

CLIENT ALERTS

Part 1: Compelling Vaccination in Certain Health Care Settings

11.12.2021

This Health Care Alert is the first in a 2-part series on the issues regarding compelling vaccinations in the health care workplace.

Because of the short timeframes in the CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (IFR) effective November 5, 2021 (CMS IFR), available [here](#), Part 1 will address the CMS IFR. (Part 2 will address the Occupational Safety and Health Administration (OSHA) emergency temporary standard (ETS) for large employers (those with over 100 employees).

Legal Challenge to CMS IFR in Missouri Based on Health Care Worker Shortages

On November 10, 2021, ten states, led by the State of Missouri, filed a lawsuit challenging the CMS IFR in federal district court in Missouri. The states claim, in large part, that the CMS IFR will exacerbate the growing crisis of health care worker shortages, and that the CMS mandate is unconstitutional. The states are asking the court to set aside the CMS IFR and to enter preliminary and permanent injunctions against its enforcement.

Despite the legal challenge in Missouri, in light of the very short time frames for compliance provided in the CMS IFR, those Medicare- and Medicaid-certified facilities covered under the CMS IFR should begin to comply with the requirements in Phase 1 of the rule.

Immediately Effective Emergency Regulation for Certain Medicare and Medicaid Certified Providers and Suppliers:

The immediately effective CMS IFR is an emergency regulation for which CMS found good cause to take immediate action to protect the health and safety of residents, clients, patients and staff. (There is an opportunity for comments to be made within the comment period which closes on January 4, 2022).

Related People

Robert H. Schwartz
Shareholder

Related Services

Health Care
Health Care Industry Team
Labor and Employment

CLIENT ALERTS

The IFR requires the covered providers to establish a process or policy to fulfill the staff vaccination requirements over 2 phases:

Phase I – *by December 5, unless staff have applied under a covered facility's process or policy for a legally recognized religious exemption or medical accommodation from the vaccine requirement (including a permitted delay in vaccination under CDC guidance), or unless staff work 100% remotely (including telehealth) with no contact with other employees or patients at any time, staff at all covered health care facilities must have received at least the first dose of the two-dose vaccine or the single dose vaccine prior to providing any care or treatment to patients.*

Phase II – *by January 4, 2022, staff must complete the primary vaccination series (except for those that are exempted).* Although the IFR follows the CDC guidance on when a person is “fully vaccinated” (i.e., 14 days after the second dose in a two-dose series or after 1 dose in a single-dose vaccination), the Phase II requirement is met on the day of the second or first shot, as applicable.

What Health Care Entities are Covered?

The CMS IFR applies to Medicare and Medicaid-certified providers and suppliers that are regulated under the Medicare health and safety standards under the Conditions of Participation, Conditions for Coverage or Requirements. These facilities are required to have processes or policies in place ensuring that all applicable staff are vaccinated against COVID-19. The IFR does not generally apply to “physician offices that are not regulated by CMS” and whose physicians and their staff do *not* provide or assist in surgical procedures in an Ambulatory Care Center. (Note: unvaccinated health care workers in physician offices may be covered by other rules such as the OSHA ETS).

Generally, the IFR applies to Medicare and Medicaid – certified provider and supplier types, Ambulatory Surgery Centers, 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, Clinics, Rehabilitation Agencies and Public Health Agencies as providers of Outpatient, Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities, Programs for All-Inclusive Care for the Elderly Organizations, Rural Health Clinics, Federally Qualified Health Centers and Long Term Care Facilities. Further, Indian Health Services are also covered by the IFR.

Excluded entities include religious non-medical health care institutions, Organ Procurement Organizations and portable x-ray suppliers are not included in the IFR requirements. Note that Organ Procurement Organizations and portable x-ray suppliers may be required to vaccinate through service arrangements with providers who are covered by the IFR.

What Health Care Workers are Covered?

CLIENT ALERTS

The CMS IFR vaccine mandate generally applies to all staff without regard to patient contact, unless such staff fall within a legally recognized religious exemption or medical accommodation under applicable federal law. In addition, staff (including telehealth workers) who are remote 100% of the time and have no contact directly with patients or other staff at any time are not subject to the vaccine requirement.

The CMS vaccine mandate also applies to students, trainees, volunteers, administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping, food service, and others who work on-site under a contract or arrangement – other than “one-off” vendors or those who provide services exclusively off-site.

What are the Exemptions from the Requirement?

Exemptions from the requirements for vaccinations include:

1. Those with recognized medical conditions for which the vaccine is contraindicated under the CDC clinical guidance.
2. Religious beliefs, observations or practices established under Title VII of the Civil Rights Act of 1964.
3. Those with legally recognized medical accommodations established under federal discrimination law.

Facilities are to establish policies and procedures for reviewing and determining requests for religious exemptions and medical accommodations consistent with federal law. There should be appropriate documentation of each request and its disposition, and compliance with federal law, including review of the EEOC’s compliance manual.

Additionally, there is a temporary delay exemption for someone who received a COVID-19 diagnosis due to clinical precautions as recommended by the CDC. Documentation includes a signed and dated document indicating the contraindication by a licensed practitioner who is not the person seeking the exemption and who is not acting within the scope of practice. However, there is no exemption for individuals with COVID-19 antibodies.

Which Vaccines are Acceptable?

In accordance with CDC guidelines, acceptable vaccines include: the single-dose vaccine (Johnson & Johnson); the multi-dose vaccine such as the Pfizer-BioNTech; active vaccines actually received by individuals who participated in clinical trials; and vaccines listed in the World Health Organizations (WHO) for emergency care that are not approved by the FDA.

Note: The “booster” is not required at this time to be considered fully vaccinated.

Is There a Testing Alternative?

CLIENT ALERTS

Previous CMS emergency regulations for Long Term Care Facilities are still in effect requiring that facility residents and staff be tested for COVID-19. Otherwise, there are no additional requirements for testing under the CMS IFR.

How will CMS Enforce the Vaccine Mandate?

Facility Accreditation: CMS will work directly with the State Survey Agencies to review compliance. A number of factors will be reviewed such as the policies and procedures of the facility and the number of cases over the last 4 weeks before a survey. Accrediting agencies will be required to update their survey process to assess facilities they accredit for compliance with vaccination regulations.

Penalties: The penalties for not complying with the CMS IFR include those penalties under the Civil Monetary Penalties Law, denial of payment and even termination from Medicare and Medicaid programs. The penalty for noncompliance by hospitals and certain other acute care/continuing care facilities is termination, but CMS has stated its goal is to bring health care facilities into compliance. Termination is indicated as a result only after a facility has an opportunity and fails to correct the deficiencies.

Can Health Care Facilities be Covered by Other Federal Vaccine Requirements?

CMS indicates that it worked with OSHA to ensure that the federal vaccine regulations were complementary, ensured maximum coverage of work forces across a multitude of settings, and were not overly duplicative. Medicare- and Medicaid-certified health care facilities should look to the CMS IFR to fulfill the vaccination requirements.

Note: The CMS IFR also says that facilities not certified are to follow the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or the OSHA ETS.

The Executive Order for federal contractors or the OSHA COVID-19 Healthcare Emergency Temporary Standard may also apply to staff not subject to the vaccination requirements. Facilities are encouraged to review these regulations and comply with any other federal requirements.

Which Law Applies: Federal or State?

CMS cites the Supremacy Clause of the US Constitution to assert that its regulations pre-empt any State law that is contrary to the CMS IFR. The Missouri lawsuit challenging the CMS IFR argues that the power to regulate vaccine mandates lies with the states.

CONCLUSION

As the above summary demonstrates, the complex CMS IFR contains a very short timeframe for Phase I. Even with the legal challenges, health care providers and suppliers should begin to comply with Phase I requirements in order to have sufficient time to review requested exemptions and accommodations in the light of staffing needs, with guidance from the EEOC and the CDC where

CLIENT ALERTS

appropriate. Further, the litigation does not preclude facilities from implementing their own mandatory vaccine policies.

Butzel draws upon an interdisciplinary team of attorneys in our health care law, labor and employment law, and federal contractor law practices in order to analyze the federal vaccine mandates applicable to health care providers and suppliers. For assistance with these critical matters, you can contact the authors of this Alert, your regular Butzel attorney, or any member of Butzel's healthcare industry group.

Robert Schwartz

248.258.2611

schwartzrh@butzel.com

Diane Soubly

737.213.3625

soubly@butzel.com

Mark Lezotte

313.225.7058

lezotte@butzel.com

Debra Geroux

248.258.2603

geroux@butzel.com