

525-535 West Jefferson Street · Springfield, Illinois 62761-0001 · www.dph.illinois.gov

MEMORANDUM

TO: Local Health Department Administrators

All Illinois Vaccine Providers

FROM: IDPH Immunization Section

DATE: August 28, 2025

RE: Immediate Action Required: 2024–2025 COVID-19 Vaccines under Emergency Use

Authorization are No Longer Authorized

2025-2026 COVID-19 Vaccines receive FDA approval

IMMEDIATE ACTION REQUIRED

The U.S. Food and Drug Administration (FDA) has revoked the Emergency Use Authorizations (EUAs) for all 2024–2025 COVID-19 vaccines that were available under EUA as of August 27, 2025. These vaccines are no longer authorized for use and must be removed from your inventory immediately.

ALL 2024-2025 COVID-19 VACCINES ARE NO LONGER AUTHORIZED

Both fully licensed and emergency use authorization COVID-19 vaccines for the 2024-2025 season are no longer authorized.

Furthermore, FDA has revoked all COVID-19 Emergency Use Authorizations (EUAs) for Pfizer-BioNTech, Moderna, and Novavax. Since Pfizer-BioNTech's Comirnaty vaccine was not fully licensed for children 6 months through 4 years of age, only Moderna's Spikevax may be administered to children in this age group.

You must immediately discontinue use of any remaining stock of the 2024-2025 COVID-19 vaccines, as they are no longer authorized for use.

AVOID ADMINISTRATION ERRORS

To minimize the risk of vaccine administration errors, all providers should immediately remove all deauthorized 2024–2025 COVID-19 vaccines from storage, even if they are unexpired.

UPDATE INVENTORIES FOR PUBLICLY FUNDED VACCINES IN I-CARE

Providers enrolled in the IDPH Vaccines for Children (VFC), or Adult Immunization Program (AIP) should:

- Account for all publicly funded doses (VFC/AIP).
- Return remaining stock to CDC's centralized distributor using the standard I-CARE spoiled/expired return process.
- Update I-CARE inventory:
 - o Delete all deauthorized 2024-2025 vaccines from inventory after accounting for doses.
 - Any remaining inventory in I-CARE will be automatically marked as inactive on September 4, 2025.

APPROVAL OF 2025-2026 FORMULATIONS:

On August 27, 2025, FDA approved the following 2025-2026 COVID-19 vaccine formulations:

COMIRNATY:

- 10 mcg formulation for use in individuals 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
- 30 mcg formulation for use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

SPIKEVAX:

- 0.25 mL formulation for individuals 6 months through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
- 0.5 mL formulation for individuals who are 65 years of age and older, or 12 years through 64
 years of age with at least one underlying condition that puts them at high risk for severe
 outcomes from COVID-19.

mNEXSPIKE:

0.2 mL formulation for individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

NUVAXOVID

0.5 mL formulation for individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

UNDERLYING CONDITIONS THAT PUT INDIVIDUALS AT HIGH RISK FOR SEVERE OUTCOMES FROM COVID-19

- Clinicians should refer to CDC's guidance, <u>Underlying Conditions and the Higher Risk for Severe COVID-19</u>, and familiarize themselves with conditions that put individuals at higher risk for severe COVID-19.
- Currently, there are several conditions on the list, including pregnancy and recent pregnancy, mood disorders, disabilities, obesity, current and former smoking, and physical inactivity that may make many individuals eligible for vaccination.

PRIVATELY PURCHASED VACCINE AVAILABILITY

Shipping of 2025–2026 COVID-19 vaccines may begin immediately.

PUBLICLY FUNDED VACCINE ORDERING

 Ordering information will be provided once ACIP issues recommendations and CDC provides endorsement.

RESOURCES

No Longer Authorized Vaccines:

- FDA | Pfizer-BioNTech COVID-19 Vaccine
- FDA | Moderna COVID-19 Vaccine
- FDA | Novavax COVID-19 Vaccine

Currently Licensed Vaccines:

- FDA | COMIRNATY
- FDA | SPIKEVAX
- FDA | MNEXSPIKE
- FDA | NUVAXOVID

CONTACT US FOR MORE INFORMATION

For help, questions or feedback, please contact the IDPH Immunization Section at dph.vaccines@illinois.gov or call 217-785-1455 and select option 2.