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CMS VACCINE MANDATE UPDATE: BIDEN ADMINISTRATION MODIFIES HEALTHCARE RULES FOR MEDICARE AND MEDICAID FACILITIES

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The vaccine mandate issued by the Center for Medicare and Medicaid Services ("CMS") has been temporarily enjoined in 25 states by order of the Fifth Circuit Court of Appeals entered on December 15, 2021. Facilities located in states that are not subject to the injunction (including North Carolina), have until January 27, 2022 to establish policies and procedures regarding vaccination, and until February 28, 2022 for eligible staff to complete a vaccination series. The CMS mandate also will be considered by the Supreme Court on January 7, 2022.

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The enforceability of the CMS vaccine mandate has not been finally decided. On November 29, 2021, a federal court in Missouri **entered an order** blocking the enforcement of the federal vaccine mandate for health-care workers in 10 states. One week earlier, a Florida federal court **declined** to enter a similar order requested by the State of Florida.

When the federal government issued its new COVID-19 vaccine mandates^[1] on November 5th for employers with 100 or more employees, the rules implemented by the Occupational Safety and Health Administration ("OSHA") received most of the media's attention. However, at the same time the White House announced new COVID-19 vaccination rules that would require some 17 million health care workers in about 76,000 hospitals, nursing homes and other health care facilities to get fully vaccinated by Jan. 4, 2022. This appeared to be an attempt, at least in part, to synchronize otherwise conflicting vaccination deadlines.

Despite that effort at synchronicity, many health care employees will not be offered the same weekly testing alternative to vaccination mandates that was included in the **Emergency Temporary Standard** ("ETS") issued by OSHA. In the case of workers employed by a Medicare- and Medicaid-certified provider or supplier, the White House cited a "higher bar" for those directly involved with patient health and safety in explaining the absence of a testing alternative.

Pursuant to the emergency regulation issued on the same day by the United States Centers for Medicare and Medicaid Services ("CMS"), health care facilities^[2] that participate in the Medicare and Medicaid programs must require all eligible staff ^[3] to receive one of the approved COVID-19 vaccines. The new regulation does not cover assisted living facilities, physician's offices, group homes or home- and community-based services because they are not subject to CMS health and safety regulations. By December 5, 2021 facilities covered by

this regulation must ensure that all eligible staff have received at least the first dose of an approved vaccine prior to providing any care, treatment or other services.[4] Following that date, all eligible staff must have received the final dose of a vaccine series by January 4, 2022. The regulation provides for exemptions based on recognized medical conditions or religious beliefs. Any such exemptions must align with federal law.[5]

CMS will ensure compliance with these requirements through established state survey and enforcement processes. If a covered provider or supplier does not meet the requirements of the new regulation, it will be cited by a surveyor as being non-compliant and will have an opportunity to return to compliance before enforcement action. For nursing homes, home health agencies and hospice (beginning in 2022), enforcement action can include civil monetary penalties, denial of payment and even termination from the Medicare and Medicaid programs. For hospitals and certain other acute and continuing care providers, enforcement can include termination from the Medicare and Medicaid programs. CMS has stated that its primary goal, however, will be to bring health care providers into compliance, although it will not hesitate to use its full enforcement authority to protect the health and safety of patients.

The updated emergency regulation follows a September CMS announcement[6] that expanded an existing emergency regulation requiring vaccinations for nursing home staff to include hospitals, dialysis facilities, ambulatory surgery centers and home health agencies, among other settings, as a condition for participation in Medicare and Medicaid.

[1] <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>

[2] "Covered facilities" include CMS-regulated Ambulatory Surgical Centers, Hospices, Programs of All-Inclusive Care for the Elderly, Hospitals, Long-Term Care Facilities, Psychiatric Residential Treatment 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, and End-Stage Renal Disease Facilities. Religious Nonmedical Health Care Institutions, Organ Procurement Organizations and Portable X-Ray Suppliers are generally not covered by the new regulation.

[3] "Eligible staff" means all current staff (and any new staff) who provide any care, treatment or other services for a covered facility and/or its patients, regardless of clinical responsibility or patient contact and whether on or off site.

[4] Although the version of the new CMS regulation published in the Federal Register references December 6th as the deadline for the first vaccine dose, both the CMS announcement and other related documents list December 5th. Given that the intent of the new regulation was likely to provide 30- and 60-day milestones for implementation (as OSHA did with the new ETS), covered facilities should strive to achieve compliance by December 5th.

[5] <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

[6] <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings>

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