



Kansas Hospital Association

Federal Vaccine Mandate Update - 1/21/22

Vaccine Mandates in the Courts

In a Nutshell

- The CMS Nov. 5, 2021, Interim Final Rule (“CMS Vaccine Mandate”) is currently enforceable.
- The OSHA Emergency Temporary Standard (“OSHA ETS”) affecting employers with 100 or more employees is not currently enforceable.

Useful Resources

- CMS Interim Final Rule (Vaccination Mandate) (Federal Register 61555 *et seq.*, Nov. 5, 2021)
(<https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>)
- CMS QSO-22-09-All (Jan. 14, 2022) (and related attachments) (<https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf>)

Useful Resources (cont.)

- EEOC Guidance:
<https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>
(Dec. 14, 2021)
- State Vaccination Law:
<https://www.sos.ks.gov/publications/Register/Volume-40/Issue-46A-November-23-2021.html>

Two Groups of States Challenged CMS Vaccine Mandate

- *Missouri v. Biden*, 2021 WL 5564501 (Nov. 2021) (the “one Kansas joined”)
- *Louisiana v. Becerra*, 2021 WL 5564501 (Nov. 2021)

Both were filed in U.S. District Courts

Preliminary Injunctions-Staying Enforcement of the CMS Mandate (Nov.-Dec. 2021)

Both US District Courts
entered preliminary
injunctions. (Nov. 2021)

The relevant Courts of
Appeals rejected the
Government's motion to
"stay" the injunction. (5th
and 8th Circuits) (Dec. 2021)

Applications to the US Supreme Court

The Government filed applications asking the US Supreme Court to “stay” both District Courts’ preliminary injunctions.

Bottom Line: The Government wanted the Supreme Court to allow CMS to enforce the CMS vaccine mandate pending disposition of the Government’s appeals in the 5th and 8th Circuits.

US Supreme Court Decision (5-4)-CMS Mandate Enforceable

The Supreme Court “stayed” the lower courts’ “preliminary injunctions” while the Government continues with its appeals in the 5th and 8th Circuits challenging the District Courts’ preliminary injunction. (Jan. 13, 2022)

Bottom Line:

- At this time, CMS can (and will) enforce the CMS Vaccine Mandate.
- The States and the Government can continue to “fight it out” in the appeals pending in the 5th and 8th Circuit; but, the language in the US Supreme Court’s Order will be persuasive and authoritative.

The Supreme Court Said

“We agree with the Government that the Secretary’s rule falls with the authorities that Congress has conferred upon” HHS. Slip Op. at p.4.

The Rule is not arbitrary and capricious.

HHS articulated adequate explanation for the Rule.

The Court found “no grounds for limiting the exercise of authorities the agency has long been recognized to have.” Slip Op. at p. 9.

OSHA Test or Vaccinate- OSHA Mandate

A complex
procedural history

OSHA issued its COVID-19
Emergency Temporary
Standard on **Nov. 5, 2021**,
requiring employers with **100
employees or more to test
employees weekly unless
they were vaccinated.**

In November 2021, the 5th
Circuit **stayed the
enforcement** of the OSHA
Mandate. BST Holdings, LLC
v. OSHA, 2021 WL 516656 (5th
Cir. Nov. 6, 2021) BST
Holdings, LLC v. OSHA, ___
F.4th ___, 2021 WL 516656
(5th Cir. Nov. 12, 2021)

Meanwhile, similar suits
were being filed in other
circuits. Subsequent to
Nov. 12, 2021, all of these
suits, including BST Holdings,
were **consolidated in the
Sixth Circuit.**

December 2021 –
6th Circuit allows
enforcement of the
OSHA Mandate

On Dec. 17, 2021, a three-judge panel of the Sixth Circuit took action allowing enforcement of the OSHA Mandate. In re MCP No. 165, Occupational Safety and Health Administration, Interim Final Rule: COVID-19 Vaccination and Testing, __ F.4th __, 2021 WL 5989357 (6th Cir. Dec. 15, 2021)

US Supreme Court Decision- OSHA Mandate

In a 6-3 Decision, the Supreme Court “stayed” the OSHA Mandate “pending disposition of the applicants’ petitions for review” in the 6th Circuit. Slip Op. at p. 9. (Jan. 13, 2022).

The Court stated that “**Applicants are likely to succeed on the merits of their claim that the Secretary lacked authority to impose the mandate.**” Slip Op. at p. 5.

“The equities do not justify withholding interim relief”, *i.e.*, the “stay pending disposition” of the petitions for review in the 6th Circuit.

Bottom Line: The OSHA Mandate is not currently enforceable.

CMS IFR Requirements

First Deadline – Feb. 14, 2022

- Policies and procedures developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; and
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the facility is compliant under the rule;
or
- If as facility has less than 100% of all staff having received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the facility is non-compliant under the rule.
 - The facility will receive notice of their non-compliance with the 100% standard.
 - A facility that is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action.
 - States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

CMS IFR Requirements

By March 15, 2022

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; and
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the facility is compliant under the rule;
Or
- If less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple-dose vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the facility is noncompliant under the rule.
 - The facility will receive notice of their non-compliance with the 100% standard.
 - A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action.
 - States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

CMS IFR Requirements

- Within 30 days - Federal, State, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys
- Within 90 days and thereafter following issuance of this memorandum - facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Temporary Exemptions

- Hospitals must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed.
- CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical precautions and considerations such as individuals with acute illness secondary to COVID-19 illness, and individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

Medical Exemptions

- Certain allergies or recognized medical conditions can be grounds for the exemption.
- Recognized clinical contraindications can be found in the CDC summary document for [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)
- Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication.
- The documentation must also include a statement recommending that the staff member be exempted from the hospital's COVID-19 vaccination requirements based on the medical contraindications.
- A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws.
- The individual who signs the exemption documentation cannot be the same individual requesting the exemption.
- Surveyors will review and verify that all required documentation is:
 - Signed and dated by physician or advanced practice provider.
 - States the specific vaccine that is contraindicated and the recognized clinical reason for the contraindication with a statement recommending exemption.

Non-Medical/Religious Exemptions

- Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospital's policies and procedures.
- Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination
(<https://www.eeoc.gov/laws/guidance/section12-religious-discrimination>) for information on evaluating and responding to such requests.
- **Note:** Surveyors will not evaluate the details of the request for a religious exemption, nor the rationale for the hospital's acceptance or denial of the request. Rather, surveyors will review to ensure the hospital has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Staff with COVID-19 Exemptions

- While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required.
- For individual staff members that have valid reasons for exemption facility can address those individually.
 - An example of an accommodation for an unvaccinated employee with a qualifying exemption could include:
 - mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines
 - physical distancing from co-workers and patients
 - re-assignment or modification of duties
 - teleworking, or
 - a combination of these actions. Accommodations can be addressed in the hospital's policies and procedures. Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.

Staff with COVID-19 Exemptions

- Accommodations can be addressed in the hospital's policies and procedures.
- Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel.
- For additional information see CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.

Staff with COVID-19 Exemptions

- For each individual identified by the hospital as unvaccinated, surveyors will:
 - Review hospital records.
 - Determine, if they have been educated and offered vaccination.
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the hospital policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.

Surveys – Level of Deficiency

Immediate Jeopardy:

- 40% or more of staff remain unvaccinated creating a likelihood of serious harm
- OR
- Did not meet the 100% staff vaccination rate standard ; observations of noncompliant infection control practices by staff (e.g., staff failed to properly don PPE) and 1 or more components of the policies and procedures were not developed or implemented.

Condition Level:

- Did not meet the 100% staff vaccination rate standard; and
 - 1 or more components of the policies and procedures were not developed and implemented.
- OR
- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

Standard Level:

- 100% of staff are vaccinated and all new staff have received at least one dose; and
 - 1 or more components of the policies and procedures were not developed and implemented.
- OR
- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Common Questions

- Are boosters required
 - Not under the current language
 - Tracking is required as part of your tracking of vaccine status, delays and exemptions
- Do the 30 and 60 day deadlines include the 14-day waiting period:
 - No, the requirements are met once the employee has received their shot.

Questions?

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