

COVID-19 Guidance


COVID-19 Vaccine Emergency Use Authorizations and Off-label Prescribing: Considerations for Healthcare Providers

Covid-19 vaccines for various age groups are covered under Emergency Use Authorizations. This guidance provides responses to questions related to whether healthcare providers may prescribe off-label uses of COVID-19 vaccines that have received Emergency Use Authorization but have not yet received a biologics license or other approval from FDA.

Question: May healthcare providers prescribe off-label uses of COVID-19 vaccines that have received Emergency Use Authorization, but have not yet received a biologics license or other approval from FDA?

This question was received in July 2021 and the response was prepared during a time of rapid developments during the month of August, 2021. The following response incorporates legal research, as well as information gleaned from public policy documents posted on the Food and Drug Administration (FDA) and the Center for Disease Control (CDC) websites prior to the approval of the Pfizer Comirnaty vaccine for certain uses on August 23, 2021. Based on this review, it appears that the CDC has not addressed the precise question presented here on its website, although CDC, as the party contracting with vaccine providers, will assess compliance and liability in the first instance and may issue further guidance. CDC information on Covid-19 vaccines can be found [here](#) and CDC's FAQs for Healthcare Professionals can be found [here](#).

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Short Answer: In general, healthcare providers must comply with the terms of any Emergency Use Authorization (EUA) and the CDC COVID-19 Vaccination Program Provider Agreement when prescribing and administering COVID-19 vaccines that have received Emergency Use Authorization, but have not yet received a biologics license from FDA

FDA has issued EUAs authorizing use of COVID-19 vaccines that have not been licensed or approved by FDA according to specified dosing and age limitations.¹ The EUAs include several limitations and restrictions on the distribution and usage of vaccines and require vaccine providers to participate in and comply with the terms of the CDC's COVID-19 Vaccination Program.

Currently, all COVID-19 vaccines authorized for emergency use are owned by the U.S. government and vaccine providers must sign a provider agreement with CDC to receive vaccines under the CDC's COVID-19 Vaccination Program. This agreement includes additional limitations on use and administration of the vaccines and requires compliance with the recommendations and requirements of the EUA, FDA, CDC, the Advisory Committee on Immunization Practices (ACIP), and state and territorial vaccination laws.

Answer:

FDA Does Not Regulate Administration of Vaccines Once Approved

Before a vaccine, or other biological product, can be introduced into interstate commerce in the United States, the FDA must issue a biologics license approving introduction of the vaccine into interstate commerce. 42 USCA § 262(a).

FDA does not regulate the practice of medicine, and under federal law, once a drug is approved by FDA:

doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. This is a widely employed practice known as “off-label” use. Off-label use does not violate federal law or FDA regulations because the FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states.


Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502, 505 (6th Cir. 2006).

Emergency Use Authorization

During a declared public health emergency, the FDA may authorize the “introduction into interstate commerce” of a drug or biological product that has not yet been approved, licensed, or cleared for commercial distribution, including a vaccine that has not yet received a biologics license.² 21 USCA § 360bbb-3. Any such authorization shall identify “each disease or condition that the product may be used to diagnose, prevent or treat within the scope of the authorization.” *Id.* at (d)(1). FDA also establishes conditions on the authorization of use “for a person who carries out an activity for which the authorization is issued” that are necessary or

¹ This analysis was completed prior to the FDA's issuance of a Biological License for the Comirnaty vaccine and has not been updated to assess any EUA that may apply to the Pfizer-BioNTech and Comirnaty COVID-19 Vaccines since the issuance of that license. Additional guidance from FDA and CDC, or analysis from the Network, may be forthcoming.

² “FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564.” See [Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders](#) (January 2017), page 40.



appropriate to protect the public health. *Id.* at (e)(1)(A). Required conditions include, among other things, conditions to ensure that health care professionals administering the product are informed of the emergency authorization, the significant known and potential benefits and risks of the emergency use, and of available alternatives. *Id.* Additional conditions on authorization could include conditions related to how the product is distributed, who may administer the product, and “the circumstances under which[] the product may be administered with respect to such use.” *Id.* at (e)(1)(B). The statute does not appear to authorize administration of an unapproved vaccine for use outside the conditions and circumstances of authorization.

Emergency Use Authorizations for COVID-19 Vaccines


The FDA issued Emergency Use Authorizations (EUA) for three vaccines to be used for “the prevention of COVID-19, as described in the Scope of Authorization section of (the EUA letter) and subject to the terms of th(e) authorization” - the [Pfizer-BioNTech COVID-19 Vaccine](#), the [Moderna COVID-19 Vaccine](#), and the [Janssen³ COVID-19 Vaccine](#).

As of the date of our review, the EUAs for each of the COVID-19 vaccines include limitations on the scope of the authorizations and additional conditions that apply to the manufacturer, distributors, emergency response stakeholders, and vaccination providers. The emergency use of vaccines under each EUA “must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization () and the Conditions of Authorization ().” The EUAs section on the scope of authorization also include product descriptions outlining, among other things, dosage information, providing for two doses of Pfizer-BioNTech COVID-19 Vaccine, two doses of the Moderna COVID-19 Vaccine, and one dose of the Janssen COVID-19 Vaccine. On August 12, 2021, FDA revised the dosing regimen to authorize a third dose of the Pfizer and Moderna vaccines for individuals who have “undergone solid organ transplantation” or “are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.”

The scope of these authorizations includes several limitations, including the following limitations relevant to the requester’s question:

- Pfizer BioNTech, Janssen Biotech, and ModernaTX will supply the vaccines as directed by the U.S. government for use consistent with the terms and conditions of each respective EUA.
- The vaccines may be administered by a vaccination provider without an individual prescription for each recipient.
- The Pfizer-BioNTech COVID-19 Vaccine will be administered by vaccination providers and used only to prevent COVID-19 in individuals ages 12 and older.
- The Moderna COVID-19 Vaccine will be administered by vaccination providers and used only to prevent COVID-19 in individuals ages 18 and older.
- The Janssen COVID-19 Vaccine will be administered by vaccination providers and used only to prevent COVID-19 in individuals ages 18 and older.

³ The Janssen COVID-19 Vaccine is also commonly referred to at the Johnson and Johnson COVID-19 vaccine.



The EUAs for each COVID-19 vaccine also include, among other conditions, the following conditions of authorization relevant to the administration of the vaccine by emergency response stakeholders and vaccination providers:

- Emergency response stakeholders will ensure the distribution and administration of the vaccine is consistent with the EUA and the CDC’s COVID-19 Vaccination Program.
- Vaccination providers will:
 - administer the vaccine in accordance with the authorization,
 - participate in and comply with the terms and training required by CDC’s COVID-19 Vaccination Program,
 - report to the Vaccine Adverse Event Reporting System (VAERS) any vaccine administration errors, whether or not associated with an adverse event, and
 - monitor and comply with requirements concerning reporting of vaccine administration data to CDC.

The “Full Emergency Use Authorization (EUA) Prescribing Information” (also called the Fact Sheet for Healthcare Providers Administering Vaccine)⁴ includes the dosing schedule for each vaccine, notes that immunocompromised persons may have a diminished immune response to the vaccine, and discusses the interchangeability of the vaccines. For the [Moderna](#) and [Pfizer](#) COVID-19 vaccines, the prescribing information indicates that there is no data available on the interchangeability of these vaccines with other COVID-19 vaccines to complete the vaccination series, and that the same vaccine product should be used for first and second doses. The [Janssen COVID-19 vaccine Fact Sheet](#) indicates that there is no data available on the use of the Janssen vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

These fact sheets for the Moderna and Pfizer COVID-19 vaccines were revised on August 12, 2021 to include the following statements about safety and effectiveness of third doses of these vaccines for individuals that have received solid organ transplants.

From an independent report (Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. *N Engl J Med*), safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine have been evaluated in persons that received solid organ transplants. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

Safety and effectiveness of a third dose of the Moderna COVID-19 Vaccine have been tested in persons that received solid organ transplants. The administration of third vaccine doses appears to be only moderately effective in increasing antibody titers, so patients should be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

⁴ This Fact Sheet and the Fact Sheet for Recipients and Care Givers are referred to as “authorized labeling” in the EUA letters of authorization.



The vaccine fact sheets also explain that:

- the vaccines are being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program which healthcare providers must enroll in and comply with, and
- vaccination providers must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS).

The CDC’s COVID-19 Vaccination Program

All [COVID-19 vaccines in the United States have been purchased](#) by the United States Government for administration exclusively by enrolled providers through the CDC COVID-19 Vaccination Program. These vaccines remain U.S. [government property until administered to the vaccination recipient](#).

Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver administer, receive shipments of, or use USG-purchased COVID-19 vaccines. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law.

Under 18 U.S.C § 641, whoever embezzles, steals, or knowingly converts to their use (or the use of another) U.S. Government property can be fined and imprisoned up to 10 years, or up to 1 year if the aggregate value of the property is less than \$1000. Anyone who receives, conceals, or retains the property known to be embezzled, stolen, or converted, with the intent to convert it for use or gain, is also liable.

Organizations that participate in the program must sign the CDC COVID-19 Vaccination Program Provider Agreement, which outlines provider requirements and legal agreements. Participating organizations agree to, among other things:

- administer the COVID-19 vaccines in accordance with all requirements and recommendations of CDC and CDC’s Advisory Committee on Immunization Practices (ACIP);
- comply with the applicable requirements “set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine;” and
- administer the vaccine in compliance with state and territorial vaccination laws.

Non-compliance with the agreement “may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. 1001, 1035, 1347, 1349.”

These laws and associated penalties include:

The False Claims Act. Penalties for violation of the False Claims Act include monetary penalties and treble damages. 31 U.S.C. § 3729.

False Statements. 18 U.S.C. §§ 1001 and 1035 relate to false statements. Under these laws, whoever knowingly and willfully “falsifies, conceals, or covers up by any trick, scheme or device material fact,” “makes any materially false, fictitious, or fraudulent statement or representation” or “makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent

statement or entry” can be fined and/or imprisoned for up to 5 years. [18 U.S.C. § 1001](#) applies broadly, and [18 U.S.C. § 1035](#) relates more specifically to false statements relating to a health care benefit program and false statements made in connection with the delivery of or payment for a health care benefit, item or service. A [health care benefit program is defined](#) as “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.”

Health Care Fraud. Under [18 U.S.C. § 1347](#), whoever knowingly and willfully executes or attempts to execute a scheme to defraud a healthcare benefit program or to falsely or fraudulently obtain any money or property of a health care benefit program may be fined and/or imprisoned for up to 10 years. The term of imprisonment can be extended up to 20 years if the violation results in serious bodily injury, which includes an injury that involves a substantial risk of death, extreme physical pain, protracted and obvious disfigurement, or protected loss or impairment of the function of a bodily member, organ, or mental faculty. The term of imprisonment is capped at life if the violation results in death. Any person who attempts or conspire to commit this offense is subject to the same penalties. 18 U.S.C. § 1349.

The CDC has informally considered several questions which have been raised frequently by vaccination program providers, and we anticipate that additional, more formal guidance may be forthcoming.

1. Non-Interchangeability of Vaccine Doses


According to the CDC’s website [COVID-19 Vaccine FAQs for Healthcare Professionals](#) the COVID-19 vaccines are not interchangeable and there has not been an evaluation of the safety and effectiveness of a mixed-product series. “[E]very effort should be made to determine which vaccine product was administered as the first dose to ensure completion of the vaccine series with the same product,” using the following strategies:

- asking recipients to bring their COVID-19 vaccination card to their appointment for the second dose, and encouraging recipients to make a backup copy,
- encouraging vaccine recipients to enroll in [v-safe](#), of [VaxTextSM](#),
- recording each recipient’s vaccination in the immunization information system (IIS) and the patient’s medical record, and
- scheduling an appointment at the same site for second dose at time of first dose.

However, in exceptional situations a provider can administer any available mRNA vaccine when it cannot be determined what product was used for the first dose. If the patient received an initial mRNA dose, but is unable to complete the series with an mRNA COVID vaccine due to a contraindication, the provider can consider administering a single dose of the Janssen COVID-19 vaccine. See also CDC’s “Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.”

2. Booster Doses

According to CDC’s website, as of the date of this memo, the need for and timing of booster doses has not been established and booster doses are currently [not recommended](#), though additional mRNA doses are recommended for “moderately to severely immunocompromised people after an initial 2-dose primary mRNA vaccine series.” On August 18, 2021, [CDC indicated](#) that they “have developed a plan to begin offering [] booster shots this fall” subject to a FDA determination of the safety and effectiveness of a third dose and ACIP issuing booster dose recommendations.



On August 12, 2021, FDA revised the EUAs for the [Pfizer BioNTech EUA](#) and [ModernaTX EUA](#) vaccines to allow a third dose for certain immunocompromised individuals. The revisions to the Pfizer BioNTech EUA “authorize for emergency use a third dose of the PfizerBioNTech COVID-19 vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.” The revisions to the ModernaTX EUA “authorize for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 28 days following the two-dose regimen of this vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.” While meeting minutes are not yet available on CDC’s website, [ACIP recommended a third mRNA dose for immunocompromised individuals](#) in an August 13, 2021 meeting.

3. Errors and deviations in administration of COVID-19 vaccine

The CDC has issued interim recommendations for [errors and deviations in COVID-19 vaccination administration](#). Errors in administration include any “preventable event that may cause or lead to inappropriate vaccine or patient harm.” Unless otherwise indicated, vaccine providers must report an error to the Vaccine Adverse Event Reporting System (VAERS). The fact sheet includes several relevant examples of errors and deviations that must be reported to VAERS. For example, if an individual under the age of 12 years received an initial dose, the CDC recommends not to provide an additional dose. If an individual between the age of 12-17 years received a Moderna COVID-19 vaccine (which has only been approved for emergency use for individuals 18 years and older) the CDC recommends that the provider may “administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group).” This is the only reference to “off-label” uses of EUA authorized COVID-19 vaccines on the CDC or FDA websites at the time this memo was written.

CDC also recommends specific responses for errors in timing of second doses of the Moderna and Pfizer vaccines; what to do if the incorrect volume or diluent volume is administered; and actions to take if “incorrect mRNA COVID-19 vaccines product [is] administered for second dose in a 2-dose series.” However, this document does not mention scenarios where a third dose is administered or an additional dose of any authorized vaccine is given after a Janssen dose.

PREP Act Coverage and State Law Liability

Providers will also want to discuss with their legal counsel liability limitations such as those included under the PREP Act, and state laws governing the practice of medicine. Additional information on the PREP Act Liability coverage can be found on the Network’s website at: [Federal PREP Act Liability Protections for COVID-19 Vaccination](#).



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This document was developed by Betsy Lawton, JD, Senior Attorney at the Network's Northern Region Office. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

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