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US Supreme Court Allows CMS COVID-19 Vaccination Rule to Go Forward – What Does This Mean To Participating Health Care Facilities?

Client Alert

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In the highly anticipated case challenging the Department of Health & Human Services (HHS), Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule mandating COVID-19 vaccinations for all staff in participating health care facilities (CMS Rule), on January 13, 2022, the Supreme Court ruled in CMS's favor and stayed enforcement of injunctions issued by two District Courts. In the 5-4 decision, the Supreme Court held that the CMS Rule fell within the authority granted by Congress to the Secretary of HHS to "impose conditions the receipt of Medicare and Medicaid funds that 'the Secretary finds necessary in the interest of health and safety of individuals who are furnished services.'" The Court likened the CMS Rule to other Conditions of Participation that are routinely imposed upon regulated facilities, which include a "longstanding litany of health-related participation conditions."

In numerous prior Client Alerts, Butzel has followed the myriad of legal challenges to the CMS Rule – and a companion case challenging the Occupational Safety and Health Administration's (OSHA) emergency temporary standard for COVID-19 vaccination and testing for large businesses – that provides analysis of these agencies' rules since their issuance. With the Supreme Court's decision paving the way for CMS to enforce its Rule, participating facilities still have questions about the impact of the Rule and what they need to do to ensure compliance. A number of these concerns have been addressed in an External FAQ issued on November 5, 2021 and updated December 28, 2021 by CMS. We highlight a number of those concerns and CMS' position below.

- **Who must be vaccinated (or have an exemption)?** According to CMS, all staff that interact with other staff, patients, clients or PACE program participants in any location (and not merely

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the clinical setting) must be vaccinated. "Staff" includes facility employees, licensed practitioners, students, trainees and volunteers. This vaccine mandate extends to staff of other entities (such as Portable X-ray Suppliers and Organ Procurement Organizations) that furnish services **under contract or other arrangements** within participating facilities (except on an infrequent, ad-hoc basis). Likewise, physicians and other practitioners that have privileges or provide services at a participating facility must be vaccinated. Also included in this indirect vaccination mandate are EMS workers that have a contractual relationship with a participating facility, such as contracts for non-emergency transportation services.

- **Must visitors be vaccinated?** CMS recognizes it cannot mandate COVID-19 vaccinations for personal visitors to facilities, such as family and friends of the patients. However, the mandate does apply to contractors that visit the facility on a regular basis.
- **When must participating facilities comply?** Due to the prior legal challenges, CMS has delayed enforcement of Phase 1 to January 27, 2022, meaning facilities must be able to prove that at least 80% of its staff are vaccinated by January 27, 2022 with 100% compliance within 60 days to avoid enforcement action.
- **Does "fully vaccinated" require boosters?** To date, CMS considers a person "fully vaccinated" if he/she has received the full series of a primary vaccination (single-dose or multi-dose depending on manufacturer). While CMS highly recommends boosters, the failure to obtain a booster is not considered noncompliance.
- **How should the facility document vaccine status?** While providing examples of acceptable documentation, the policies and procedures for documenting vaccine status are left to the facilities' discretion.

With the Supreme Court's ruling, participating facilities throughout the United States must take steps toward compliance with the vaccine mandate for its staff and contractors by the January 27, 2022 deadline. We will continue to monitor HHS for new developments on the timeline for compliance. If you have any questions please contact the authors of this alert or any member of Butzel's Health Care Industry team.

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