



MASSACHUSETTS HEALTH & HOSPITAL ASSOCIATION
HEALTHCARE LEGAL COMPLIANCE FORUM

COVID-19 Hot Compliance Topics

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WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Agenda

1. Federal Vaccine Mandates
2. Unwinding Regulatory Flexibilities
3. Provider Relief Fund Audits and Enforcement Actions
4. Other things deserving your attention in 2022...

Federal Vaccine Mandates



1. Federal Employee Mandate (EO 14043)

- Completed vaccination by November 8 (unless qualify for exception); new employees fully vaccinated before commence work
- OPM guidance – progressive discipline for non-compliant employees (counseling & education, suspension, termination)

2. Federal Contractor Vaccine Mandate (EO 14042)

- All covered federal contractor employees must complete vaccination by January 4, 2022 (unless qualify for exception)
- References OPM guidance
- Federal district court in Arizona denied motion for preliminary injunction; similar motions scheduled for hearing in Georgia (December 3) and Florida (December 7)

3. OSHA Vaccination and Testing Emergency Temporary Standard

- Following 5th Circuit's order staying the rule, OSHA announced it would suspend enforcement pending outcome of litigation

CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule



- Applies to all provider types subject to Conditions of Participation, Conditions for Coverage, or Requirements for Participation
 - Does not include physician offices, EMS providers, assisted living facilities, home & community-based services)
 - If subject to this rule, not subject to federal contractor or OSHA rule
- Status
 - Federal district court in Florida denied injunctive relief on November 20
 - Federal district court in Missouri enjoined CMS' enforcement in ten states on November 29
 - Federal district court in Louisiana enjoined CMS' enforcement nationwide on November 30
 - CMS on December 2 announced it was staying implementation and enforcement pending resolution of litigation , but noting providers may move forward with voluntary compliance

Hospital Regulations

- For PPS hospitals, amends 42 CFR 482.42 - Infection Prevention and Control and Antibiotic Stewardship Programs
 - New subsection (g) - COVID–19 Vaccination of hospital staff
 - Develop and implement specific P&Ps to ensure *all staff* fully vaccinated
- Similar regulatory provisions for other provider types
- No additional data reporting requirements

'All Staff'

Includes -

- Hospital employees
- Licensed practitioners (medical staff)
- Students, trainees, volunteers
- Individuals who provide care, treatment, or other services for hospital and/or its patients, under contract or by other arrangement

Does not include –

- Staff who exclusively provide telehealth services outside hospital setting who have no direct contact with patients and other staff
- Staff who provide hospital support services performed exclusively outside hospital setting who have no direct contact with patients and other staff
- Vendors, volunteers, or professionals who infrequently provide ad hoc, non-health care services or services that are performed exclusively offsite and not at or adjacent to any site of patient care

Required Policies & Procedures

1. Process to ensure all staff have received initial dose prior to providing any services for hospital and/or its patients and thereafter are fully vaccinated (unless exempt/temporary delay)
 - Fully vaccinated = 2 weeks after completion of primary vaccination series (including all required doses of a multi-dose vaccine)
 - No alternative to vaccination (e.g., routine testing, antibodies)
2. Process to ensure implementation of additional precautions for all staff not fully vaccinated (in process of becoming fully vaccinated or granted exemption)
 - E.g., source control (masking), testing, distancing, modified job duties

Required Policies and Procedures, con't

3. Process for tracking and securely documenting vaccination status of all staff (including receipt of booster doses)
 - Include process for documenting temporary delays in vaccination due to CDC-recommended clinical precautions and considerations (e.g., individuals who received monoclonal antibodies)
4. Process by which staff may request exemption based on ADA disability, medical condition, or sincerely held religious belief
 - Include process for tracking and securely documenting information provided by those requesting and receiving exemptions; use templates created by Safer Federal Workforce Task Force
 - For each medical exemption, must have signed and dated recommendation from state-licensed practitioner acting within scope of practice that lists recognized clinical reasons vaccination is contraindicated
 - For religious belief exemption, not required to validate sincerity of belief (Bristol Myers lawsuit)

Implementation

- All P&Ps must be developed and implemented by December 6 - EXCEPT ‘full vaccination’ not required until January 4
 - “Staff who have completed a primary vaccination series by this date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination”
- Documentation
 - Providers “have the flexibility to use the appropriate tracking tools of their choice”
 - Examples of acceptable forms of proof of vaccination
 - CDC COVID–19 vaccination record card (or legible photo)
 - Record card fraud? (Detroit RN charged in September for stealing cards from VA hospital and selling via Facebook Messenger; Michigan resident charged in September for importing counterfeit cards from China and selling via Facebook and Instagram; Chicago pharmacist charged in August for selling cards on e-Bay; California homeopathic doctor arrested in July for falsifying cards)
 - Documentation of vaccination from health care provider or EHR
 - State immunization information system record

Compliance

- Regulation does not specifically mandate termination of staff not vaccinated by deadline
- Follow 'progressive discipline' guidance from OPM and Safer Federal Workforce Task Force ?

Enforcement

- CMS will NOT use new COVID-19 Vaccination Coverage among Health Care Personnel quality measure to monitor compliance
- CMS will issue interpretive guidelines (including survey procedures) and will advise and train State surveyors on how to assess compliance
 - Consistent with OPM and Safer Federal Workforce Task Force?
- State surveyors will conduct on-site compliance reviews as part of re-certification surveys and complaint surveys; accreditation organizations also will assess for compliance
 - Review of P&Ps, number of resident and staff COVID-19 cases over last 4 weeks, list of all staff and their vaccination status
 - Interviews and observations

Enforcement, Con't

- Hospitals to be cited based on severity of deficiency
 1. Immediate Jeopardy
 - Serious scope of non-compliance, failure to address deficiencies, close interaction with patients of unvaccinated staff.
 - Termination within 23 days following citation if not immediately addressed
 2. Condition-Level Citation
 - Substantial non-compliance that must be addressed to avoid termination
 3. Standard-level citation
 - Minor non-compliance; continued operation subject to facility's agreement to CMS-approved plan of correction
- “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.”

Unwinding Regulatory Flexibilities

- Current PHE declaration terminates in mid-January; likelihood of renewal?
- Regulatory flexibilities terminate with end of PHE
 1. Expanded capacity
 2. Burden relief
 3. Provider enrollment relief
 4. Stark Law waivers
 5. HIPAA enforcement discretion
 6. Patient inducement enforcement discretion
 7. DEA waivers
 8. Expanded telehealth coverage
- Review and track changes to internal policies and practices; establish process to complete unwind

Provider Relief Fund Audits & Enforcement Actions



- Enforcement actions to date
 - False certification of eligibility
 - Mis-use of funds for personal purposes
- OIG Work Plan – audit of General Distribution applications and payments
- PRF Audit Contracts (from ProPublica COVID-19 contract listings)
 - KPMG (program integrity support) - \$3 million
 - Kearney & Company (PRF audit support) - \$1.6 million
 - Creative Solutions Consulting (audit and financial review services) - \$729K
- Audit-related provisions in Terms & Conditions

Other Things Deserving Your Attention in 2022...

1. Cybersecurity
2. Price Transparency
3. No Surprises Act
4. Information Blocking
5. HIPAA Privacy Rule updates
6. Health Care Fraud Self-Disclosure Protocol
7. Diagnosis coding
8. Physician compensation arrangements
9. E/M changes
10. Opioid prescribing practices
11. Compliance program operations



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