

Talking Points

Moderna COVID-19 Vaccine EUA Amendments

General

With the FDA's EUA revisions announced April 1, the Moderna vaccine will be available in two different vials by early May: the current Maximum 11 dose vial and a new Maximum 15 dose vial. The vial will remain the same size but will be filled to the higher volume.

- A new NDC has been issued for the larger volume Moderna vial, which has been given a range of 13-15 doses in the EUA.
- Moderna is planning to transition all manufacturing to the new vial during the month of May. During the month, awardees and partners will receive allocations that include quantities of both Moderna vaccine vials. The proportion of existing Moderna NDC/new Moderna NDC in each awardee's and partner's allocation will evolve over the course of the transition period.

Clinical

The Moderna larger volume vial may contain 15 0.5mL doses of vaccine. However, it will not always be possible to extract the 15th dose. This is based on the overfill in the vial and the type of syringes used to administer the vaccine. Therefore, vaccination providers should expect to withdraw 13-15 doses from each vial.

- Each dose must contain 0.5mL of vaccine.
- When the amount of vaccine remaining in the vial is not a complete 0.5mL dose, discard the vial and the residual vaccine regardless of the number of doses withdrawn. Do NOT save vials to combine residual vaccine from more than one vial to get a complete dose. An unextracted 15th dose does NOT count as waste (see wastage table below).
- Vaccination sites should continue to reliably extract 10 doses from the current volume vial and plan to extract 14 doses from the new larger volume vial using the ancillary kit supplies provided.

Ancillary Kits

Ancillary kits will be reconfigured to extract a maximum of 14 doses per vial, plus a 5% surplus to account for damage or wastage.

- Moderna worked closely with CDC and United States Pharmacopeia (USP) to test combinations of available needle and syringe supplies to optimize the number of available doses.
- Results demonstrate that a combination of low dead-volume and non-low dead-volume syringes and needles may be required to consistently extract 11 and 15 doses from both vials addressed in the EUA.
- Ancillary kits for the Moderna large volume vials will be configured to support 14 doses per vial (minimum order: 140 doses). In keeping with the way ordering works today, awardees and partners will place vaccine orders and VTrckS will automatically add the corresponding ancillary kit to match the vaccine that is ordered.
 - USG cannot provide supplies to withdraw a 15th dose. If a provider chooses to withdraw a 15th dose from the vial, USG cannot replace the supplies used or provide additional syringes.

Wastage

- The Wastage Reporting Table provides guidance to determine if a dose should be reported as waste. Wastage does not negatively impact a provider but is simply a means for accounting for inventory.
- Failure to extract a 15th dose does not result in reportable waste.
- Jurisdictions should not report wastage if additional 11th and 15th doses from either vial cannot be extracted (see Wastage Reporting Table).

Allocations/Ordering Caps/Inventory

- The projected allocations data in Tiberius will be updated on April 27, for allocations after the effective date. Over a three-week period, jurisdictions and partners will receive allocations and ordering caps made up of the existing and new Moderna NDCs.
- The new NDC will result in a minimum order and interval of 140 doses. While still available, the existing NDC will continue to have a minimum order and interval of 100 doses.
- During the month of May, providers may receive both Moderna NDC vials. Awardees should plan to transition from both NDCs early in the month to a single NDC for the larger-volume vial by the end of May. Providers should pay careful attention to implementing a “first in/first out” inventory approach to ensure vaccine does not reach expiration. Providers should not use vial volume labeling to assume inventory expiration dates but, instead, should check expiration dates regularly.

Data Systems

We are updating IT systems for both ordering and allocation processes to include the new, larger volume vial.

- CDC and HHS systems will be updated to include the new product by April 25.
- During the week of April 25, jurisdictions and federal partners should plan to update impacted systems to reflect the new NDC.
- Allocations will be made in Tiberius on April 27.
- Immunization information systems should see the first order cap in VTrckS on April 29.
- There will be no interruptions to CDC IT systems during this transition.
- IT systems impacted by this change include:
 - VTrckS
 - New ancillary kit NDC to support administration of 140 doses of vaccine
 - New vaccine NDC with a 140-dose minimum order size and increment
 - NDC crosswalk tables: [IIS](#) | [NDC Crosswalk tables](#) | [Code Sets](#) | [HL7 Data](#) | [Vaccines](#) | [CDC](#)
(During the transition period, awardees and partners will receive allocations of both the current and the new Moderna NDC)
 - Tiberius
 - New NDC with an updated dose count/vial
 - New allocations for the new vaccine NDC
 - VPoP
 - New dose count/vial
 - Update number of doses per package

- There will be no system changes for:
 - VAMS (updated vaccine table will allow users to add new Moderna NDC and log 14 doses per vial for inventory)
 - VaccineFinder (users will be able to log into the portal and add the new Moderna NDC and report 14 doses per vial for inventory)

Storage and Handling

The following updates have been made to the EUA regarding storage and handling of Moderna vaccine.

Frozen Vaccine

- Moderna vials can now be stored frozen between -50° to -15°C (-58° to 5°F). This is an increased range from the original temperatures. This new, wider temperature range is consistent with temperature requirements for other recommended vaccines stored in the freezer.

Refrigerated Vaccine/Unpunctured Vials

- Unchanged: Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours. This is an increase from 12 hours.

Punctured Vials

- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F) for up to 12 hours. Vials should be discarded 12 hours after the first puncture. This is an increase from 6 hours.