

Preparing for Phase 1 Of The CMS Vax Mandate: December 5, 2021 Is Fast Upon Us

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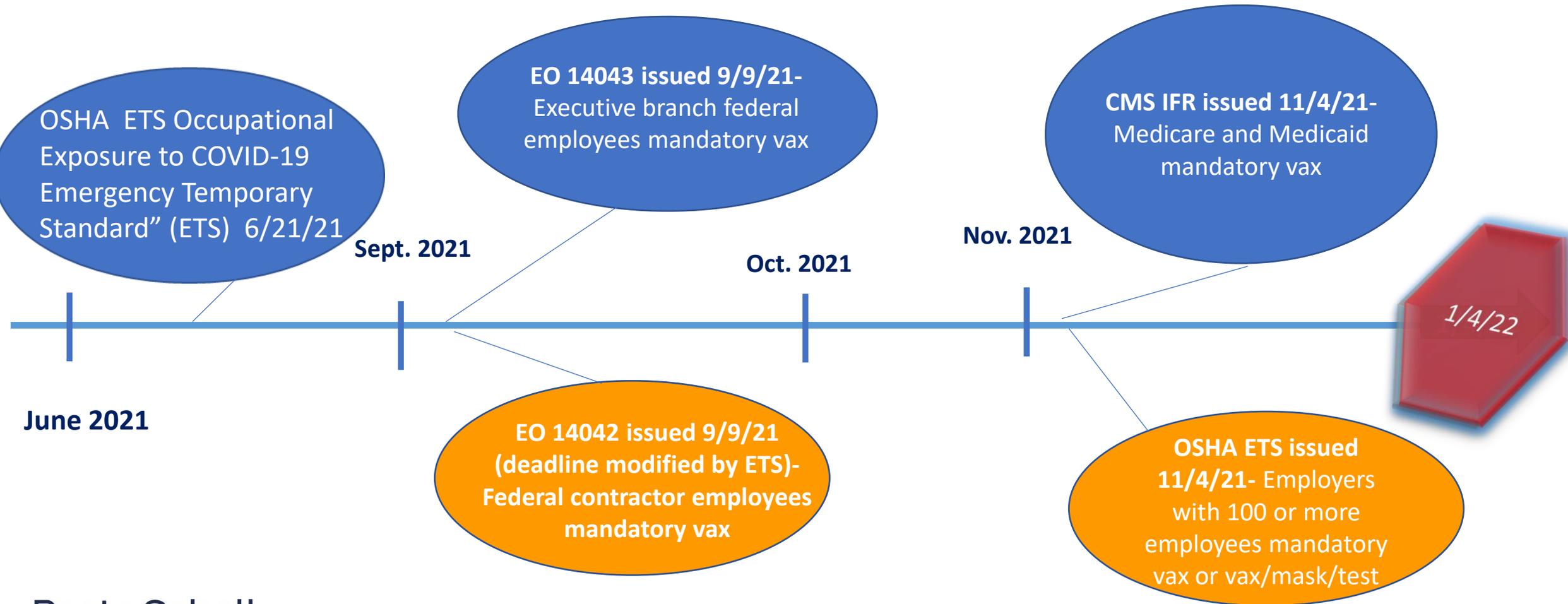
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November 11, 2021

Timeline of Federal COVID-19 Requirements



New Federal Vaccination Mandates

- All Medicare/Medicaid certified healthcare facilities
- Interim final rule (IFR) issued November 5, 2021 (CMS)
- Allows limited medical and religious exemptions but no testing opt-out
- All federal workers and federal contractors
- Employers with >100 employees enforced by OSHA Emergency Temporary Standard (ETS) issued November 5, 2021

Lawsuit Challenging CMS Interim Final Rule (IFR)

- 10 states filed federal challenge to the CMS IFR on November 10
 - Missouri, Kansas, Nebraska, Arkansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire
- Regulation is narrow in application to Medicare and Medicaid-certified provider and supplier types regulated under Medicare health and safety standards covered health care facilities
- No Pennsylvania cases as of November 11, 2021

Lawsuits Challenging OSHA's Large Employer ETS

- 5th Circuit Court of Appeals issued a *stay* based on appeals filed by Texas, Mississippi, Utah, Louisiana, South Carolina, and Utah
- Other states that have challenged include Alabama, Alaska, Arizona, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Dakota, Tennessee and Wyoming
- Outcome unknown but advice is to prepare for implementation

Compliance Deadlines

PHASE 1: December 6, 2021

- Policies and procedures
 - Exemptions
 - Accommodations
 - Tracking
- All staff must have first dose of vaccine or have pending or been granted a lawful exemption *before* providing any care, treatment, or other services

PHASE 2: January 4, 2022

- All staff fully vaccinated except if granted an exemption or if vaccination must be temporarily delayed for clinical reasons
- All new staff must be vaccinated or have an exemption *before* providing any care, treatment, or other services

Who Is Covered By The IFR?

- Ambulatory Surgery Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Long Term Care Facilities
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Psychiatric Residential Treatment Facilities (PRTFs)
- Rural Health Clinics/Federally Qualified Health Centers

Who Must Be Vaccinated?

- Staff, regardless of clinical responsibility or patient contact who provide any care, treatment, or other services for the facility and/or its patients:
 - Facility employees
 - Licensed practitioners
 - Students/ trainees
 - Volunteers
 - ▶ Administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others
 - ▶ Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement
 - ▶ All staff that interact with other staff, patients/residents/clients in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care

Any Exceptions?

- Employees who exclusively provide telehealth or telemedicine services outside facility with no direct contact with residents or other staff
- Employees who provide support services performed exclusively outside facility with no direct contact with residents or other staff
- Individuals who infrequently provide ad hoc non-health care services (e.g., 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)
- Other individuals who may infrequently enter a facility 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

Vaccination Examples

- Transport and emergency medical services: must be vaccinated *if* they have a professional relationship with a CMS-regulated healthcare entity
- Pharmacies: IRF applies *if* they go onsite to covered facilities
- CMS issuing guidance for surveyors that will mirror IRF requirements
- CMS expects a case-by-case determination for vendors/contractors
- Does not apply to visitors

Exemptions

Medical Exemptions

- Must provide accommodation process for individuals with medical conditions/disabilities
- Must provide reasonable accommodation unless doing so creates:
 - (1) undue hardship; or
 - (2) poses direct threat to employees/others
- Undue hardship/direct threat includes analysis of
 - Type of industry/workplace
 - Job duties (contact with others vs. isolation)
 - Safety considerations

Religious Exemptions

- Must provide accommodation process based on employee's "sincerely held religious belief, practice, or observance"
- Includes traditional organized religion, as well as uncommon, informal, unorganized beliefs, and beliefs that seem illogical or unreasonable to others
- May deny if accommodation poses "undue hardship"
 - More than a *de minimis* cost
 - Monetary cost
 - Burden on employer's business (reduced job performance, infringing on other employee's rights, impairs workplace safety)

Information For Medical Exemptions

- All documentation confirming recognized clinical contraindications to COVID-19 vaccines, and which supports the staff member's request:
 - Must be signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice
 - 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
 - Must include a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on the recognized clinical contraindications

Information For Religious Exemptions

- No required forms or specific proof
- 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
- Person-centered inquiries, must be case-by-case
- CMS suggests federal template:
https://www.saferfederalworkforce.gov/downloads/RELIGIOUS%20REQUEST%20FORM_FINANCIAL%20REVIEW_20211003%2010.29%2011am.pdf
- EEOC template: <https://www.eeoc.gov/sites/default/files/2021-10/EEOC%20Religious%20Accommodation%20Request%20Form%20-%20for%20web.pdf>

What is a “Sincerely Held” Religious Belief?

- Assume that a request for religious accommodation is based on sincerely held religious beliefs
- An objective basis for questioning either the religious nature or the sincerity of a particular belief justifies limited factual inquiry
 - Whether employee has acted in a way that is inconsistent with the claimed belief
 - Whether employee is seeking a benefit or an exception that is likely to be sought for nonreligious reasons
 - Whether the timing of the request is questionable
 - Whether the employer has other reasons to believe that the employee is seeking the benefit for secular reasons

Examples

- I had COVID so I am immune and do not need to be vaccinated—NO
- The vaccine has microchips—NO
- I might not be able to get pregnant—NO
- My body is a holy temple and I cannot desecrate it with any vaccines—Maybe
- Granting one request for religious accommodation does not mean others have to be approved on the same

What is a Reasonable Accommodation?

- CMS goal is to reduce transmission
- Testing, source control, physical distancing
 - N95s, face shields and goggles
- Assign to non-patient care areas with low risk when possible
- Teleworking
- Reassignment

Where Do You Keep These Records?

- All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files
- Must have a process for collecting and evaluating exemption requests
 - Include tracking and secure documentation of information provided by staff who have requested exemption
 - Facility's decision on the request
 - Any accommodations that are provided
- Create files for job applicants, contractors, volunteers

What Will Surveyors Look For?

- Compliance will be assessed during complaint and recertification surveys
 - COVID-19 vaccination policies and procedures including plan for vaccinating staff, providing exemptions and tracking staff vaccinations
 - Number of resident and staff COVID-19 cases over last 4 weeks
 - List of all staff and their vaccination status
 - Interviews and observations

Required Components Of Policies/Procedures

- Process for ensuring all staff (except for those staff who have pending requests for, or who have been granted, exemptions or for whom COVID-19 vaccination must be temporarily delayed) have received the first dose of the vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents by December 6, 2021
- Process for ensuring all staff (except those for whom vaccination must be temporarily delayed) are fully vaccinated by January 4, 2022
- Process for ensuring the implementation of additional precautions to mitigate transmission and spread of COVID-19, for all staff who are not fully vaccinated
- Process for tracking and securely documenting vaccination status of all staff
- Process for tracking and securely documenting the vaccination status of any staff who have obtained any booster doses as recommended by the CDC

Required Components Of Policies/Procedures

- Process by which staff may request an exemption
- Process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption
- Process for ensuring that requests for medical exemptions include all required information
- Process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed
- Contingency plans for staff who are not fully vaccinated for COVID-19

Acceptable Proof of Vaccination

- Record of immunization from a healthcare provider or pharmacy
- Copy of the COVID-19 Vaccination Record Card
- Copy of medical records documenting the vaccination
- Copy of immunization records from a public health, state, or tribal immunization information system
- Copy of any other official documentation that contains type of vaccine administered, date(s) of administration, and the name of the healthcare professional(s) or clinic site(s) administering the vaccine(s)

Best Practices

- Update Facility Assessment
- Update Disaster Plan
- Update COVID-19 Safety Plan

To Mandate Or Not To Mandate?

- Personal care homes and assisted living residences not included in the CMS IFR
- How many employees do you have?
- Where do they work?
- How is your campus arranged?
- What will Department of Human Services (DHS) expect?

OSHA's ETS For Large Employers

- Emergency Temporary Standard (ETS) for employers with >100 employees issued November 4, 2021 *but* fate uncertain due to current legal challenges
- Does not apply to
 - Healthcare providers covered by CMS IFR
 - Employers that provide healthcare services or healthcare support services subject to the "Occupational Exposure to COVID-19 Emergency Temporary Standard"
 - Workplaces covered under the Safer Federal Workforce Task Force COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors

OSHA ETS Gives Employers More Options Than CMS IFR

- Develop, implement, and enforce workplace policy to:
 - Require mandatory vaccinations, *or*
 - Permit employees to choose vaccination status, but unvaxed employees must:
 - ▶ Wear face coverings indoors or when in vehicle with another person for work
 - ▶ Test at least weekly if in the workplace; or
 - ▶ Test within 7 days before returning to work if away for 1 week or longer

KEY COMPLIANCE DATES

REQUIREMENT	30 DAYS AFTER PUBLICATION	60 DAYS AFTER PUBLICATION
Establish policy on vaccination	X	
Determine vaccination status of each employee, obtain acceptable proof of vaccination, maintain records and roster of vaccination status	X	
Provide support for employee vaccination	X	
Require employees to promptly provide notice of positive COVID-19 test or COVID-19 diagnosis	X	
Remove any employee who received positive COVID-19 test or COVID-19 diagnosis	X	
Ensure employees who are not fully vaccinated wear face coverings when indoors or when occupying a vehicle with another person for work purposes	X	
Provide each employee information about the ETS; workplace policies and procedures; vaccination efficacy, safety and benefits; protections against retaliation and discrimination; and laws that provide for criminal penalties for knowingly supplying false documentation	X	
Report work-related COVID-19 fatalities to OSHA within 8 hours and work-related COVID-19 in-patient hospitalizations within 24 hours	X	
Make certain records available	X	
Ensure employees who are not fully vaccinated are tested for COVID-19 at least weekly (if in the workplace at least once a week) or within 7 days before returning to work (if away from the workplace for a week or longer)		X



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