MedPro Group
a Berkshire Hathaway company

PATIENT SAFETY & RISK SOLUTIONS

Frequently Asked Questions About COVID-19 Vaccination, Precautions, and Healthcare Operations During the Pandemic

In response to the evolving COVID-19 pandemic and ongoing vaccination administration, we have developed responses to some frequently asked questions (FAQs) about the vaccines and other common concerns from our insureds. These FAQs also provide links to online resources that further clarify and elaborate on specific topics.

Q: Should I have my patients sign a consent form before I administer a 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 related to immunizations exist.

The Pfizer, Moderna, and Janssen/Johnson & Johnson vaccines were authorized under an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and it will now be marketed as Comirnaty (koe-mir'-na-tee) for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under an EUA, including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

The FDA has published fact sheets for recipients and caregivers that describe the risks and benefits of getting the COVID-19 vaccine:

- Pfizer-BioNtech COVID-19 Vaccine Fact Sheet
- Moderna COVID-19 Vaccine Fact Sheet
- Janssen COVID-19 Vaccine Fact Sheet

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/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 receive the vaccine, refer to MedPro Group's article *12 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. The Centers for Disease Control and Prevention's (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 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 employees' files.

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

Q: How can I navigate the changing masks mandates in relation to continuing to require, or not requiring masks, in my healthcare facility?

A: Although policy orders regarding mask mandates are changing, the CDC continues to recommend that individuals wear masks in public settings. CDC's *Guidance for Wearing Masks: Help Slow the Spread of COVID-19* discusses specific mask recommendations.

Employers are required to adhere to OSHA standards to ensure compliance with providing a safe workplace for their employees; therefore, healthcare facilities can require face masks or coverings in an effort to safeguard patients, staff members, and visitors.

Q: What steps can I take if patients refuse to follow COVID-19 prevention strategies and safety precautions at my facility?

A: Insureds can implement various measures to assist with managing COVID-19 safeguards. To proactively prevent issues with patients, develop written policies that outline COVID-19 prevention strategies as well as their rationale. Educate all providers and staff members on these policies and communicate them to patients via your website, social media, portal messaging, and postings in entryways and waiting rooms. Also make patients aware of COVID-19 precautions during appointment scheduling.

If some patients have serious concerns about wearing masks due to health issues, have a healthcare provider speak to them and find possible alternatives (e.g., a face shield or telehealth appointment).

Patients who arrive at your practice and refuse to follow safety precautions — as long as they don't require acute care — should be asked to reschedule their appointments for another time or have a telehealth appointment (if appropriate). Do not argue with patients about the validity of COVID-19 precautions or individual civil liberties and rights. Explain the practice's commitment to safety and policies, and reinforce that they are not negotiable. Consider having designated individuals within the practice communicate with patients who resist policies or become argumentative.

Lastly, all instances of nonadherence to the organization's COVID-19 policies should be documented in patients' health records, including the information communicated to them prior to the appointment, the objectives circumstances of the encounter, and how the situation was resolved. For more detailed information, see MedPro Group's article *Managing Patients Who Refuse to Wear Masks or Adhere to Other COVID-19 Safety Precautions*.

Q: Do I need to continue to use screening forms and document vaccination status for COVID-19?

Screening for COVID-19

A: Providers should continue to screen patients for COVID-19 symptoms. The CDC has not yet recommended a return to pre-pandemic practices and still advises screening and triage for everyone entering a healthcare facility. The CDC also recommends that infection control practices should be maintained, such as wearing masks while indoors (even for fully vaccinated individuals), practicing hand hygiene, and using engineering controls (e.g., plexiglass barriers and placement of chairs at least 6 feet apart).

Until vaccination becomes more widespread — and until more is known about how long vaccine protection lasts and how effective the vaccines are against COVID-19 variants — these safety precautions will remain vital.

For more information, see the following resources:

- Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Documenting vaccination status

For practices administering the COVID-19 vaccines to patients

A: All COVID-19 vaccination providers must document vaccine administration in their internal health record documentation systems within 24 hours of administration. They also must use their best efforts to report vaccination data to the Immunization Information System (IIS) as soon as practicable, but no later than 72 hours after administration. COVID-19 vaccination documentation should be retained as required by applicable state law. For more information, see CDC COVID-19 Vaccination Program Provider Requirements and Support.

For practices not administering the COVID-19 vaccines to patients, or for practices that have patients who receive COVID-19 vaccines elsewhere

A: Vaccination history is one of the elements of a complete patient medical history and physical examination, even if the healthcare provider obtaining the medical history did not administer the vaccines (e.g., vaccines that were administered outside of the United States or by a different provider). Further, documentation regarding a patient's vaccination status may be helpful in guiding diagnosis and treatment if a patient becomes ill after receiving the COVID-19 (or any other) vaccine.

Adverse events that occur after the administration of a vaccine licensed in the United States should be reported to the CDC and FDA using VAERS. VAERS has both mandatory and voluntary reporting requirements for suspected post-vaccination adverse events. Further, healthcare providers and the general public can report an adverse event to VAERS. For these reasons, documentation of COVID-19 vaccination status is recommended, and documentation should include the information in the following sample.

COVID-19 Vaccination Status *Please fill out the form and add your initials in the appropriate box.*	
☐	I have not received any COVID-19 vaccine. _____ *(initials)*
☐	I received the Johnson & Johnson COVID-19 vaccine. _____ *(initials)* Date of vaccine: _____
☐	I received the **first dose only** of the Moderna or Pfizer *(circle which vaccine)* COVID-19 vaccine. _____ *(initials)* Date of vaccine: _____
☐	I received the **first and second doses** of the Moderna or Pfizer *(circle which vaccine)* COVID-19 vaccine. _____ *(initials)* Date of vaccine dose 1: _____ Date of vaccine dose 2: _____
☐	I was vaccinated outside of the United States and received a vaccine not currently authorized in the United States. _____ *(initials)* Name of vaccine: _____ Date of vaccine dose 1: _____ Date of vaccine dose 2 (if applicable): _____

Q: Can I refuse to treat patients who refuse to be vaccinated against COVID-19?

A: Vaccination status isn't a legally protected status like race or religion, and providers generally have the right to treat the patients they wish to treat. However, we urge caution when dismissing patients to avoid allegations of patient abandonment.

When it comes to patients in your practice who have declined to be vaccinated against COVID-19, we recommend the following steps:

- Post signage at your door stating that masks are still required for entrance. You should also include this requirement in your telephone messaging and on your website.
- Continue to follow all CDC and state guidelines regarding infection control in your practice setting.
- Encourage all patients who qualify for a COVID-19 vaccine to receive one. This CDC Resources Page can assist in this endeavor.

- For patients who still refuse to be vaccinated, determine whether telehealth encounters are appropriate based on their needs/conditions.
- If you need to see an unvaccinated patient in your practice setting, take the following steps:
    - When scheduling and confirming the appointment, tell the patient that wearing a mask or other appropriate face covering is required while at the practice.
    - Insist that the patient wear his/her mask. Depending on the patient's needs, a face shield may be an appropriate alternative.
        - ✓ The practice's providers and staff members may also want to consider face shields for close contact, depending on the practice's specialty and services provided.
    - Upon arrival, have the patient check in via telephone rather than in person at the registration desk.
        - ✓ If feasible, have the patient wait in the car until you are ready for the appointment.
    - Have the patient go directly to the exam room rather than a waiting area.
        - ✓ If available, have the patient use a side entrance or an entrance that has less traffic.
    - Wear a mask or face shield during the appointment, and follow all appropriate protocols when providing care to the patient.

Ultimately, if you wish to discharge patients who refuse to be vaccinated, you may do so, subject to the following:

- Advise patients that it is practice policy for all qualified patients to be vaccinated against COVID-19. (**Note:** If this is your practice policy, consider signage and messaging to that effect.)
- Verify that the patient does not have any immediate medical needs and that dismissal would not impact his/her ongoing care based on those needs.

- Determine whether the patient's vaccination refusal is based on a valid vaccine contraindication or genuinely held religious belief. If either is the case, we do not recommend dismissing the patient.
- Follow standard advice regarding the dismissal of a patient. This includes dismissal in writing and at least 30 days of notice (offering to treat in an emergency situation only), so the patient has an opportunity to obtain appropriate care elsewhere.

Q: How should I respond to patients inquiring about providers' or staff members' vaccination status?

A: The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) established standards related to the disclosure of sensitive patient health information. Explain to your patients that you maintain the confidentiality and privacy of patients', providers', and staff members' personal and protected health information, and that HIPAA precludes you from discussing the vaccination status of any person in the office. Additionally, provide patients with reassurance that the practice continues to follow all CDC-recommended screening and infection prevention processes.

Q: What actions should my organization take when certain services cannot be provided due to a COVID-19 surge?

A: Foremost, it is essential to communicate with patients and other providers so they are aware (a) why services are not available, and (b) what alternatives or solutions the provider/organization has put in place to address the unavailability of certain services. Additionally, consider providing the name and business phone number or email address of a contact person in case patients or providers have additional questions.

Finally, documenting changes or variations in care as a result of the COVID-19 pandemic is a crucial risk management strategy. Here are some documentation examples:

- "In response to the COVID-19 surge and increased hospitalizations, we are halting elective procedures on [DATE] to redistribute nursing staff to support other patient care activities."

- "In response to the COVID-19 surge and increased hospitalizations, we have hired [NUMBER] locums providers/agency nurses on [DATES] from [COMPANY] to address staffing shortages."
- "In response to the COVID-19 surge, we stopped offering cardiac catheterization procedures on [DATE], but have an agreement in place with [FACILITY] to provide emergency cardiac catheterizations until we resume this service."
- "In response to the COVID-19 surge and staffing shortages, we decided on [DATE] to allow asymptomatic healthcare providers who have had a higher-risk exposure to SARS-Cov-2, but who are not known to be infected, to shorten their duration of work restriction per the CDC's guidance *Science Brief: Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing*."
- "In response to the recent increase in demand for COVID-19 rapid testing, and the reduced [INVENTORY LEVELS OF TESTING SUPPLIES and/or LEVELS OF STAFF], in-house testing will be limited to emergency department and inpatient care areas as well as for outpatients who are at very high risk. All other COVID-19 tests will be sent to the [HEALTH CENTER or UNIVERSITY HEALTH CENTER] reference laboratory, with results typically available within three (3) business days."

For more information about managing staffing shortages, see the CDC's Strategies to Mitigate Healthcare Personnel Staffing Shortages.

Q: Is it appropriate to provide a patient a letter/documentation to present to his/her employer/school as an exemption from vaccine mandates?

A: Completing a medical exemption note for the COVID -19 vaccine is deemed the provision of patient care and must adhere to all applicable patient care standards.

All providers are expected to give patients appropriate education and guidance about the vaccine that aligns with current CDC guidelines. Very few individuals actually qualify for a medical exemption from the COVID-19 vaccine. Currently, unless a patient is allergic to one of the components of each vaccine, there is no significant reason to exempt a patient.

All currently authorized COVID-19 vaccines **may be administered** to people who have underlying medical conditions; the Advisory Committee on Immunization Practices does not state a product preference. This includes people who have:

- Immunocompromising conditions or who take immunosuppressive medications or therapies
- Autoimmune conditions
- A history of Guillain-Barre syndrome
- A history of Bell's palsy
- A history of dermal filler use

A provider should abstain from furnishing anyone with a medical exemption in the absence of a justified contraindication or based upon information that is known to be inaccurate. Holding a strong opinion against COVID-19 vaccination is not an indication for exemption. A provider is not obligated to provide a medical note of exemption if he/she determines that a patient does not have a justified reason for the exemption. (**Note:** Any misrepresentation of medical information in relation to exemptions may be reported to applicable state professional boards.)

Lastly, many employers/schools are requiring the healthcare professional giving the medical exemption to state the specific reason for the exemption. Most of these entities are requesting that the provider complete an organization-specific form, and these forms generally contain a release for the patient to sign granting permission for this information. If a form does not contain a release from the patient, be sure to have the patient consent to the release of his/her medical information.

For more information, see the following resources:

- Contraindications and Precautions to mRNA COVID-19 Vaccination
- Janssen COVID-19 Vaccine (Johnson & Johnson) Questions
- Moderna COVID-19 Vaccine Questions

- Pfizer-BioNTech COVID-19 Vaccine Questions

Q: What do I need to know as the FDA revokes COVID-19-Related Emergency Use Authorizations?

A: In response to the COVID-19 pandemic, the FDA issued a number of EUAs for vaccines, drug and biological therapeutic products, and medical devices, including ventilators and personal protective equipment. The purpose of the EUAs was to facilitate the availability and use of medical countermeasures needed to combat the pandemic when no adequate or approved alternatives were available. However, "as new evidence emerges about the effectiveness of tests and treatments, and supply chain problems begin to subside,"[3] the FDA has started to revoke some of the EUAs. Providers who continue to use treatments, products, and devices in ways that are no longer approved face professional liability and financial risks, including loss of immunity under federal and state immunity laws.

To address this issue, providers should stay alert to evolving FDA guidance and any changes in EUAs. Providers also should keep track of any treatments, products, and devices that they are using in ways allowable only under emergency authorization. If an EUA is revoked, certain steps should be followed — similar to the actions that would occur with a product recall. The provider (or a designated individual) should (a) remove the affected treatment, product, or device from the inventory and put it in a secure location, (b) document the actions taken and when they were taken, and (c) communicate the change in status as well as the actions taken to all staff members.[4] For more information, see the FDA's Coronavirus Disease 2019 (COVID-19) EUA Information.

Endnotes

[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 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 www.govinfo.gov/content/pkg/CFR-2012-title29-vol4/xml/CFR-2012-title29-vol4-sec1630-2.xml

[3] Brady, M. (2021, August 9). Providers face increased legal risk as FDA ends emergency use. *Modern Healthcare*. Retrieved from www.modernhealthcare.com/safety/providers-face-increased-legal-risk-fda-ends-emergency-use

[4] Ibid.