

MANDATORY VACCINE POLICIES

December 9, 2021

Where are we now? Where do we go from here?

Amie K. Wilcox

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Roadmap

- CMS Vaccine Mandate
 - Does it apply?
 - If so, how do we comply?
- Other Vaccine Mandates
- We'll also touch on:
 - OSHA Emergency Temporary Standard
 - Recent Mandate Litigation
 - Surprise Billing Rule

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CMS Interim Final Rule

- The CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (“CMS Rule”)
- Implements mandatory vaccine requirements announced by the Biden Administration in September

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The Mandate

All covered staff must receive the first dose of a two-dose FDA approved or a single-dose FDA approved vaccine by **December 5, 2021.***

All covered staff must be fully vaccinated (14 days after last dose)** by **January 4, 2022.**

*effectively December 6, 2021

**CMS relaxed this in a subsequent FAQ, making it clear that individuals who had completed a vaccination regimen on the compliance date are in compliance.

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The Exemptions

- Recognized Medical Conditions
- Strongly Held Religious Beliefs, Observances, or Practices
- **No other exceptions.**

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CMS Rule > Conflicting State Law

- Many states have passed laws which prevent businesses / facilities in the state from requiring vaccination
- Others have required additional exemptions, like a weekly testing option or exemption with proof of antibody presence.
- CMS Rule supersedes these state laws

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CMS Rule Applies to....

Providers and suppliers regulated by the CMS Conditions of Participation.

Generally, does not apply to physician offices, but may apply to clinics that:

- Are Provider-Based (Outpatient Department of Hospital) or
- Provide physical therapy or speech pathology services that are subject to the CMS Conditions of Participation

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Full List of Covered Facilities

Ambulatory Surgical Centers	Comprehensive Outpatient Rehabilitation Facilities
Hospitals	Community Mental Health Centers
Hospices	Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
Psychiatric Residential Treatment Facilities	Home Infusion Therapy suppliers
Long Term Care Facilities (but not facilities like Assisted Living)	Rural Health Clinics / Federally Qualified Health Centers
Intermediate Care Facilities for Individuals with Intellectual Disabilities	End-Stage Renal Disease Facilities
Home Health Agencies	

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Who Must Be Vaccinated?

The Rule applies to all employees, licensed practitioners, trainees, students, and volunteers.

Contractors who provide care, treatment, or other services, or have contact with those individuals who do, are also covered.

Note: Comments indicate that this would not include “individuals who infrequently provide ad hoc non-health care services (such a san annual elevator inspection)”

Factors: frequency of entry, contact with other individuals, additional safety measures, use of shared common areas

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Who Must be Vaccinated?

- Any staff member on site at a covered health facility who provides patient care, or interacts with staff who provide patient care
- Applies to staff who perform duties offsite, but not full telework staff.
- Applies to providers who provide patient care at health facility (for example, members of the Medical Staff)

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Question 1

Choose which of the following the CMS Mandate applies to:

- A) All vendors, students, and Medical Staff.
- B) Employees only.
- C) FedEx and USPS.
- D) Employees, Medical Staff, and Volunteers.

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Exemptions – Medical Exemption

- Required to establish exemption process for Recognized Medical Conditions (Required by Americans with Disabilities Act of 1990 (ADA))
- A valid request for accommodation must include specific documentation.

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Exemptions – Medical Exemption

Documentation must:

- Confirm recognized clinical contraindication to COVID-19 vaccine
- Support staff requests for medical exemption from vaccine
- Be signed and dated by licensed practitioner (may not be individual requesting exemption) who is acting within respective scope of practice
- Specify which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
- Include statement by the authenticating practitioner recommending that the staff member should be exempted from the requirement based on the recognized clinical contraindications.

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Approving a Medical Exemption

If exemption request meets previous criteria, should be approved unless accommodation would be “undue hardship” for employer

“Undue Hardship” – ADA defines as “an action requiring significant difficulty and expense.”

Factors: cost + number of individuals in need of accommodation

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Question 2

An employee submits a request for a medical exemption, describing that she is wary of the long-term health effects of the vaccine for pregnant women. Should you:

- A) Grant the request.
- B) Deny the request.
- C) Request additional information.
- D) Grant the request if the employee cited scientific evidence.

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Religious Exemption

- Required to grant exemption request for Strongly Held Religious Beliefs, Observances, or Practices by Title VII of the Civil Rights Act of 1964
- Employer must have enough information to make the employer aware that a conflict exists between the applicant's religious observance, practice, or belief and COVID-19 vaccination.

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Religious Exemption EEOC Guidance

- If the employer reasonably needs more information, the employer and applicant should discuss the request.
- Applicant may need to explain the religious nature of the belief, observance, or practice and the way it conflicts with the vaccination requirement.
- “In determining if a conflict exists, it is irrelevant that the employer does not view the work requirement as impacting a religious belief, or that most people of the applicant’s faith would not; it is the **applicant's own religious** belief that is relevant.”

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Religious Exemption

1. Does the exemption request establish a sincere strongly held belief, observance, or practice? Develop a standardized process for documentation to be provided.
2. Does the exemption request explain why the vaccine requirement is in conflict with this sincerely held belief, observance, or practice?
3. Is the requested accommodation a reasonable one?
4. If granted, does the requested accommodation impose an undue hardship on operations and the health and safety of coworkers?

Undue Hardship – the proposed accommodation poses more than a *de minimus* cost or burden (lower standard than ADA).

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No Evading Vaccination

No exemption request may be granted when the exemption request is solely to evade vaccination.

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No Further Guidance

CMS declined to give further guidance on considering religious exemption requests.

Instead, the CMS Rule references the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination.

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Question 3

An employee submits a request for exemption based on the following statement: "My religion teaches that the body is a temple and I should not put anything harmful into it." Do you –

- A) Grant the exemption.
- B) Deny the exemption.
- C) Request additional information that confirms the belief above is sincerely held.
- D) Request additional information that confirms the belief above is sincerely held and describes how complying with the vaccine policy violates this sincerely held belief.

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Question 4

An employee submits a request for exemption based on the following statement: "I trust that God will keep me safe and healthy." Do you –

- A) Grant the exemption.
- B) Deny the exemption.
- C) Request additional information that confirms the belief above is sincerely held.
- D) Request additional information that confirms the belief above is sincerely held and describes how complying with the vaccine policy violates this sincerely held belief.

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Recommended Documentation

Recognized Medical Condition	Sincerely Held Religious Belief, Observation or Practice
<p>A signed and dated statement from a licensed practitioner (other than yourself) that:</p> <ul style="list-style-type: none"> • Confirms a recognized clinical contraindication to COVID-19 vaccine; • Specifies which of the COVID-19 vaccines are clinically contraindicated for you to receive and the recognized clinical reasons for the contraindications; • Recommends that you should be exempted from the requirement based on the recognized clinical contraindications. 	<ol style="list-style-type: none"> 1. A written statement from the individual explaining the belief, practice, or observance and why it conflicts with COVID-19 vaccination; and 2. A supporting written statement on letterhead (if applicable) from a clergy member, fellow congregant, or other individual who is aware of the individual's religious practice or belief.

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Documentation for Compliance

Covered Facilities must have separate processes for:

1. Tracking and securely documenting vaccination status (including recommended booster doses)
2. Tracking and securely documenting exemption requests
3. Tracking and secure documentation of vaccination status of staff for whom vaccination must be temporarily delayed as recommended by CDC for clinical precautions and considerations

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Contingency Plans for Unvaccinated

CMS requires facilities to develop a process for implementing additional precautions for any staff who are not vaccinated

Potential accommodations for exempted staff could include, but are not limited to:

- Testing
- Physical Distancing
- Source control

*In all cases – facilities **must** ensure that they minimize risk of transmission of COVID-19 to at-risk individuals*

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Enforcement

CMS will work with State Survey Agencies – Accrediting Organizations will follow.

- State Survey Agencies will conduct onsite compliance reviews for the requirements of the CMS Rule during both Recertification Surveys and Complaint Surveys

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Enforcement

Surveyors will check to determine if a facility has met three basic requirements:

1. Having a process or plan for vaccinating all eligible staff
2. Having a process or plan for providing exemptions and accommodations for those who are exempt
3. Having a process or plan for tracking and documenting vaccinations

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Enforcement for Non-Compliance

- Facilities that are out of compliance will be cited and provided an opportunity to return to compliance.
- If not, enforcement remedies include:
 - Civil Monetary Penalties
 - Denial of Payment
 - Termination from the Medicare and Medicaid program

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The OSHA Rule

The Occupational Safety and Health Administration (OSHA) issued a corresponding vaccination and testing emergency temporary standard (The OSHA Rule).

Requires covered employers to ensure its employees are either fully vaccinated or tested on a weekly basis. Non-vaccinated employees are also required to continue wearing face coverings.

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Who is covered by the OSHA Rule?

Employers with 100 or more employees

Healthcare Providers who are exempt from the CMS Rule (for example, a physician clinic) but have more than 100 employees are subject to the OSHA Rule.

If your facility is subject to the CMS Rule, the OSHA Rule does not apply to you.

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Exemptions from the OSHA Rule

Includes medical and religious exemption

AND a testing exemption. Unvaccinated employees may submit negative tests weekly.

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Who pays for testing?

The OSHA Rule does not require employers to pay for testing.

However, some state laws or local requirements may add to this requirement. For example, Arkansas law does require employers to pay for weekly testing.

Additionally, the Fair Labor Standards Act may require an employer to pay if the cost of the test would take the employee below minimum wage for the week.

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OSHA ETS for Healthcare Providers

The first OSHA ETS (issued June 10) is still in effect.

Covered healthcare employers are required to develop a COVID-19 plan

Most notably, the ETS may require employers to remove employees from the workplace and provide medical removal protection benefits.

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Medical Removal from the Workplace

Required where the employer knows that the employee:

1. Is COVID-19 positive;
2. Has been told by a healthcare provider they are suspected to have COVID-19;
3. Has recent loss of taste and/or smell;
4. Is experiencing both a fever and new unexplained cough / shortness of breath; or
5. For unvaccinated employees with no symptoms, was notified by employer that employee was in close contact to a person who is COVID-19 positive.

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Medical Protection Benefits

Employees who are removed from the workplace pursuant to the ETS are entitled to normal benefits and payment (up to \$1,400 per week) for the first two weeks they are absent.

Beginning on the third week, the payment obligation is reduced to 2/3 of regular pay (capped at \$200 per day)

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Which Mandate Applies?

1. If the CMS Mandate applies to you, you don't need to comply with any other mandates.
2. If the CMS Mandate does not apply and you have more than 100 employees, you should comply with the OSHA Rule.
3. If the CMS Mandate does not apply to you, check to see if you have any federal contracts.

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Mandate Litigation

CMS Vaccine Rule Enjoined:

- United States District Court for the Eastern District of Missouri
 - 10 States (including Arkansas) filed a legal challenge to the CMS Mandate in the United States District Court for the Eastern District of Missouri
 - Injunction issued on November 29, 2021 preventing enforcement of the CMS Mandate in these states until the case is heard.
- United States District Court in Louisiana issued injunction on November 29, 2021 covering all remaining states.

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Mandate Litigation

Next Steps:

- All District Court rulings have been appealed to their respective U.S. Courts of Appeal
- If conflicting appeals decisions are reached, it is possible the Supreme Court will need to intervene.

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Mandate Litigation

What does this mean for me?

- The injunction could be overturned *at any time*.
- If overturned, there may be no grace period for coming to compliance.
- Safest option: prepare to comply.

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Surprise Billing Rules

- Two Interim Final Rules were published this year, implementing the provisions of the No Surprises Act (signed into law as a part of the Consolidated Appropriations Act of 2021).
- Effective January 1, 2022

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Surprise Billing Rules

- Applies to “balance billing” – billing the patient for the difference between the billed charge and the amount paid by their plan or insurance (usually for out-of-network charges)
- Does not apply to people with coverage such as Medicare, Medicaid, VA, Tricare (already prohibited balance billing)

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Surprise Billing Rule

- Restricts surprise billing for patients in employer-sponsored and individual health plans who:
 - Receive emergency care;
 - Receive non-emergency care from out-of-network providers at in-network facilities; and
 - Receive air ambulance services from out-of-network providers

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Surprise Billing Rule

- Prohibits out-of-network charges for items and services provided by an out-of-network facility *unless* certain notice and consent is given.
- Otherwise, patient cost-sharing is limited to the amount that would be charged for in-network care.
- For emergency care, Rule requires emergency services to be covered without any prior authorization and regardless of whether a provider or facility is in-network.

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Surprise Billing Rule

- **Consent Exception** – may apply in limited cases; will not apply in some situations where surprise bills are likely (for example, ancillary services connected to non-emergency care such as anesthesia or radiology).
- Where it does apply, specific requirements exist regarding the content of notices and consents.

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Surprise Billing Rule

- **Required Notice** – requires providers and facilities to make publicly available, post on a public website, and provide to individuals a one-page notice about the requirements of this Rule and how to report a violation.
- **Good Faith Estimates Required** – for uninsured or self pay patients. The Rule sets forth specific time frames this estimate is required to be furnished within. If patient is billed substantially in excess (at least \$400 in excess) of estimate, will be subject to arbitration process.

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Surprise Billing Rule

Independent Dispute Resolution Process Established

- Provider or Facility and Payers
 - To determine amount of payment owed to provider/facility as a result of treating patients as in-network for out-of-network charges
- Provider or Facility and Self Pay Patient
 - To determine amount of payment owed if substantially in excess of good faith estimate

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Surprise Billing Rule

Independent Dispute Resolution Action	Timeline
Initiate 30-business-day open negotiation period	30 business days, starting on the day of initial payment or notice of denial of payment
Initiate independent dispute resolution process following failed open negotiation	4 business days, starting the business day after the open negotiation period ends
Mutual agreement on certified independent dispute resolution entity selection	3 business days after the independent dispute resolution initiation date
Departments select certified independent dispute resolution entity in the case of no conflict-free selection by parties	6 business days after the independent dispute resolution initiation date
Submit payment offers and additional information to certified independent dispute resolution entity	10 business days after the date of certified independent dispute resolution entity selection
Payment determination made	30 business days after the date of certified independent dispute resolution entity selection
Payment submitted to the applicable party	30 business days after the payment determination

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AMIE K. WILCOX *Healthcare*



awilcox@fridayfirm.com



501-370-3320



www.fridayfirm.com/awilcox



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www.FridayFirm.com



400 West Capitol Ave. Suite 2000 | Little Rock, AR 72201
3350 South Pinnacle Hills Pkwy. Suite 301 | Rogers, AR 72758