠 🔒 https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html 🔍 📄



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Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)

Updated June 3, 2020, 12:00 AM [Español](#) [Print](#)

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Post-Vaccination Considerations for Workplaces >

Postmortem Guidance >

Nursing Homes and Long-Term Care Facilities >

Optimizing PPE Supplies

N95 and Other Respirators

Facemasks

Eye Protection

Gowns

Gloves

TRACKING VACCINATIONS

- Track and securely document:
 - Each staff member's vaccination status, including
 - Specific vaccine received
 - Dates each dose received
 - Staff who have obtained booster doses.
 - Specific booster received
 - Date the booster is received
 - Staff who have been granted an exemption.
 - Type of exemption and supporting documents
 - Staff for whom vaccination is temporarily delayed.
 - Reason for delay
 - When staff may safely resume duties

(42 CFR 482.42(g)(3)(iv)-(viii); Hospital Attachment, QSO-22-07-ALL)

TRACKING VACCINATION

- Facilities may use any tracking tool they choose.
- CDC provides tool:
<https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html>
- Vaccination might be documented in:
 - Immunization records
 - Health information files
 - Other relevant documents

(CMS FAQs)

- Beware confidentiality concerns
 - ✓ ADA
 - ✓ HIPAA
- Ensure records available if surveyed.

CONTINGENCY PLAN

- Have contingency plan for staff who are not fully vaccinated, including:
 - Actions facility will take when staff refuse to vaccinate;
 - Precautions for exempt staff who are not fully vaccinated;
 - Actions facility will take if deadlines not met, e.g.,
 - Actively seeking replacement staff through advertising
 - Obtaining temporary vaccinated staff until permanent vaccinated staff can be found.

(42 CFR 482.42(g)(3)(x); Hospital Attachment, QSO-22-07-ALL)

ENFORCEMENT

Nursing Homes, HHAs and Hospices

- Civil monetary penalties
- Denial of payments
- Termination of participation in Medicare/Medicaid

Others

- Termination of participation in Medicare/Medicaid

ENFORCEMENT

- “CMS’s primary 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.”

(QSO-22-09-ALL; CMS FAQ)

- Survey agencies will address through surveys:
 - Standard recertification surveys.
 - Complaint surveys.
 - Accreditation agencies.
- Survey agencies will review:
 - Policies and procedures
 - Number of staff and COVID cases over last 4 weeks
 - List of staff and vaccination status

(CMS FAQ)

ENFORCEMENT

- By the Phase 2 deadline, facilities should have:
 - Policies and procedures implemented.
 - 100% vaccination except for staff with:
 - Pending request or granted exemption, or
 - Condition warrants temporary delay due to medical condition as recommended by the CDC.
- If facility is less than 100% compliant:
 - Facility has >90% vaccination + plan to achieve 100% vaccination in 30 days = no enforcement.
 - Otherwise, facility is subject to enforcement.

(QSO-22-09-ALL)

ENFORCEMENT

- Immediate jeopardy
 - 40% or more staff unvaccinated, or
 - Less than 100% vaccinated + noncompliant infection control + 1 or more required policies not developed or implemented.
- Condition level
 - Less than 100% of staff vaccinated and 1 or more policies not developed or implemented, or
 - 21-39% of staff remain unvaccinated
- Standard level
 - Less than 100% of staff vaccinated and 1 or more policies not developed or implemented, or
 - Less than 100% of staff vaccinated but making good faith efforts toward vaccine compliance.

(Hospital Attachment, QSO-22-07-ALL)

ENFORCEMENT

- CMS may lower the citation level and/or enforcement action if
 - Facility has no or has limited access to vaccine, and the hospital has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies); or
 - Facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

(Hospital Attachment, QSO-22-07-ALL)

REMEMBER: ENSURE YOU'VE IMPLEMENTED POLICIES

- ✓ Ensure all staff are fully vaccinated unless exempted.
- ✓ Process to request exemptions per federal law.
- ✓ Ensure unvaccinated staff adhere to protections to mitigate spread of COVID-19.
- ✓ Track and securely document vaccination status.
- ✓ Contingency plan for staff who have not completed primary vaccination series.

HANDLING EXEMPTIONS



EXEMPTIONS: GENERAL CONSIDERATIONS

- The facility must comply with applicable federal anti-discrimination and civil rights laws, including:
 - Americans with Disabilities Act (“ADA”);
 - Section 504 of the Rehabilitation Act;
 - Title VII of the Civil Rights Act of 1964;
 - Pregnancy Discrimination Act;
 - Genetic Information Nondiscrimination Act (“GINA”).

(86 FR 61568)

EXEMPTIONS: GENERAL CONSIDERATIONS

- Federal law provides basis for exemptions
- State laws are preempted if broader exemptions are available under state law
- “While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required.” (Hospital Attachment, QSO-22-07-ALL)
- Consider that “staff” includes several categories who are not employees
 - May not be “legally required” to provide accommodation

EXEMPTION PROCESS

- Must have process for staff to request exemption based on federal law.
 - Medical reasons recognized by CMS
 - Disability under ADA/Rehabilitation Act
 - Sincerely held religious belief under Title VII

(42 CFR 482.42(g)(3)(vi))

- Process should cover:
 - How exemption requested.
 - To whom request made.
 - Evaluating the request.
 - Applicable standards for exemptions.
 - Documentation supporting request.
 - Determination regarding request.
 - Accommodations granted.

(Hospital Attachment, QSO-22-07-ALL)

MEDICAL EXEMPTION

- Must be based on clinical contraindications recognized by CDC.
- Must include statement from licensed practitioner (other than the staff member seeking exemption) acting within scope of practice and applicable law that:
 - Vaccination is clinically contraindicated;
 - Identify recognized clinical reason for contraindication;
 - Recommendation staff member be exempted from hospital's vaccination requirement.
 - Signed and dated by practitioner.

(42 CFR 482.42(g)(3)(viii); 86 FR 61572)

MEDICAL EXEMPTION: TEMPORARY DELAYS

- Vaccination may be delayed for certain staff if vaccination contraindicated based on CDC guidance, e.g.,
 - Allergies
 - Recognized medical conditions

(42 CFR 482.42(g)(3)(i))

- Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinicalconsiderations.pdf>.

TEMPORARY DELAY

- Must document if vaccination temporarily delayed due to medical reason recognized by CDC, e.g.,
 - Acute illness secondary to COVID-19 illness
 - Received monoclonal antibodies or convalescent plasma for COVID-19 treatment.
- Staff member must be vaccinated after the condition for delay is resolved unless other exemption granted.

RELIGIOUS EXEMPTION

- Request based on sincerely-held religious belief.
 - Traditional beliefs/organized religion not required
 - Non-theistic “moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.”
- See Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination, <https://www.eeoc.gov/laws/guidance/section12-religious-discrimination>.

RELIGIOUS EXEMPTION

- “Surveyors will **not** evaluate the details of the request for a religious exemption, nor the rationale for the hospital’s acceptance or denial of the request. Rather, surveyors will review to ensure the hospital has an effective process for staff to request a religious exemption for a sincerely held religious belief.” (Hospital Attachment, QSO-22-07-ALL)
- Employer should err on side of granting facially valid request.

ACCOMMODATIONS FOR EXEMPTED STAFF

- Reassign staff, e.g., to non-patient care areas, duties that reduce risk of infection, remote work, etc.
- Physical distancing when possible
- NIOSH-approved N95 masks or higher
- Weekly testing
- Recommended action per CDC guidance, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>
- Recommended action per OSHA guidance.
- Other?

(Hospital Attachment, QSO-22-07-ALL)

ADVERSE ACTION AGAINST STAFF



ADVERSE ACTION AGAINST STAFF

■ Employees

- CMS does not directly tell entities to terminate non-compliant employees w/o an exemption
- Contingency plan:
 - Should include a deadline for all unvax'd staff to become vax'd
 - Impose deadlines and indicate actions if deadline not met
 - Address actively seeking “replacement staff”
- Substantial compliance: hospital has met the requirement by more vax'd employees or “replacing unvaccinated staff with vaccinated staff”

ADVERSE ACTION AGAINST STAFF

- Non-employed medical staff members
 - Contracts often require compliance with policies or compliance with applicable laws and regulations
 - Medical staff bylaws, rules or policies usually require compliance with facility bylaws, rules or policies
 - Consider appropriate amendments to policies or rules
 - Corrective action under medical staff bylaws

ADVERSE ACTION AGAINST STAFF

- Contractors
 - Contracts often require compliance with facility policies and/or compliance with laws
 - Amend contracts to require vaccination
- Others treated as staff
 - Board members
 - Students
 - Volunteers
- Non-contracted service or material provider

CONFIDENTIALITY OF VACCINE INFO



ADA AND EMPLOYEE CONFIDENTIALITY

Under ADA:

- Employer may ask whether employee has been tested for COVID, is vaccinated, or is experiencing symptoms.
 - Not a disability-related question.
 - Do not ask follow up questions.

(29 CFR 1630.14; EEOC Guidance (5/21))

ADA AND EMPLOYEE CONFIDENTIALITY

Under ADA:

- Employer must keep employee health info confidential, including vaccination status.
 - Store separately from medical file.
 - May disclose to supervisors or managers to allow necessary accommodations.
 - May require those who are not vaccinated to wear a mask subject to reasonable accommodation.

(29 CFR 1630.14; EEOC Guidance (5/21))

- Voluntary (?) display of sticker confirming able to work without a mask

➤ *Check local laws.*

HIPAA

Patients

- No general HIPAA exception for COVID.
- To use or disclose PHI, need:
 - Patient authorization, or
 - HIPAA exception, e.g.,
 - Treat, pay, operation
 - Public health
 - Imminent threat
 - Law requires disclosure
 - OSHA surveillance
 - Others

Employees

- If obtained vaccine info solely as employer, HIPAA does not apply.
- If obtained vaccine info as either (i) a healthcare provider, or (ii) a health plan, HIPAA applies, i.e., need
 - Employee's authorization, or
 - HIPAA exception.

REQUIRING EMPLOYEES TO DISCLOSE VACCINATION STATUS

“Does the HIPAA Privacy Rule prohibit a covered entity or business associate from requiring its workforce members to disclose to their employers or other parties whether the workforce members have received a COVID-19 vaccine?”

“No. The Privacy Rule does not apply to employment records, including employment records held by covered entities ... acting in their capacity as employers. Thus, the Privacy Rule generally does not regulate what information can be requested from employees as part of the terms and conditions of employment that a covered entity ... may impose on its workforce, such as the ability of a covered entity ... to require its workforce members to provide documentation of their vaccination against COVID-19 or to disclose whether they have been vaccinated to their employer, other workforce members, patients, or members of the public.

(<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html>)

ACCESSING EMPLOYEE'S VACCINATION INFO

- Generally need patient's HIPAA-compliant authorization.
- Potentially relevant HIPAA exceptions:
 - Treatment, payment or healthcare operations (e.g., qualifications of members, compliance, etc.).
 - For public health activities.
 - To family, friends and others involved in patient's care.
 - To avert serious and imminent threat of harm.
 - Required by law.
 - To public health agency.
 - Employer's medical surveillance of workplace if certain conditions met, including surveillance required by OSHA and written notice to employee.

(<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html>)

REQUIRING EMPLOYEES TO DISCLOSE VACCINATION STATUS

“For example, the Privacy Rule **does not prohibit** a covered entity ... from requiring or requesting each workforce member to:

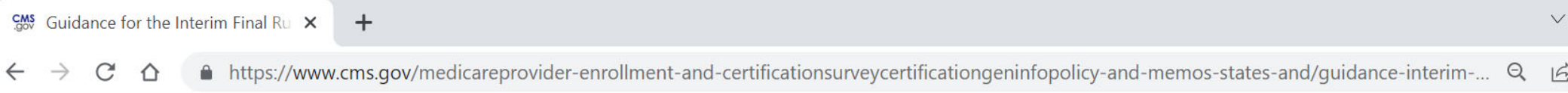
- “Provide documentation of their COVID-19 ... vaccination to their current or prospective employer.
- “Sign a HIPAA authorization for a covered health care provider to disclose the workforce member’s COVID-19 ... vaccination record to their employer.

...

- “Disclose whether they have received a COVID-19 vaccine in response to queries from current or prospective patients.”

(<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html>)

HTTPS://WWW.CMS.GOV/MEDICAREPROVIDER-ENROLLMENT-AND-CERTIFICATIONSURVEYCERTIFICATIONGENINFOPOLICY-AND-MEMOS-STATES-AND/GUIDANCE-INTERIM-FINAL-RULE-MEDICARE-AND-MEDICAID-PROGRAMS-OMNIBUS-COVID-19-HEALTH-CARE-STAFF-0



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Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Title	Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination
Memo #	QSO-22-07-ALL
Posting Date	2021-12-28
Fiscal Year	2022
Summary	<p>CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). •On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers. •CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements. •The guidance in this memorandum does not apply to the following states at this time: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming. Surveyors in these states should not undertake any efforts to implement or enforce the IFC.</p>

Downloads

- [QSO-22-07-ALL \(PDF\)](#)
- [QSO-22-07 ALL Attachment A - LTC \(PDF\)](#)

QSO-22-07-ALL (12/28/21)

QSO-22-09-ALL (1/14/22)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-09-ALL

DATE: January 14, 2022

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations
Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus
COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following states: Alabama,

ATTACHMENTS FOR SPECIFIC PROVIDER TYPES

Hospital Attachment QSO-22-07-ALL

This attachment is a supplement to and should be used in conjunction with QSO 21-07-ALL memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

The regulations and guidance described in this attachment do not apply to the following states at this time: Alabama, Alaska, Arizona, Arkansas, , Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming. **Surveyors in these states should not undertake any efforts to implement or enforce the regulation.**

A-0792

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

- (g) ***Standard: COVID-19 Vaccination of hospital staff.*** The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of

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The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in the minds of many of our clients. We are here to guide our clients through the challenges and opportunities that arise in this dynamic industry.

Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)



Webinars and
Publications

- Owners of healthcare assets
- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies
- Rehabilitation centers

QUESTIONS?



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