Stakeholder COVID-19 Vaccine Emergency Use Authorization (EUA) FAQs

Will a prescription be necessary for a vaccine under an EUA?

As of December 9, 2020, no EUAs have been issued to authorize the use of COVID-19 vaccines. If EUAs are issued for COVID-19 vaccines, it is expected that those vaccines may be administered without the requirement for an individual prescription for each vaccine recipient from an authorized healthcare provider. Under an EUA, FDA has an option to waive prescription requirements, if appropriate, depending on the authorized product specifics, authorized use, and/or emergency circumstances. In addition to an EUA, other legal authorities and/or plans may apply to vaccine administration:

- Legal authorities for relevant emergency response agencies (e.g., state, local, tribal and territorial health departments, healthcare professional licensing boards);
- Standing orders issued by a state health officer or applicable medical control officials or an executive order issued by a governor to authorize certain healthcare providers (e.g., nurses, pharmacists) to administer COVID-19 vaccine;
- State COVID-19 vaccination and emergency response plans; and
- CDC's COVID-19 Vaccination Program.

Does an EUA have any impact on standing orders?

Standing orders are a type of medical order authorized or allowed under state laws. They permit the delegation and delivery of healthcare services through standardized criteria and procedures. Standing orders are one mechanism to enable non-physician healthcare providers (e.g., nurses, pharmacists) to assess and vaccinate persons who meet the criteria for vaccination without requiring a direct, individual order each time.

During emergencies, states might use other legal mechanisms to facilitate vaccine administration, such as executive orders, emergency regulations, or position statements from licensing boards. FDA does not issue standing orders. However, it is expected that EUAs for COVID-19 vaccines would allow flexibility so that states could use their own mechanisms, like standing orders, to authorize appropriate healthcare providers to administer COVID-19 vaccine(s). States should review any applicable authorizations of certain healthcare providers to administer COVID-19 vaccine under the Public Readiness and Emergency Preparedness (PREP) Act Declaration for Medical Countermeasures against COVID-19 (e.g., qualified pharmacy technicians and state-authorized pharmacy interns acting under the supervision of a qualified pharmacist). It is also expected that vaccine administration would be in accordance with the stakeholder's official COVID-19 vaccination and emergency response plans and that vaccination providers would be enrolled in the CDC COVID-19 Vaccination Program.

Statutes and regulations regarding the use of standing orders (or similar mechanisms) vary by state. States should review their statutory and regulatory language to ensure standing orders can cover the administration of an unlicensed vaccine that has been authorized by FDA for emergency use under an EUA. Specifically, states should ensure that state law does not preclude the use of standing orders for an investigational product authorized under an EUA. States should also ensure their state laws permit the administration of COVID-19 vaccines intended to be used under EUAs (i.e., the language of the state's laws is either broad enough to include COVID-19 vaccines or specifically lists the COVID-19 vaccines, depending on how the state's laws are written) and that COVID-19 vaccines are administered within the scope of authorized use under the applicable EUA.

Can a COVID-19 vaccine be administered to populations not included in the authorized use of the vaccine under its EUA?

No. Use of any vaccine in populations outside the scope of its EUA would be an unauthorized use of the vaccine. Each EUA issued by FDA will describe the scope of the vaccine's authorized use, including populations (e.g., age groups) to which the vaccine may be administered. The scope of what is authorized under each EUA will be based on the available safety and efficacy data from populations studied in clinical trials.

In order for liability protections under the Public Readiness and Emergency Preparedness (PREP) Act to apply, the use of the vaccine must be under an appropriate regulatory mechanism (e.g., an EUA, investigational new drug application, or approved biologics license application). Therefore, if a vaccine is authorized for use under an EUA, any use beyond the scope of what is described in the EUA would not be eligible for applicable liability protections under the PREP Act or injury compensation available under the Countermeasures Injury Compensation Program.