

CMS Vaccine Rules Could Create FCA Risks For Cos.

By **Andrew O'Connor, Mark Gaioni and Coleman Gay** (November 18, 2021)

On Nov. 5, the Centers for Medicare & Medicaid Services published an interim final rule requiring COVID-19 vaccinations for staff at health care providers that participate in Medicare and Medicaid.[1]

Like the Occupational Safety and Health Administration and federal contractor mandates before it, the interim rule has already drawn legal challenges seeking to block its implementation.[2]

While those cases proceed, however, the estimated 76,000 health care providers covered by the interim rule must consider how to design and implement plans to ensure the vaccination of over 17 million health care workers across the country.[3]

In doing so, providers should consider not only the risk of direct enforcement of the rule, but also the risk of qui tam lawsuits under the False Claims Act. While CMS may exercise its discretion prudently, individual employees and professional relators may look to shortfalls in this rapidly developing area to pursue treble damages and civil penalties under the FCA.

Below we offer a brief overview of the interim rule, discuss its potential interaction with the FCA, and suggest steps that health care providers can take now to mitigate their risk.

The Interim Rule

Under the interim rule, covered facilities must implement policies and procedures to ensure that all staff are vaccinated for COVID-19. The rule covers not only staff who perform their work duties at a covered facility's site of care, but also staff who have the potential to have contact with patients or on-site workers.

The interim rule does not apply to staff who perform their work 100% remotely, staff who perform their duties exclusively off-site, or individuals who infrequently provide ad hoc services unrelated to health care.

CMS announced that covered facilities should ensure vaccination in two phases:

- In Phase 1, providers must develop policies and procedures to ensure that, by Dec. 6, affected staff will have received the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine before providing any care or other services for a covered facility.
- In Phase 2, effective Jan. 4, 2022, providers must ensure that all staff subject to the rule are fully vaccinated for COVID-19, except for those who have been granted exemptions or who have a documented medical condition justifying nonvaccination.



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Certain allergies, recognized medical conditions, or religious beliefs, observances or practices may provide grounds for exemption.

CMS' rule comes on the heels of two other federal vaccine mandates. OSHA recently issued an emergency temporary standard applying to employers with 100 or more workers.[4] The president also issued an executive order imposing vaccination requirements for federal contractors.[5] According to CMS, its rule takes "priority above other federal vaccination requirements,"[6] though covered facilities may be subject to additional state and local mandates, as well.[7]

CMS announced that it will issue interpretive guidelines describing its plan for enforcement of the interim rule, but its initial announcement suggests that state survey agencies may be primarily responsible for ensuring compliance.[8]

State survey agencies may review covered facilities' implementation of vaccination policies and procedures, examine staff vaccination lists, and conduct interviews with staff to verify their vaccination status.[9]

According to CMS, covered facilities cited for noncompliance may be subject to sanctions including civil money penalties, denial of payment for new admissions, or termination of the Medicare or Medicaid provider agreement.[10]

Potential FCA Risk

As providers race to draft policies, classify workers and administer vaccinations, they should also consider another risk: potential FCA suits.

While CMS has indicated its willingness to work collaboratively with providers before taking enforcement action,[11] U.S. attorney's offices and private qui tam relators suing in the name of the U.S. may be more aggressive. The risk of whistleblower actions may be particularly acute given reports of disaffected health care workers worn down by the pandemic.[12]

Although the FCA is not a vehicle for addressing garden-variety regulatory violations,[13] qui tam relators — private whistleblowers entitled to a share of the money they recover on behalf of the U.S. — routinely pursue FCA cases on the basis of alleged regulatory shortfalls.

Under the so-called false certification theory, relators argue that a provider's claims for reimbursement certify, expressly or impliedly, that the provider is in compliance with applicable CMS rules. If a provider is out of compliance and still submits the claim, the theory goes, that claim for reimbursement may be false or fraudulent.[14]

Relators pressing a false certification argument based on alleged violations of the interim rule would face significant hurdles.

For example, relators would need to prove that the covered facility's noncompliance was material to CMS' decision to pay for services actually rendered and that the facility had the requisite state of mind required by the FCA. But that may not stop relators from filing a suit seeking treble damages and hefty civil penalties.

The takeaway: Noncompliance with the interim rule has the potential to generate risk, even absent immediate enforcement attention from CMS.

Steps Health Care Providers Can Take to Mitigate FCA Risk

Given the sweeping requirements and fast-approaching deadlines described above, providers have their work cut out for them to quickly implement the interim rule. While no policy can entirely forestall FCA suits, there are steps that providers can take to reduce the risk of litigation and best position themselves for success if they are sued.

Ensure that policies and decision making are consistent and well documented.

Providers will face an array of line-drawing and classification challenges as they sort out which federal and state vaccination mandates apply to which employees. At the same time, they can expect to be inundated with exemption requests from employees who are likely to be confused about differing vaccination and testing requirements.

Clear policies, applied consistently, with thorough documentation will help guard against future FCA challenges. Providers who can show that they made reasoned decisions based on good faith interpretations of the rules will be better positioned to establish that they did not act with the state of mind the FCA requires.

Be transparent with regulators.

Providers should consider raising questions and implementation challenges with regulators and should be transparent during any audits or inspection. Such transparency will head off any argument the government was misled, and the government's continued payment would be very strong evidence that any issues were not material to the reimbursement decisions being challenged.[15]

Foster an environment that encourages employees to raise concerns.

Providers should take steps to encourage any staff who detect noncompliance to raise their concerns through internal compliance hotlines or other channels. Having effective internal systems to ensure compliance allows providers to remediate any deficiencies directly and reduces the likelihood that staff will turn to outside mechanisms — such as a qui tam lawsuit — to address concerns.

Make good faith efforts.

Above all, providers should make good faith efforts to comply with the interim rule. Accidental noncompliance and reasonable mistakes are generally not actionable under the FCA. While good faith is no guarantee against whistleblower claims being filed, providers who can show genuine efforts to comply will be better positioned to defend those suits.

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[1] CMS Interim Final Rule, 86 Fed. Reg. 61,555, 61,555-61,627 (Nov. 5, 2021).

[2] On November 10, 2021, ten state attorneys general filed a lawsuit in the federal district court for the Eastern District of Missouri seeking an order declaring the rule unlawful under the Administrative Procedure Act (APA).

[3] Press Release, CMS, Biden-Harris Administration Issues Emergency Regulation Requiring COVID-19 Vaccination for Health Care Workers (Nov. 4, 2021), <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care>.

[4] On November 6, 2021, the Fifth Circuit issued an order granting an emergency motion to stay the OSHA emergency temporary standard pending expedited judicial review.

[5] The Executive Order applies to federal contractors and subcontractors who enter an agreement, or an extension of existing agreement, with the federal government on or after October 15, 2021. It requires federal agencies to ensure, "to the extent permitted by law," that contracts require covered entities to comply with guidance published by the Safer Federal Workforce Task Force, which includes a vaccination mandate. Executive Order, President Biden, Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors (Sept. 9, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/>.

[6] If multiple such rules apply to a healthcare provider, CMS interpretive guidance states that the Interim Rule "takes priority above other federal vaccination requirements" and that healthcare providers should "look to those requirements first." FAQ Guidance, CMS, CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule, <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>.

[7] See, e.g., Press Release, California Dep't of Public Health, California Implements First in the Nation Requirement that Workers in Health Care Settings be Fully Vaccinated (Aug. 5, 2021), <https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-242.aspx> (requiring healthcare workers in certain care settings to be fully vaccinated by Sept. 30, 2021); Executive Order, State of Illinois, Executive Order 2021-27 (Oct. 15, 2021), <https://www.illinois.gov/content/dam/soi/en/web/illinois/documents/government/executive-order-2021-27.pdf> (requiring "all healthcare workers" to be fully vaccinated by Nov. 30, 2021 or else submit to weekly testing); Public Order, City and County of San Francisco, Order of the Health Officer No. C19-07y (updated Oct. 13, 2021), <https://www.sfdph.org/dph/alerts/files/C19-07-Safer-Return-Together-Health-Order.pdf> (requiring health care workers in certain settings to be fully vaccinated by Sept. 30, 2021).

[8] Press Release, CMS, *supra* note 3.

[9] Interim Final Rule, 86 Fed. Reg. 61,555 at 61,574.

[10] *Id.* In a Frequently Asked Question (FAQ) guidance published alongside the rule, CMS stated that its goal is to bring covered facilities into compliance with the Interim Rule. Termination would generally occur only after providing a covered facility with an opportunity to make corrections and come into compliance. FAQ Guidance, CMS, *supra* note 6; see also Press Release, CMS, *supra* note 3.

[11] See FAQ Guidance, CMS, *supra* note 6; Press Release, CMS, *supra* note 3.

[12] See, e.g., Andrew Jacobs, Frontline Health Care Workers Aren't Feeling the 'Summer of Joy', *New York Times* (July 1, 2021), <https://www.nytimes.com/2021/07/01/health/covid-nurses-doctors-burnout.html>.

[13] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016).

[14] See *Escobar*, 135 S. Ct. at 1995.

[15] See *id.* at 2003.