



## Will you be ready when the COVID-19 vaccines arrive?

December 1, 2020

'Tis the season to be jolly! This holiday season may be merrier if the recently announced COVID-19 vaccination candidates obtain approval and/or authorization for use in preventing COVID-19 by the U.S. Food and Drug Administration (FDA).

Now that two companies have submitted applications to the FDA for approval and/or authorization and there is a real possibility that a COVID-19 vaccine will soon be available for use in the U.S., are you making a list and checking it twice?

On the good list (a.k.a what we know):

- The US Centers for Disease Control and Prevention (CDC) is meeting proactively to provide guidance about allocation of initial supplies of COVID-19 vaccines and priority of administration to high risk and critical populations.
- The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) has meetings set this month to discuss requests for emergency use authorization (EUA) of two COVID-19 vaccination candidates. The VRBPAC provides advice on the safety and effectiveness data submitted in the EUA request which will hopefully expedite the final decision by the FDA on whether to authorize the vaccine for emergency use.
- The American Medical Association worked with the Centers for Medicare and Medicaid Services to publish an [update to the CPT code set](#) to include new COVID-19 vaccine-specific codes. The accepted addition of these codes report COVID-19 vaccines and the immunization administration of such vaccines.
- The Ohio Department of Health (ODH) has an [interim plan](#) for COVID-19 vaccine distribution and administration for the residents of Ohio which includes COVID-19 Vaccination Provider recruitment and enrollment. Other states have similar vaccine distribution and administrative plans.

On the bad list (a.k.a. what we don't know):

- We don't know the FDA requirements for emergency use administration of COVID-19 vaccines; these will be necessary for protocols on storage and handling, as well as prescriber and vaccinator qualifications and training.
- We don't have final information from FDA and CDC regarding relevant contraindications or potential lower efficacy for certain populations. This information will be necessary for providers to counsel patients/recipients.
- Vaccine supply availability is unknown; methodology for actual deployment of vaccinations is also yet to be determined.
- It's unclear whether there will be any additional requirements or conditions issued by the CDC or ODH for COVID-19 vaccine distribution/redistribution and/or administration.

What can be done now?

Health care providers should review their organization's current vaccination policies and consider how a COVID-19 vaccination fits within their policy parameters, including any medical or religious accommodations. Changes to your vaccination policies will require communication and education.

If you have enrolled as a COVID-19 Vaccination Provider:

1. Know the terms and conditions of the vaccine provider agreement as non-compliance of any enrolled COVID-19 vaccination provider may impact fulfillment of COVID-19 vaccine product orders and could result in action by the federal government.
2. Work with your IT department to ensure you have the up-to-date CPT code set and necessary reporting systems needed for COVID-19 vaccine supply tracking, vaccination administration documentation and adverse event reporting.
3. Be prepared for ODH site visits prior to commencing and while administering COVID-19 vaccinations. ODH's interim COVID-19 Vaccination Plan contemplates site visits to verify storage, staffing, testing and training of the required IT systems noted above.

The COVID-19 vaccine process is moving quickly so stay tuned. Happy Holidays and while the merry bells keep ringing, we'll bring vaccine news to you!

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