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Illinois State Medical Society

Status of COVID-19 Federal and State Waivers and Related Lessons Learned

MEDICAL STAFF
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PRESENTED BY HALL RENDER'S MEDICAL STAFF SERVICES TEAM

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Agenda

- Legal Update: Recent Case Law Developments
- COVID-19 Update: Status of Federal & State Waivers
- COVID-19 Update: Vaccine Mandates

Legal Update: Recent Case Law Developments

Legal Update: Recent Case Law Developments

- Corporate Negligence:
  - A hospital (or physician group) may owe a non-delegable duty of care to its patient even if the hospital does not serve as a comprehensive health center
    - *Johnson v. Lutton*, 466 F.Supp.3d 472 (M.D. Pa 2020)
- Potential Bias in Peer Review Hearing Officers:
  - The possibility of future employment does not create a presumption that a hearing officer has a financial incentive to favor the hospital and does not, without more, require disqualification for bias
    - *Natarajan v. Dignity Health*, 492 P.3d 294 (Cal. 2021).
- Peer Review Immunity:
  - Participants in hospital peer review process that does not deviate from its practitioner peer review policy and is not motivated by malice entitled to immunity pursuant to peer review immunity statute, even if competitor for patient referrals was catalyst for peer review
    - *Sherr v. HealthEast Care System*, 999 F.3d 589 (8th Cir. 2021).

Legal Update: Recent Case Law Developments

- NPDB reportable events
  - A description of the results of an investigation is a reportable statement under HCQIA even when a physician resigns under investigation
    - *Doe v. Rogers*, 498 F.Supp.3d 59 (D.C. Cir. 2020)
  - Adverse Action Report (as submitted):
    - In June 2009, the physician commenced practice at the Hospital in thoracic and general surgery. On Friday, October 2, 2009, the physician performed a laparoscopic appendectomy on a 14–year–old female. In the course of performing the procedure, the physician inadvertently removed part of one of the patient's fallopian tubes. On or about Monday, October 5, 2009, the physician agreed to refrain from exercising his surgical privileges pending the Hospital's investigation of this matter. By letter dated October 7, 2009, the physician advised the Hospital that he resigned from the Hospital effective October 16, 2009. Accordingly, the Hospital took no further action regarding the physician's privileges or employment. However, the Hospital's quality assurance review of this matter indicates departures by the physician from standard of care with regard to the laparoscopic appendectomy that he performed on October 2, 2009

Legal Update: Recent Case Law Developments

- Late career physicians:
  - *EEOC v. Yale New Haven Hospital Inc.* (filed Feb. 11, 2020)
    - Hospital adopting and implementing Late Career Practitioner Policy that requires that any individual age 70 and older who applies for, or seeks to renew, medical staff privileges at hospital take both an ophthalmologic and a neuropsychological medical examination
    - EEOC alleged that in implementing the policy and applying it only to individuals age 70 and above, defendant hospital violated federal anti-discrimination law (Age Discrimination in Employment Act and Americans with Disabilities Act)
    - Litigation remains pending

COVID-19 Update: Status of Federal & State Waivers

2020-2021: Defining Years

- Pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- More than 785,000 U.S. deaths/49M cases through December 7, 2021
- Unemployment claims swelled to 26.5+M
- Once a generation experience
- The health care industry has a lot to learn
- Social, cultural, economic and health care norms are being reshaped
- What have we learned?

CMS Blanket Waivers: Credentialing and Privileging Flexibilities

- Retroactive effective date of March 1, 2020 through the end of the emergency declaration
  - Public Health Emergency most recently extended through January 16, 2022
- Authorizing expanded scope of practitioner privileges:
  - Suspension of Medicare Physician/APP supervision & collaboration requirements
- Authorizing expanded duration of practitioner privileges:
  - Suspension of Medicare credentialing and re-credentialing requirements
- Authorizing the transferability of physician credentialing
  - Suspension of certain site-specific credentialing requirements
- Authorizing credentialing process flexibility
  - Waiving of bylaws required credentialing and privileging process

CMS Blanket Waivers: Encouraging Medical Staff Optimization

- Providing more efficient care for more patients:
  - Authorizing the provision of certain benefits such as daily meals, laundry services and childcare to members of the medical staff
  - Suspension of requirement to complete medical records within 30 days following discharge
  - Suspension of 48-hour requirement for authenticating verbal orders
  - Suspension of requirement to provide information about advance directive policies to patients

Being Compliant or Being Flexible?

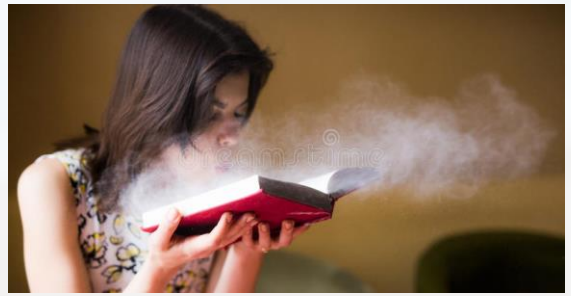
- This PHE has stressed most aspects of hospital operations and care delivery
  - An effective pandemic response requires flexibility, agility and access to resources (and good judgment)
- It is an understatement to refer to the health care industry as highly regulated
  - With oversight and enforcement at all levels
  - A "compliance" mindset is in our DNA
- How is a highly regulated hospital/medical staff able to effectively adapt to what a pandemic demands?
- Bylaws/policies/processes are not the law, but they play one on TV
  - Knowing when you can, can't and shouldn't "color outside the lines" is a skill
- See this as the as a real opportunity for innovation
- The lines are not so bright:
  - Federal guidance – 1135 waivers, non-regulatory guidance; state guidance – licensing boards and facility-licensing authorities; accreditation organizations

Bylaws/Policies/Processes

- Did/do your bylaws, rules, policies address your needs?
- Do you need your own "1135" waivers?
  - Flexibility on responsibilities and duties
  - Flexibility on delegating authority
  - Flexibility on forming and use of ad hoc or subcommittees
  - FPPE/OPPE – QA/PI
  - Election/Appointment terms
  - Flexibility on qualifications; volume or patient activity requirements
  - Scope of urgent amendment authority?

"Work-ups": Practice Makes Perfect

- Were/are your credentialing and privileging policies ready for battle?
- Was/is your credentialing team ready for battle?
- Did you need to blow dust off of a policy?
- Source of guidance?
- Did you stress test your policies?
- Professional development justification
- Consider adding a component to your onboarding/orientation programs (or maybe this is the nudge to get that off the ground)



Meeting Management

- Medical staffs are meeting factories
- Current burdens are high
- Consider the following flexibilities:
  - Meeting frequency/schedule
  - Meeting notice
  - Quorum
  - Consent agendas
  - MEC authority
  - Physician leader delegating authority
  - Meeting format, e.g., Zoom, Teams, WebEx, GoToMeeting, etc.

Maintaining Peer Review Privilege

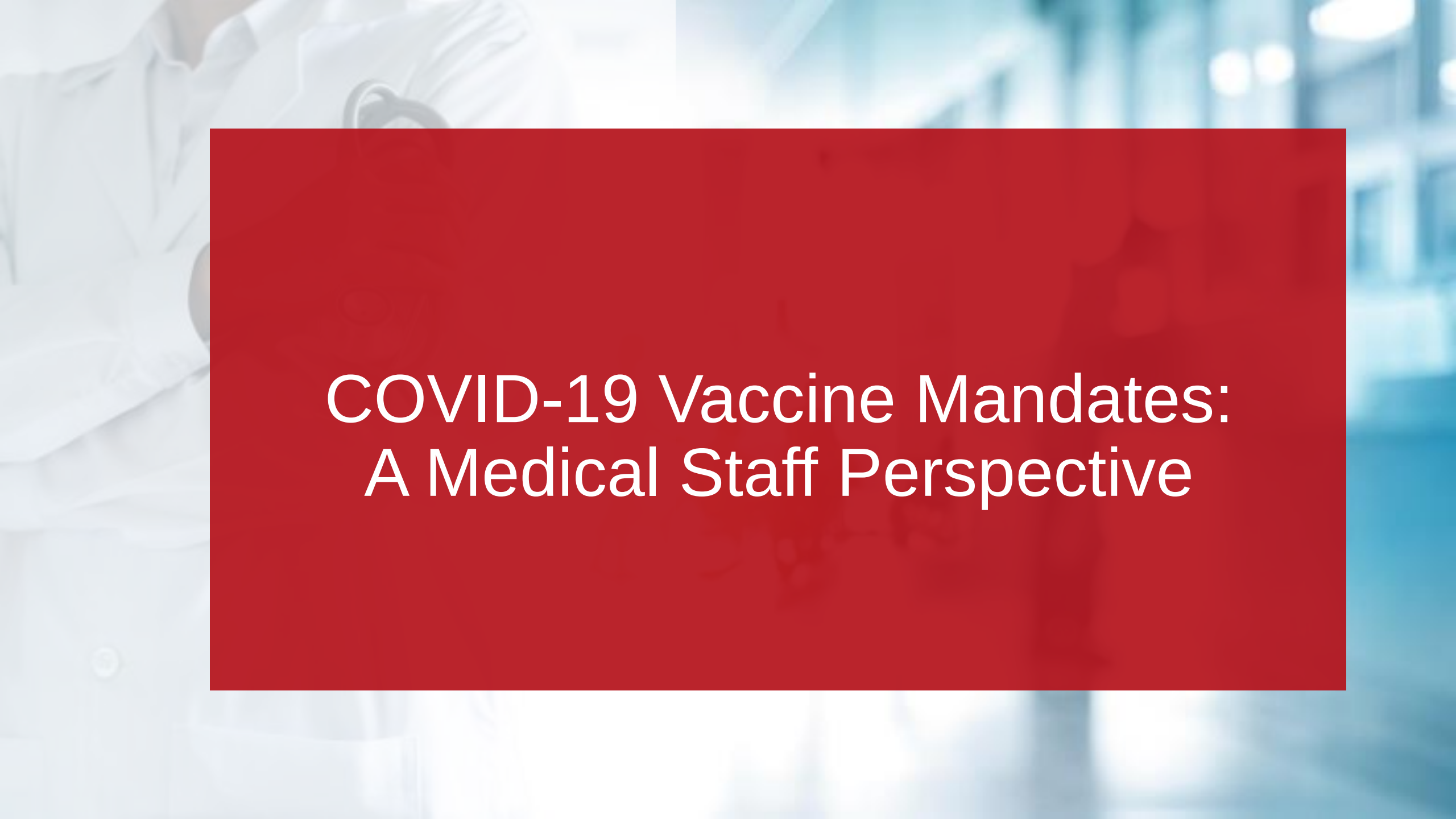
- Public health emergency exceptions or peer review statues are few and far between
- Many hospitals have developed or are developing physician-led resources/committees that are serving in traditional or "should be" peer review capacities, e.g., utilization review, triage/LPP, quality management
- Be mindful of how these committees and resources plug-in to existing peer review committee structures, processes, reporting obligations, documentation practices, etc.

Provider Health

- Provider health is never more important and value never more appreciated
- This PHE is creating demands, stress, grief, perceived duty or futility, and so on - the likes of which we've not experienced
- Self-harm and suicide
- Does your physician/practitioner wellness function work?
- Did your Health Committee last meet in 2016?
- Is now the time to prioritize the value of a comprehensive approach to practitioner well-being?

Best Practices

- Prepare your post-apocalyptic communication plan now:
  - Expiration of privileges, reappointment process, etc.
- Keep a running list of what worked, didn't work, what fell apart and the questions you encountered
- Flag bylaws or policy provisions that created confusion or ineffective
- Be intentional about being flexible
- Anticipate legislation and regulation
- Arrange for a post-pandemic assessment with MS leadership



COVID-19 Vaccine Mandates: A Medical Staff Perspective

Overview

- Vaccine Progress
- Vaccine Mandates
- Legal Challenges
- Implementation
- Enforcement

Vaccination Progress

- As of December 7, 2021, CDC data shows that 236M Americans - (71.1%) of the total population have received at least one dose of a vaccine
  - 47M have received a booster dose
- Top 3 States:
  - Vermont (74%), Rhode Island (73.7%), Maine (72.9%)
- Bottom 3 States:
  - Mississippi (47.1%), Alabama (46.5%), Wyoming (46%)
- According to most recent AMA survey, 96% of physicians surveyed have been fully vaccinated; no significant difference in vaccination rates across regions
  - Of those who were not yet vaccinated, 45% indicated they plan to get vaccinated

Vaccination Progress Cont.

- It appears that after an initial period of rapid uptake, vaccination rates are slowing
- This may be the result of several factors:
  - Mixed messaging
  - Concerns about safety
  - Concerns about new technology used
  - Reports about declining effectiveness
  - Fact that a fully vaccinated individual can still contract and/or spread COVID-19

Early Authority

- COVID-19 Vaccine, OSHA, CDC and workplace safety
  - Organizations have an obligation under to provide employees/staff/volunteers with a safe working environment
  - OSHA and CDC have both published extensive guidance on workplace safety during the pandemic
    - Social distancing
    - Masks
    - OSHA's return to work guidance
  - All of these guidance documents were issued prior to a vaccine
- State Mandates:
  - At least 22 states have adopted mandatory vaccination requirements

Federal Vaccine Mandates

- OSHA Healthcare ETS - June 2021
- CMS Vaccine Mandate - November 2021
- OSHA Vaccine Mandate - November 2021

CMS Vaccine Mandates

Requirements of Rule

- Requires COVID-19 vaccinations for individuals working in Medicare- and Medicaid-participating facilities
- As well as individuals working in certain other settings involving face-to-face interactions with patients

Affected Facilities/ Suppliers by Rule

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

Personnel Subject to Rule

- Facility/provider employees;
- Licensed practitioners;
- Students, trainees and volunteers; and
- Individuals who provide care, treatment or other services for the facility/provider and/or its patients, under contract or other arrangement
  - *CMS intends to interpret the last category very broadly and cites examples of administrative team members and Organ Procurement Organization team members as individuals subject to the Rule due to the potential for even incidental or irregular contact with patients*

Challenges to Federal Mandates

- **Legal Challenge to CMS Rule**—Multiple states have challenged the CMS Rule
  - Briefing from parties is scheduled to happen quickly
  - The CMS Rule appears to be on solid legal footing
  - We do not recommend a "wait and see" compliance approach
- **Legal Challenges to OSHA Vaccine ETS**—6th Circuit Court of Appeals hearing the legal challenges / OSHA suspended its enforcement of its mandate pending outcome of litigation
- **State OSHA plans vs. OSHA Vaccine ETS**—some states with OSHA plans (e.g., AZ) may not follow federal OSHA plan. That would open the door for federal OSHA to revoke the state plan and assume regulatory oversight

Beyond Regulations

- AHA and AMA support of COVID-19 vaccine mandates for health care workers
  - *"We call for all health care and long-term care employers to require their employees to be vaccinated against COVID-19"*
- Nearly 60 others…
- Provided it's "feasible and fair"

Existing Obligations

- Existing federal and state obligations, whether as an employer or health care provider
- Medicare Conditions of Participation:
  - Patients have the right to receive care in a safe setting
  - Comply with all applicable federal, state and local laws
  - Maintain an Infection Control Program; applies to medical staff; audited by QA/PI program
  - Medical staff carries out its joint responsibility for ensuring infection control issues are addressed

Implementation

- Where are you starting from – Community mindset? Culturally?
- What do your current bylaws, rules and regulations, and policies say about immunization/vaccination obligations?
  - Bylaws v. Rules/Regulations v. Policy v. Law
  - Do you need to initiate an "urgent amendment"?
  - 1135 blanket waiver flexibility?
- What is your current process, e.g., flu vaccine?
  - What does or does not work about it?
  - Is it equipped for volume, complexity of requests, etc.
- Depending on the final rule, your process may resemble your employment process

Implementation: Medical and Religious Exemptions

- Regardless of the source of the mandate (State law, Federal law, internal policy) be prepared to address requests for exemption if employees have…
  - A **disability** that would make it unsafe for them to receive the vaccine; or
  - A **sincerely held religious belief** against receiving vaccines
- Medical based exemptions are protected under the ADAAA
- Religious based exemptions are protected under Title VII

Implementation: Medical and Religious Exemptions

- Religious based exemption requests are much more difficult because "religion" is defined broadly under Title VII:
  - Not limited to traditionally recognized religions
  - Might include "individualized" beliefs not associated with any particular religion
  - Might include "individualized" interpretations of traditionally recognized religions
- "Sincerely held" is a subjective standard
  - EEOC has said employers should assume employee is telling truth absent objective evidence to the contrary
- When might an individual's belief be insincere?
  - Political and social beliefs, safety concerns and "conspiratorial" beliefs do NOT qualify as religious based exemptions

Implementation: Processing Requests For Exemptions

- Have a consistent process
- Consider developing a policy, request forms and decision forms
- Will you have an exemption request "committee?"
- Determine how closely you'll scrutinize requests (understanding there is legal risk of "over" or "under" scrutinizing)
- Individualized/interactive discussions are important if you're declining requests
- If requests are denied, can they appeal?
- If requests are approved, communicate alternate infection control protocols required and warning of non-compliance disciplinary action
- An "approved" exemption is not a "free pass" from the mandate
  - Depending on source of mandate or simply your policy, employees whose exemptions are approved might be subject to additional infection control measures

Implementation: Defending Vaccination Mandates

- Medical/religious exemptions will be the source of a coming wave of litigation…
- Whether vaccine mandates are legal is not the real question. They are. They always have been. Objecting individuals consistently lose these cases and there's no meaningful reason to expect that to change
- Key issues to be litigated:
  - Applicability of "undue hardship" defense
  - Federal law preemption (e.g., vaccine passports/state laws prohibiting mandates/additional state law exemptions)

Implementation: Have a Vaccination Policy

- Determine how you plan to approach vaccinating staff
- Address interactive process for both ADA and religious objections
- Be clear on concept regarding those who raise safety objections may be considered protected whistleblowers
- Include a "No Retaliation" statement regarding whistleblowers
  - Be as clear here as in your compliance program
- Establish mechanism for vaccination:
- Consider what will you do for providers who have an adverse reaction?
- Provide education/resources – address the skeptical providers
- Determine how you will roll out the Policy

Enforcement

- So, what if providers that are not employed refuse?
  - Existing authority
  - Existing process
  - Risk assessment
- Is compliance a basic qualification and/or ongoing obligation?
  - Remember the general obligation to comply with federal and state laws
- Pick your poison:
  - Voluntary absence?
  - Administrative suspension?
  - Summary suspension?
  - Leave of absence?

Over the Horizon Considerations

- Practitioner health
- Staffing shortages
- Virtual care, consumerism and convenience
- COVID-19 the endemic
- Post-COVID-19 litigation

Questions?

Contact Us

For more information on these topics visit hallrender.com.

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