

How Health Care Cos. Can Untangle Web Of Vaccine Mandates

By **Craig Leen, Sarah Carlins and Erinn Rigney** (October 13, 2021)

Since President Joe Biden's announcement of multiple vaccine mandates in September, health care employers have been scrambling to determine how these overlapping requirements will affect their operations.

Although the focus of these pending mandates has been on larger employers, many smaller employers may be subject to a vaccination requirement in their roles as federal contractors and subcontractors, or as recipients of Medicare or Medicaid funding.

Indeed, health care employers are in a uniquely challenging position, as health care is the only industry already subject to an Occupational Safety and Health Administration emergency temporary standard addressing COVID-19.[1]

Now, under the newly announced mandates, the health care industry will be subject to an additional OSHA emergency temporary standard[2] for companies with 100 or more employees, requiring vaccinations with a testing opt-out; a new Centers for Medicare & Medicaid Services interim final rule requiring vaccinations with no testing opt-out; and a new federal contractor mandate requiring vaccinations with no testing opt-out.

Complicating matters further, because of increased demand for health care services related to the pandemic, the health care industry can hardly afford to lose employees who do not want to be vaccinated. Additionally, employers in the industry will need to process and consider the many requests for religious and disability accommodations likely to be submitted.

While the industry has been left in limbo, anxiously awaiting further guidance from various governmental agencies, there are a number of steps health care employers can take to prepare. This article will help health care employers do so by explaining the interaction between the applicable standards and providing practical suggestions for creating a plan.

CMS Interim Final Rule

Biden's plan expands on the administration's prior Aug. 18 announcement that the U.S. Department of Health and Human Services would issue new regulations requiring vaccination for all nursing home staff as a condition of participating in Medicare and Medicaid.[3]

As HHS had yet to issue those regulations when Biden made his most recent announcements about vaccination mandates, it is expected that the CMS interim final rule will require both nursing home staff and employees of all health care facilities that receive funds from Medicare and Medicaid to be fully vaccinated.

The CMS interim final rule will thus expand the previously announced nursing home



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vaccination mandate to many additional health care facilities in the U.S., and will apply to nursing home staff as well as staff in hospitals and other CMS-regulated settings, including clinical staff, individuals providing services under arrangements,[4] volunteers, and staff not involved in direct patient, resident or client care.[5]

Although some states have begun to adopt vaccination mandates for the health care industry, the CMS interim final rule will develop a uniform standard across all covered entities. The CMS interim final rule is expected to be issued this month.

Scope of Coverage

Although the guidance provided by the Biden administration specifies that the definition of "facility" will include hospitals, dialysis facilities, ambulatory surgery centers and home health agencies, it also states that it is not limited only to these settings.[6]

Given that CMS defines the term "facility" broadly, any medical provider that is also a Medicare and Medicaid recipient will likely be included in the scope of the mandates.[7]

In addition, the guidance will apply even to individuals not involved in direct patient care.

This new action will protect patients of 50,000 providers and over 17 million health care workers in facilities that receive Medicare and Medicaid funding.[8]

Interim Final Rule Process

Generally, a federal agency such as CMS begins the rulemaking process[9] by publishing a notice of proposed rulemaking, which notifies stakeholders of the agency's intent to make a rule on a particular issue.

The proposed rule is published in the Federal Register, and the public may submit comments and questions pertaining to the proposed rule. The agency uses this initial feedback to revise and finalize the final rule.

However, agencies may sometimes skip this notice and comment period and proceed to issuing an interim final rule when the agency has "'good cause' to find that the notice-and-comment process would be impracticable, unnecessary, or contrary to the public interest," as noted by a rulemaking process guide published by the Office of the Federal Register.[10]

An interim final rule goes into effect immediately upon publication. The public may still comment on an interim final rule for a period of time after publication, and the agency may alter the rule if warranted by stakeholder input, and then publish the revised final rule in the Federal Register.

Although the CMS interim final rule will focus specifically on a vaccination mandate for health care entities, OSHA's prior health care temporary standard includes some requirements related to the COVID-19 vaccine, and it exempts certain workplaces from coverage if the workforce is fully vaccinated.

Specifically, certain well-defined hospital ambulatory care settings, as well as home health care settings where all employees are fully vaccinated, are not required to comply with OSHA's health care temporary standard so long as all nonemployees are screened prior to entry, and people with suspected or confirmed COVID-19 are not present.[11]

Therefore, once the CMS interim final rule is issued, many more health care settings may be exempted from coverage under the health care temporary standard by achieving a fully vaccinated workforce.

Additionally, once a covered health care employer complies with the CMS interim final rule, it may lessen the financial impact of the medical removal protection benefits[12] employers are obligated to provide, since fully vaccinated, asymptomatic workers are not required to quarantine following workplace exposure.

Finally, though not a specific vaccination mandate, the health care temporary standard does direct covered entities to provide time off for employees to obtain and recover from the COVID-19 vaccine.[13] Employers covered by both OSHA's health care temporary standard and the CMS interim final rule will need to ensure employees are provided the requisite paid leave in order to receive and recover from the vaccine, including booster shots.

Health care employers with 100 or more employees may also be subject to OSHA's temporary standard for large employers, and will need to comply with those regulations as well.

The CMS interim final rule will likely be similar to the federal contractor mandate in that it will probably not provide for an optional testing requirement. Thus, covered employers will likely need to implement a mandatory vaccination program, with weekly testing, at minimum, for those with approved accommodations.

Though there is currently a lack of clarity as to the logistical aspects of OSHA's temporary standard for large employers, especially regarding the testing mandate, health care employers that comply with the CMS interim final rule will likely satisfy their workplace safety obligations under the new standard.

Potential for Multiple Regulations to Apply

As noted above, several agencies will likely pass regulations and guidance regarding vaccine mandates in the upcoming weeks, and the Safer Federal Workforce Task Force[14] has already done so for the federal contractor mandate.

Health care employers should expect to be subject to more than one set of rules, with guidance coming from various agencies.

They must also be aware of whether their state or municipality has implemented vaccination mandates applicable to their workforces. Several states have already proposed or enacted such mandates with regard to health care employees.

Staffing Considerations

As widespread vaccine skepticism still exists, employers may face staffing shortages if employees refuse vaccinations for nonprotected reasons or leave for positions at companies that fall outside the definition of covered facilities.

Though the expansion of the CMS interim final rule from nursing homes to most health care settings may complicate a health care worker's ability to transition to a noncovered setting in an effort to avoid the vaccination mandate, some percentage of employees may simply quit rather than comply with the requirements.

Health care employers in particular can expect to face staffing shortages as a result.

While an entity may thus think that noncompliance with the CMS interim final rule may alleviate the burden of too few staff, the penalty associated with ignoring the mandate would be hefty. It is anticipated that sanctions for noncompliance would be similar to those associated with any other violation of CMS conditions of participation, up to and including termination of participation with Medicare and Medicaid, in addition to potential fines related to violation of OSHA's temporary standard for large employers.

Addressing Accommodations

Employers should also ensure their human resources departments are prepared to process increased numbers of accommodation requests related to the CMS interim final rule, OSHA's temporary standard for large employers and contractor vaccine mandates.

The administration has indicated in guidance that accommodation requests based on disability or medical reasons, as well as accommodations based on sincerely held religious beliefs, must be considered consistent with the Americans with Disabilities Act, Title VII of the Civil Rights Act, the Rehabilitation Act and a 1965 executive order on federal contractor equal employment opportunity[15] as part of compliance with the various mandates.

The Office of Federal Contract Compliance Programs, which regulates many health care organizations that are federal contractors, has published guidance[16] recommending that companies have centralized accommodation systems, grant requested accommodations promptly where a basis is shown, and consider alternative accommodations that pose less burden prior to denying an accommodation request that may cause an undue hardship.

The U.S. Equal Employment Opportunity Commission, which enforces anti-discrimination laws related to accommodations, outlines similar requirements in its guidance[17] related to the COVID-19 vaccination, which provides examples of accommodations and other best practices.[18]

Though health care organizations are more likely to have addressed the accommodation process as it relates to a vaccination program before — such as with influenza vaccines — the COVID-19 vaccine and associated requisite mandates present unique legal and practical considerations.

Therefore, health care companies must ensure that necessary personnel and infrastructure are in place to manage a potentially high volume of accommodation requests.

Preparation is Key

Ultimately, the best defense for health care organizations is to be proactive in establishing a compliance program.

As an initial step, employers should determine which portions of their workforce are subject to the different vaccine mandates, and then determine a process for ensuring all employees in this group are fully vaccinated by the compliance deadline.

Additionally, covered employers should inform employees of the accommodation process and seek to review and respond to accommodation requests promptly.

This will ensure that all employees subject to the vaccination mandate are either fully

vaccinated, or have been granted an accommodation and are complying with the requirements of the accommodation, such as testing and masking, or potentially telework when the deadline for compliance arrives.

Finally, employers should maintain detailed records as to proof of vaccination and accommodations, keeping in mind privacy obligations under federal, state and local law.

Because of the complexity of the various vaccination mandate requirements, even if a federal agency or regulator ultimately has concerns with how a health care entity implements the CMS interim final rule, OSHA's temporary standard for large employers and/or contractor vaccine mandates, they are much more likely to provide compliance assistance or impose limited sanctions if they believe the entity has acted in good faith in accordance with an established and consistently applied plan.

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[1] See K&L Gates LLP June 11, 2021 Legal Alert, "COVID-19: OSHA Opts To Limit Covid-19 Emergency Temporary Standard To Certain Healthcare Employers" (<https://www.klgates.com/COVID-19-OSHA-Opts-to-Limit-COVID-19-Emergency-Temporary-Standard-to-Certain-Healthcare-Employers-6-11-2021>).

[2] See K&L Gates LLP 10 September 2021 Legal Alert, "COVID-19: President Biden Targets Private Employers and Federal Employees and Contractors In His "Path Out Of The Pandemic" (<https://www.klgates.com/COVID-19-President-Biden-Targets-Private-Employers-and-Federal-Employees-and-Contractors-in-His-Path-out-of-the-Pandemic-9-10-2021>).

[3] See <https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/18/fact-sheet-president-biden-to-announce-new-actions-to-protect-americans-from-covid-19-and-help-state-and-local-leaders-fight-the-virus/>.

[4] This includes services performed by an entity other than the entity that submits the claim.

[5] <https://www.whitehouse.gov/covidplan/> (Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings).

[6] Ibid.

[7] <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/QMY-Facilities>.

[8] See *supra*, note 4.

[9] https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

[10] *Id.* at 8.

[11] See 29 § C.F.R. 1910.502(a)(2)(iv)-(v).

[12] See 29 § C.F.R. 1910.502(l)(5).

[13] See 29 § C.F.R. 1910.502(m).

[14] The President's executive orders provided for additional subregulatory guidance from the Safer Federal Workforce Task Force, which may potentially be utilized to impose additional obligations on contractors and health care facilities.

[15] Executive Order 11246.

[16] https://www.saferfederalworkforce.gov/downloads/Draft%20contractor%20guidance%20doc_20210922.pdf.

[17] [https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=.](https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=)

[18] See, Equal Employment Opportunity Commission, "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws" (May 28, 2021).