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CMS to Issue Interim Rule Imposing Vaccine Mandate for Healthcare Settings

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Husch highlights

On September 9, 2021, President Biden announced a new vaccine mandate for healthcare workers employed at most Medicare- and Medicaid-certified facilities; continued participation in Medicare and Medicaid programs is conditioned on compliance with this vaccine mandate.

New regulations related to the vaccine mandate for healthcare settings will be promulgated by the Centers of Medicare & Medicaid Services (CMS) with an anticipated release of an Interim Rule in October 2021.

Despite limited information released at this time regarding the mandate, a few observations can be made regarding the current regulatory landscape, support within the healthcare industry, and anticipated legal challenges that may impact forthcoming regulations.

On September 9, 2021, President Biden announced a COVID-19 Action Plan, Path Out of the Pandemic, which aims to reduce the number of unvaccinated individuals by increasing the number of individuals subject to vaccine mandates. Among its provisions, the plan: (1) imposes new vaccine mandates on healthcare staff or workers employed at most Medicare- and Medicaid-certified facilities, including hospitals, dialysis facilities, ambulatory surgical settings and home health agencies (collectively referred to as “healthcare facilities”) and (2) conditions continued participation in Medicare and Medicaid programs on compliance with the vaccine mandate. The purpose of the new requirement is to protect vulnerable and elderly patients in healthcare

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facilities from the "direct and indirect threats" posed by unvaccinated workers as a source of COVID-19 outbreaks and infections.

New regulations to be promulgated by CMS

To implement the vaccine mandates on healthcare workers, CMS–in collaboration with the Centers for Disease Control and Prevention (CDC)–will expand emergency regulations previously authorized on August 18, 2021, that require nursing home staff to receive COVID-19 vaccinations. The expanded regulations will establish vaccine requirements for all providers and suppliers that participate in the Medicare and Medicaid programs. CMS anticipates the release of an Interim Final Rule with a comment period in October 2021.

The Administration estimates that approximately 50,000 providers and a majority of approximately 18 million healthcare workers will be covered by the new vaccine mandate. Although many questions regarding the anticipated obligations under the new regulations have not been disclosed yet, limited answers to some questions may be inferred from recent disclosures on related matters.

How will healthcare facilities track and report the vaccination status of healthcare workers?

CMS has not specifically provided information on the method by which healthcare facilities must track and report the vaccination status of its workers under the new vaccine mandate. The reporting system could be analogous to or build on the quarterly data collection system disclosed in a recent final rule issued by CMS that includes provisions establishing a process measure to track COVID-19 vaccination coverage among healthcare personnel (HCP) in healthcare facilities such as acute care facilities.

On August 13, 2021, CMS published a lengthy Final Rule that establishes a data collection system as part of its Hospital Inpatient Quality Reporting Program referred to as a "COVID-19 HCP vaccination coverage measure" that is analogous to the influenza HCP vaccination measure. The COVID-19 vaccination coverage measure previously was included in the December 21, 2020, list of measures under consideration for use in Medicare programs.

Under the measure, beginning in the fourth quarter of 2021 (October 1–December 31, 2021), healthcare facilities such as in-patient/hospital, post-acute care, other-long-term care, ambulatory care and outpatient service care settings will submit vaccination data quarterly through the CDC's National Healthcare Safety Network (NHSN), the same web-based infection surveillance system used to report influenza vaccination coverage among HCPs. The healthcare facilities willreport the "percentage of HCPs who receive a complete COVID-19 vaccination course" according to measure specifications. Healthcare facilities will report data collected by the healthcare facility during one self-

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selected week of each month during the quarter. The quarterly vaccination coverage rate for each facility will be based on the average of the data from the three weekly rates submitted by the facility for each quarter. CMS will publicly report the COVID-19 HCP vaccination coverage rate for each healthcare facility.

Whether the data collection and reporting system for the COVID-19 vaccine mandate on healthcare workers will build on the quarterly CMS COVID-19 HCP vaccination coverage measure or, perhaps, be similar to the annual EEO-1 data collections is unknown at this time. The final rule of the CMS COVID-19 HPC vaccination coverage measure notes that the measure is a "process measure that assesses HCP vaccination coverage rates, not an outcome measure for which hospitals are held directly accountable for a particular outcome and does not require HCP to receive the vaccination." Further, the rule explains that the purpose of the COVID-19 HCP vaccination coverage measure is "to allow hospitals to identify the appropriateness and effectiveness of their initiatives to improve vaccination coverage and would provide customers with important information."

How will CMS enforce the vaccine mandate?

Although CMS has not released enforcement information with regard to the vaccine mandate on healthcare facilities, it has been reported that CMS intends to adopt a progressive approach to enforcement of the vaccine mandate similar to the enforcement approach used with respect to nursing homes that do not adhere to staff vaccination requirements. The stepped approach would consist of: (1) providing notice to facilities that are not in compliance with the mandate; (2) assessing civil penalties; (3) denying payments to noncompliant facilities; and ultimately, (4) removing facilities from the Medicare/Medicaid program for continued noncompliance.

Given that the new mandate on healthcare facilities is an expansion of the emergency regulations imposed on nursing homes, the likelihood exists that the enforcement approaches will be similar.

More questions than answers exist until regulations are published

Numerous questions regarding the vaccine mandate for healthcare workers exist, such as:

Treatment of requests for religious and medical exemptions from the vaccine mandate and reasonable accommodation and undue hardship considerations;

Available alternatives to vaccination, if permitted under the Plan, such as increased testing, masking and physical distancing;

Recordkeeping issues related to recording the vaccination status of individuals and if permitted under the Plan, the testing results for individuals who remain unvaccinated;

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Employer obligations to provide paid time off to individuals who must undergo increased testing or receive vaccines;

Impact of state laws permitting conscientious objections; and

Impact of the vaccine mandate on bargaining rights of labor unions.

As regulations are promulgated, we will update information regarding these and other issues related to the vaccine mandate.

Healthcare industry support for vaccine mandates for workers

Before President Biden's vaccine mandate on healthcare workers, many hospitals around the country had already begun to impose COVID-19 vaccine mandates on their personnel.

The Brown School of Public Health is tracking and confirming hospitals and hospital systems with vaccine mandates, and it updates its hospital vaccine tracker on a daily basis. As of the September 14, 2021, according to the tracker, 286 hospitals or hospital systems have imposed full vaccine mandates on their personnel, 9 have imposed partial mandates and 94 have not imposed vaccine mandates on their personnel.

The Brown School of Public Health data and a statement by the American Hospital Association demonstrate the increasing support by the hospitals and hospital systems of mandatory COVID-19 vaccines for healthcare workers. Similarly, healthcare associations such as the American Medical Association, the American College of Physicians, the American Academy of Pediatrics, and the American Academy of Allergy, Asthma, and Immunology are among approximately 50 signatories to a joint statement calling on all healthcare and long-term care employers to mandate COVID-19 vaccines for employees.

Potential challenges to the vaccine mandate

The vaccine mandate is supported by significant members of the healthcare industry. The joint statement describes their commitment to the vaccine mandates as "the logical fulfillment of the ethical commitment of all healthcare workers to put patients as well as residents of long-term care facilities first… to ensure their health and well-being." Yet, legal challenges to vaccine mandates imposed on healthcare workers are expected. These challenges may come from various parties, including individuals, hospitals or hospital systems, healthcare associations, states or state Attorneys General.

Legal challenges expected from individuals against healthcare employers

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With respect to legal challenges filed against individual employer vaccine mandates, Supreme Court precedent and the Equal Employment Opportunity Commission (EEOC) guidance confirm that private employers can require employees to be vaccinated against COVID-19. In one of the first lawsuits filed to challenge a healthcare employer's right to impose vaccine mandates on employees, *Jennifer Bridges et al. v. The Methodist Hospital*, a Texas court dismissed the lawsuit in its entirety holding that the mandate presented no violation of Texas law or of public policy. Despite the judicial precedent supporting employers' ability to impose vaccines on employees, lawsuits continue to be filed by employees who allege that the fully approved Food and Drug Administration (FDA) vaccine is unsafe or who challenge denial of religious or medical exemptions. Conscientious objection laws passed in some states also afford individuals an avenue to challenge employers' vaccine mandate.

It is important to acknowledge that the Biden Administration's vaccine mandate for healthcare workers provides some additional protection to healthcare employers by taking the decision to require vaccinations out of the employers' hands.

Legal challenges expected to be filed against the Biden Administration

With respect to challenges against the federal mandate on healthcare facilities that receive federal funding, there is strong legal precedent to support the federal mandate. Legal challenges from employers, governors and state Attorneys General who disagree with the policy, legality and federal authority to impose vaccine mandates are anticipated.

While the federal authority for the mandate arises from CMS' authority to set safety standards for healthcare facilities that receive federal funding, we expect the plaintiffs to assert arguments similar to those challenging the Affordable Care Act (ACA), which imposed mandates and penalized states as opposed to individual employers. We also expect additional challenges based on the concept of federal overreach.

What this means to you

While there is judicial support for the President's Plan to impose vaccine mandates on healthcare workers in CMS-regulated settings, there will undoubtedly be legal challenges. The publication of regulations by CMS will provide the information necessary to further evaluate the President's vaccine mandate for healthcare settings, and we will continue to monitor and provide information to outstanding questions as the information is released.

Contact us

If you have additional questions regarding measures to consider regarding the vaccine mandate imposed on healthcare workers in your healthcare facility or system, contact Tom Godar, Barb Grandjean, Brian Hendrix, Tom O'Day or your Husch Blackwell attorney.

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Other offerings

To assist with the preparation and implementation of vaccine policies, Husch Blackwell's COVID-19 Vaccine Policy Generator for Employers is an affordable tool that helps companies of all sizes quickly prepare, customize and implement workplace policies related to COVID-19 vaccines that are compliant with federal, state and local law.

We offered a webinar discussing legal considerations and the future of vaccine mandates. You can register for the on-demand recording for more information on this topic.

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