



Donald A. Balasa, JD, MBA
AAMA CEO and Legal Counsel

How Will Medical Assistants Be Impacted by the CMS COVID-19 Vaccination Rule?

Several lawsuits challenging the Centers for Medicare & Medicaid Services (CMS) Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule and other federal regulations discussed in this article are being litigated as of the date of this article's publication. The outcomes of these lawsuits will determine the enforceability and effects of the various federal COVID-19 vaccination rules. Therefore, the verbs in this article are in the future tense.

On November 5, 2021, the CMS issued its interim final rule with comment period titled “Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination”¹ (hereafter referred to as “CMS vaccination rule” or “IFC”), which requires staff of Medicare- or Medicaid-certified providers and suppliers to be vaccinated against COVID-19. There has been considerable confusion and misinformation about whether, and how, this IFC and other federal vaccination rules will affect medical assistants. The purpose of this article is to explain the provisions of this IFC and dispel any uncertainty about the applicability of federal vaccination laws to medical assistants.

What Is the Scope of the Vaccination Rule?

The United States Congress has given the CMS authority over many, but not all, health care providers and suppliers. In a frequently

asked questions² (FAQs) document for its vaccination rule, CMS explains the scope of its rule as follows:

The staff vaccination requirements apply to Medicare- and Medicaid-certified provider and supplier types (collectively, “facilities”) that are regulated under the Medicare health and safety standards known as Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements. Facilities are required to have a process or policy in place ensuring that all applicable staff are vaccinated against COVID-19.²

The following is a non-exhaustive list of Medicare- and Medicaid-certified provider and supplier types²:

- Ambulatory surgical centers
- Federally qualified health centers
- Home health agencies
- Hospices
- Long-term care facilities, including skilled nursing facilities
- Rural health clinics

Which Medical Assistants Are and Are Not Covered by the CMS Vaccination Rule?

Medical assistants working in Medicare- or Medicaid-certified providers and suppliers (such as those listed in the previous section) are required to meet the requirements of the CMS vaccination rule. Medical assistants who do not work in CMS-certified providers and suppliers are not covered by the CMS vaccination rule. However, as explained below, medical assistants may be required to be vaccinated under other federal regulations. Note the following from the interim final rule with comment period:

This IFC directly applies only to the Medicare- and Medicaid-certified providers and suppliers. ... *It does not directly apply to other health care entities, such as physician offices, that are not regulated by CMS [emphasis added].* Most states have separate licensing requirements for health care staff and health care providers that would be applicable to physician office staff and other staff in small health care entities that are not subject to vaccination requirements under this IFC.¹

Why Does the CMS Vaccination Rule Not Cover Physician Practices and Other Settings?

This important question is answered in the CMS FAQs document:

CMS is using the authority established by Congress under the Social Security Act to regulate Medicare- and Medicaid-certified health facilities. Sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services general authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged. ... This authority does not extend to certain facilities nor independent physicians/clinicians.²

Are Some Medical Assistants Required to be Vaccinated under Other Federal Regulations?

Medical assistants not covered by the CMS vaccination rule may be covered by other federal regulations—such as the executive order on COVID-19 safety protocols for federal contractors.³

Increasing numbers of physician practices and clinics are being purchased by hospitals and large health systems, some of which may employ hundreds or even thousands of staff—including medical assistants. Medical assistants working for employers with more than 100 staffers may be required to be vaccinated by the Occupational Safety and Health Administration (OSHA) COVID-19 Healthcare Emergency Temporary Standard.

Are There Exemptions from the Vaccination Requirement of the CMS Vaccination Rule?

As is the case with other federal COVID-19 vaccination programs, the CMS vaccination rule allows for legitimate medical and religious exemptions. Exemptions must be supported by the appropriate documentation. A religious exemption must be based on sincerely held religious beliefs, observances, or practices.

Does the CMS Vaccination Rule Allow Staff to Opt Out of the Vaccination Requirement?

Unlike the OSHA COVID-19 Healthcare Emergency Temporary Standard, the CMS vaccination rule does not allow unvaccinated staff to choose the option of periodic COVID-19 testing and practicing protective measures such as physical distancing and mask wearing.

How Can the CMS Vaccination Rule Affect Externing Medical Assisting Students?

If an externship or practicum site for a medical assisting academic program is subject to the CMS vaccination rule (or another federal or state vaccination rule), the externship site is required to ensure that externing students are vaccinated (or are granted a medical or religious exemption). A CMS FAQ directly addresses this scenario:

This vaccination requirement applies to eligible staff working at almost all CMS-certified facilities that participate in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment, or other services for the facility and/or its patients. This includes facility employees, licensed practitioners, *students, trainees, and volunteers* [emphasis added].²

If the CMS Vaccination Rule Conflicts with the Laws of the State in Which a Medical Assistant Is Working, Which Law Must Be Followed?

One of the legal challenges to the CMS vaccination rule (and the other federal vaccination laws) is whether they usurp the constitutional authority of states to pass laws to protect the health, safety, and welfare of their residents. However, if the CMS vaccination rule is upheld by the federal courts (probably the United States Supreme Court), the Supremacy Clause of the United States Constitution provides that federal statutes are the highest law of the land and supersede any state laws.

OSHA COVID-19 Healthcare Emergency Temporary Standard

The requirements of the OSHA COVID-19 Healthcare Emergency Temporary Standard are different in some respects from those of the CMS vaccination rule. A description of these differences is beyond the scope of this article. However, feel free to email me at DBalasa@aama-ntl.org with questions.

Conclusion

Medical assistants should not assume that—because they work in a physician practice or outpatient clinic and are not covered by the CMS vaccination rule—they need not be mindful of any federal vaccination requirements. With increasing numbers of medical assistants being employed by large health systems with more than 100 employees, medical assistants might be required to be vaccinated under the OSHA COVID-19 Healthcare Emergency Temporary Standard. ♦

Questions about COVID-19 vaccination requirements under one of the federal regulations should be directed to AAMA CEO and Legal Counsel Donald A. Balasa, JD, MBA, at DBalasa@aama-ntl.org.

References

1. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination. *Fed Regist.* 2021;86(212):61555-61556. To be codified 42 CFR §416, 418, 441, et al. Accessed December 15, 2021. <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf>
2. Centers for Medicare & Medicaid Services. *CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule FAQs*. December 2, 2021. Accessed December 15, 2021. <https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf>
3. Executive order on ensuring adequate COVID safety protocols for federal contractors. The White House. September 9, 2021. Accessed December 15, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/>