

PATIENT SAFETY & RISK SOLUTIONS

Frequently Asked Questions on COVID-19 Vaccination

In preparation for administering the coronavirus disease 2019 (COVID-19) vaccines in healthcare settings, we have developed some frequently asked questions (FAQs) and answers to assist healthcare providers. Also included are many links to online resources to further clarify and elaborate on specific elements of the COVID-19 vaccination.

Q: What precautions should be taken when administering the COVID-19 vaccine in the healthcare setting?

A: As with any vaccine, care should be taken prior to administration of the COVID-19 vaccine to assess for appropriateness and possible contraindications to inoculation. Monitoring for side effects should also occur.

The Centers for Disease Control and Prevention (CDC) has provided recommendations regarding the amount of time patients should be monitored in the office given their particular comorbidities. CDC's Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States discusses in detail the clinical considerations that should be reviewed prior to administration of the COVID-19 vaccine. A review of the monitoring time that should be incorporated into the visit given the patient's history of allergies to past vaccines or other vaccine components is included in Appendix B of that online resource.

Q: Should I have my patients sign a consent form before I administer the COVID-19 vaccine to them?

A: No federal requirement for informed consent related to immunizations of any kind exists. Some states have informed consent laws covering either procedural requirements (e.g., whether the patient's consent can be verbal or must be written) or substantive requirements

(e.g., types of information required). Check your state's medical consent law to determine whether any specific informed consent requirements relating to immunizations exist.

Both the Pfizer and the Moderna vaccines are available for distribution under an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). FDA has published two fact sheets that describe the risks and benefits of getting the COVID-19 vaccine:

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older
- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

These fact sheets are *not* to be used as informed consent forms, but they can assist with the informed consent process as long as they comply with appropriate state laws. They also contain information that may be useful to the patient later, such as what to do in case of an adverse reaction.

Q: What should I do if a patient does not return for the second dose of the COVID-19 vaccine?

A: If a patient does not return for the second dose of the vaccine, you should attempt to contact the patient and determine the reason. It may be a practical reason, such as the patient's work schedule, so arrange alternative times to ensure the patient's compliance.

If a patient refuses the second dose because of myths regarding the vaccine, re-educate the patient on the vaccine's safety, the importance of taking the second dose to complete the process, and the possible consequences of not doing so.

If the patient continues to refuse a second dose or you are unable to contact him or her, send a letter to the patient's home outlining the importance of receiving the second dose of the vaccine and the possible consequences of not doing so. Consider sending the letter via

certified/registered mail as well as routine postal delivery, and retain a copy of the letter in the patient's health record.

Additionally, be sure to document the dates and times of all attempts to contact the patient and any patient responses in the patient's health record. For further information on addressing a patient's hesitancy to take the vaccine, refer to MedPro Group's *Eight Tips for Addressing COVID-19 Vaccine Hesitancy Among Patients*.

Q: Does my malpractice insurance cover administration of the COVID-19 vaccines?

A: Yes, MedPro Group will pay claims that an insured becomes legally obligated to pay, subject to all the terms, conditions, limits, and exclusions described throughout the policy. CDC's Provider Agreement requires that the provider keep a health record, submit vaccine administration data, store and handle the vaccine in compliance with the package insert, report adverse events to the Vaccine Adverse Event Reporting System (VAERS), and provide a vaccination card to recipients. Compliance with the Provider Agreement will significantly reduce exposure to allegations of negligence.

To assist you in staying current with the CDC and state guidelines, please consult the online resource below:

• CDC COVID-19 Vaccination Program Provider Agreement & Profile Addendum

Q: Can I require employees to receive a COVID-19 vaccine?

A: No federal or state mandates for COVID-19 vaccinations exist. However, healthcare employers may choose to make this vaccination a condition of employment.

Mandatory COVID-19 vaccination programs and requirements vary from state to state. Employers mandating vaccinations must design their policies and processes to comply with any federal, state, and/or local regulations or requirements, and they must also document both informed consent and refusal in an employee's file.

Additionally, the Americans with Disabilities Act mandates that an employer assures that an "employee will not pose a direct threat to the health or safety of individuals in the

workplace."¹ However, if a vaccination requirement screens out an individual with a disability, the employer must show that an unvaccinated employee would pose a direct threat due to a "significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation."²

Clearly, an unvaccinated individual can expose others to the virus. If the direct threat cannot be reduced to an acceptable level, the employer can exclude the employee from physically entering the workplace, but this does not mean the employer may automatically terminate the worker. The employer will need to determine whether any other rights apply under the Equal Employment Opportunity (EEO) laws or other federal, state, and local authorities. For example, if an employer excludes an employee based on an inability to accommodate a request to be exempt from a vaccination requirement, the employee may be entitled to accommodations such as performing the position remotely.

In addition to MedPro Group's COVID-19 Vaccination Resources, you can obtain more information on federal, state, local, and Equal Employment Opportunity Commission (EEOC) guidelines and regulations in the online resources below:

- What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws
- CDC Vaccines & Immunizations: COVID-19 Vaccination

¹ U.S. Equal Employment Opportunity Commission. What you should know about COVID-19 and the ADA, the Rehabilitation Act, and other EEO laws. Retrieved from https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

² Code of Federal Regulations. (2012, July 1). Labor definitions. 29 C.F.R. 1630.2(r). Retrieved from https://www.govinfo.gov/content/pkg/CFR-2012-title29-vol4/xml/CFR-2012-title29-vol4-sec1630-2.xml