Client Alert: New CMS Regulations Mandating Vaccination of Health Care Facility Staff

BY PETER J. MARTIN • NOVEMBER 5, 2021

On November 5, 2021, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule requiring that a wide variety of providers and suppliers participating in the Medicare program ensure their staff are fully vaccinated for COVID-19 unless exempted. Of interest to the provider community are certain entities and individuals who are outside the scope of this interim final rule:

The new rule covers CMS-regulated entities referred to as "facilities" but *not* independent physician offices. "Facilities" include hospitals, nursing homes, ambulatory surgery centers, home health agencies, community and rural health centers, clinics, hospices, PACE programs and end-stage renal disease facilities. CMS notes that such offices and the licensed professionals who work in them may be subject to state vaccination requirements.

The new rule requires all "staff" at facilities to be vaccinated and does not exclude from "staff" those who perform patient care services on a sporadic or infrequent basis. "Staff" would not include those who provide patient care services on an unscheduled basis but would include those who provide services under contract or arrangement, regardless of how frequent those services are provided. CMS remarks that "any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care, including staff or patients" must be fully vaccinated under the rule. We can expect facilities to protest the breadth of this requirement.

Facilities are not required to mandate vaccination for all individuals who enter the facility. This would include not just patients and visitors, but individuals who infrequently provide ad hoc non-health care services. The vaccination mandate also does not apply to telehealth provider services provided entirely off-site.

Implementation of the new rule will take place in two phases. The first phase begins 30 days after the rule's publication (December 6, 2021), and requires that facilities have ensured that all non-exempted staff have received at least the first dose of a multi-dose vaccine or a single-dose vaccine. At the first phase, facilities must also have developed and implemented appropriate policies and procedures. The second phase is effective 60 days after publication (January 4, 2022) and imposes the requirement that all non-exempted applicable staff are fully vaccinated. Staff are considered to be "fully vaccinated" only after completion of 14-day period after receiving the second of a multi-dose vaccine or the single-dose vaccine, but for purposes of the rule the facility has met the vaccination requirement if a staff member has received that dose without having completed the 14-day waiting period.

The requirement that facilities develop and implement policies and procedures during the first rule phase will be burdensome for some providers. Those policies will have to include documenting vaccination status, creating a process for receiving and adjudicating claimed exemptions from the vaccination requirement, dealing with medically-

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indicated vaccination delays, implementation of additional precautions related to staff who are not yet fully vaccinated, documenting and tracking those who have received a vaccine booster, and contingency plans for staff who are not fully vaccinated. Facilities that already have infection control policies and procedures will find these additional requirements less burdensome.

Comments on the new rule are due January 4, 2022, and we can anticipate refinements to the requirements sometime after that date.

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