

COVID-19 Emergency Use Authorization (EUA) and Vaccine Information Statement (VIS)

The Food and Drug Administration (FDA) indicated it would likely approve a COVID-19 vaccine through a Biologic License Application (BLA) or an Emergency Use Authorization (EUA). Currently, there is no Vaccine Information Statement (VIS) for a COVID-19 vaccine. **When the BLA or EUA becomes available, it must be provided to vaccine recipients until a VIS is generated.**

The purpose of this document is to help providers understand the differences between these documents and when/how they should be provided to patients.

- A **Biologic License Application (BLA)** is approved only if the FDA determines substantial evidence of safety and effectiveness from adequate, controlled trials.
- An **Emergency Use Authorization (EUA)** is used during an emergency to facilitate the availability of unapproved products that diagnose, treat, or prevent serious or life-threatening diseases. The standard for a EUA is the product “might be effective.” EUAs have historically been used to allow the deployment of a medical countermeasure when known potential benefits outweigh known potential risks. The risk and benefit analysis can vary across populations.
- A **Vaccine Information Statement (VIS)** is a document produced by the Centers for Disease Control and Prevention (CDC) that informs vaccine recipients – or their parents or legal representatives – about the benefits and risks of a vaccine they are receiving. A VIS is required by law to be given to vaccine recipients before every vaccine administration.

For more information about the EUA approval process, visit the [FDA website](#).

How/When to give a BLA/EUA/VIS

- Paper copies can be printed and given to patients before vaccination.
- Permanent, laminated office copies may be given to patients to read before vaccination (*Be mindful of COVID-19 cleaning recommendations*).
- Patients may view on a computer monitor or other video display.
- Patients may read on their phone or another digital device by downloading the pdf file.
- Patients may be given a copy during a prior visit or told how to access it through the internet so that they can read it in advance. These patients must still be offered a copy to read during the vaccination visit as a reminder.
- ***Patients must still be offered a copy to take away following vaccination. The patient may decline.***

REMINDER: BLA/EUA/VIS must be given to vaccine recipients at each immunization encounter before administering the immunization.