





NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Recommend Updated (2024-2025) Respiratory Virus Vaccines

September 3, 2024

Background:

COVID-19 activity has been increasing over the summer, and other respiratory diseases are expected to become more common in the coming months. Vaccines are available for COVID-19, influenza, and RSV. For many of these, vaccination in late summer and early autumn will allow individuals to build immunity in time to prevent and/or reduce severity of these diseases when they are most commonly circulating. Additionally, many of these vaccines have received updated formulations and/or eligibility guidelines.

COVID-19

On August 22, 2024, the FDA approved and granted emergency use authorization (EUA) to the 2024-2025 formulation of both the Moderna COVID-19 and the Pfizer-BioNTech COVID-19 vaccines for everyone 6 months of age and older. On August 30, the FDA granted EUA to the updated 2024-2025 Novavax COVID-19 vaccine. The updated COVID vaccines were also endorsed by the Advisory Committee on Immunization Practices (ACIP) and the CDC.

The 2024-2025 mRNA formulations include a monovalent component that corresponds to the Omicron lineage JN.1 and the KP.2 strain. Novavax includes a monovalent component that corresponds to the Omicron lineage JN.1 strain. The updated vaccines are expected to bolster immunity and produce neutralizing antibodies to current circulating variants.

Previous Vaccine Formulations Are No Longer Authorized

As part of FDA's actions, the 2023–2024 Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States. All 2023-2024 Novavax vaccine has already expired. To minimize the risk of vaccine administration errors, providers should:

- Remove all 2023–2024 mRNA COVID-19 vaccines from storage units immediately, even if they are not expired.
- Return all unused 2023–2024 mRNA COVID-19 vaccines to CDC's centralized distributor using the normal process for returning and return reason as "Spoiled". In the clinical notes, state "COVID-NO LONGER AUTHORIZED FOR USE".

Eligibility for the Updated (2024-2025) COVID Vaccines:

Moderna or Pfizer mRNA vaccine:

- Individuals 5 years of age and older are eligible for a single dose of either the Moderna or Pfizer COVID-19 Vaccine (2024-2025 formulations) if it has been at least two months since the most recent COVID-19 vaccine. This recommendation is regardless of previous vaccination history.
- Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2024–2025 COVID-19 vaccine. Children who have completed an initial series should receive one or two doses of the updated (2024-2025) vaccine (timing and number of doses depends on the previous COVID-19 vaccine received).
- People who are moderately or severely immunocompromised should complete a 3-dose initial series with at least one dose of the 2024–2025 COVID-19 vaccine and may receive 1 or more additional 2024–2025 COVID-19 vaccine doses.
- COVID vaccine can be given at any time during pregnancy. COVID-19 vaccination is recommended for people who are pregnant, trying to get pregnant now, or who might become pregnant in the future, and people who are breastfeeding. Maternal vaccination protects infants younger than age 6 months from severe COVID-19 and hospitalization.

Novavax COVID-19 vaccine:

- Individuals 12 years of age and older who have never been vaccinated with any COVID-19 vaccine should receive two doses of Novavax, adjuvanted (2024-2025 formulation) administered 3 weeks apart.
- Individuals 12 years of age and older who have been vaccinated only with one dose of any Novavax COVID-19 vaccine are eligible to receive one dose of the updated (2024-2025)
 Novavax COVID-19 vaccine administered at least 3 weeks after the previous dose.
- Those 12 years of age and older who have been vaccinated with a prior formula of a COVID-19 vaccine from another manufacturer or with two or more doses of a prior formula of the Novavax COVID-19 vaccine are eligible to receive one dose of the updated (2024-2025)
 Novavax COVID-19 vaccine at least 2 months after the last dose of a COVID-19 vaccine.
- For individuals 12 years of age and older who are moderately to severely immunocompromised, an additional dose of Novavax, adjuvanted (2024-2025) may be administered at least 2 months following the last dose.

Safety Considerations:

- The FDA believes the safety of the updated (2024-2025) vaccines will be consistent with previous vaccine formulations. The updated (2024-2025) vaccines are the same platform as previous formulations, only the strain has changed.
- People, especially males ages 12–39 years, should be made aware of the rare risk of
 myocarditis and pericarditis following receipt of these vaccines; the option for an extended
 interval between doses; and the benefit of COVID-19 vaccination in reducing the risk of severe
 outcomes from COVID-19, including the possibility of cardiac sequelae.





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• The side effect profile of the updated vaccines (2024-2025) appears to be similar to that of the previous formulations.

Influenza

- CDC recommends that everyone 6 months of age and older can receive an influenza vaccine.
- The 2024-2025 influenza vaccine is trivalent. FDA did not recommend the quadrivalent vaccine this season since the B/Yamagata strains have not been detected since March 2020.
- Adults 65 years and older should receive an adjuvant or high-dose influenza vaccine formulation if available but can receive any age-appropriate vaccine if they are unavailable.
- ACIP and CDC do not consider egg allergy of any severity to be a contraindication or a precaution to administration of any influenza vaccine (egg-based or non-egg-based). Safety measures beyond those recommended for receipt of any vaccine are not recommended
- Influenza vaccine is safe in pregnancy and can be given at any time during pregnancy.

Respiratory Syncytial Virus (RSV)

- There are three RSV vaccines licensed by the U.S. Food and Drug Administration for use in adults aged 60 and older in the United States.
 - GSK's AREXVY
 - Moderna's mRESVIA
 - o Pfizer's ABRYSVO
- The RSV vaccine is not currently an annual vaccine, so individuals do not need to receive a dose every season.

In June 2024, the CDC updated recommendations for the RSV vaccines. For adults who did not receive RSV vaccine previously:

- Everyone ages 75 and older should receive the RSV vaccine.
- People ages 60–74 who are at increased risk of severe RSV, meaning they have certain chronic medical conditions, such as lung or heart disease, or they live in nursing homes, should receive the RSV vaccine.
- On September 22, 2023, ACIP and CDC recommended maternal Pfizer RSVpreF (Abrysvo)
 vaccination in pregnant persons as a one-time dose at 32-36 weeks using seasonal administration
 (meaning from September–January) for prevention of RSV in infants under 6 months of age.
- Only Pfizer RSVpreF (Abrysvo) may be administered to pregnant persons; Arexvy (GSK) and mRESVIA (Moderna) vaccines should not be administered during pregnancy.
- Infants born during the RSV season (typically October through March) should receive a single dose
 of Nirsevimab (Beyfortus) within 1 week after birth if the birth parent did not receive RSV vaccine
 at least 14 days prior to delivery.
- Nirsevimab is recommended for:
 - All infants younger than 8 months entering their first RSV season. Except in rare circumstances, most infants younger than 8 months of age do not need nirsevimab if they were born 14 or more days after their mother got an RSV vaccine.

 Some children ages 8 through 19 months who are <u>at increased risk for severe RSV</u> <u>disease</u> and entering their second RSV season.

Additional Considerations:

1. **Up to date status:** CDC currently defines "up to date" with COVID-19 vaccine as having completed all recommended age-appropriate doses, including at least one dose of the 2024-2025 COVID-19 vaccine.

2. Co-administration of Vaccine:

- COVID-19 vaccines may be administered without regard to timing of other vaccines.
- Flu vaccine and RSV vaccine can be administered at the same time as COVID-19 vaccines.
- 3. People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination.

Access To Updated Vaccines:

- Most health insurance plans (including Medicaid) will cover COVID-19, RSV and influenza
 vaccines at no cost. Influenza and COVID are covered under Medicare Part B, and RSV is covered
 under Medicare Part D.
- Children eligible for the <u>Vaccines for Children</u> (VFC) program also may receive both flu and COVID from a provider enrolled in that program, including public health offices
- Adults without health insurance can get both COVID and flu vaccines at most public health offices at no cost.
- For help locating pharmacies that have vaccines: Find pharmacies near you (vaccines.gov)
- For help finding vaccine appointments, call the NMHealth Helpline: 1-833-796-8773

Additional Resources:

- 1. Updated clinical recommendations for COVID vaccine: <u>Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC</u>
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory
 Committee on Immunization Practices United States, 2024–25 Influenza Season | MMWR (cdc.gov)
- 3. Immunization Education & Tools for Healthcare Providers (nmhealth.org)
- 4. Full recommendations for RSV vaccine can be found here: RSV (Respiratory Syncytial Virus) Immunizations | CDC
- 5. Updated recommendations on influenza vaccination will be found here: <u>Seasonal Influenza</u> Vaccination Resources for Health Professionals | CDC
- 6. COVID-19 Vaccine fact sheets for vaccines under EUA and product inserts for vaccines that have been FDA approved (Moderna Spikevax and Pfizer Comirnaty) are available and are accessible here: Coronavirus Disease 2019 (COVID-19) | FDA
- 7. Vaccine Information Sheets (VIS): Vaccine Information Statement | Current VISs | CDC
- 8. Epidemiologic information for respiratory viral infections in New Mexico can be found here: <u>Viral Respiratory Infection Dashboard</u>



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9. Vaccine record access: to check if you are up to date on vaccinations visit our public portal VaxView NM-online portal: https://vaxview.doh.nm.gov/. If you need assistance accessing profile for Vax View NM, call our helpdesk at 833-882-6454 Monday-Friday 8am-5pm (closed from 12pm-1pm for lunch). Voicemails can be left, and an agent will return call.

<u>New Mexico Health Alert Network</u>: To register for the NM Health Alert Network, please visit the following site https://nm.readyop.com/fs/4cjZ/10b2</u> Please fill out the registration form completely and click Submit at the bottom of the page, to begin receiving Important health alerts, advisories, and updates.

<u>Please Note</u> that our system also utilizes text messaging to notify members of important health information. Due to FCC Regulation changes that are designed to decrease the amount of unwanted spam text messages sent each year to citizens, please save, this phone number (855) 596-1810 as the "New Mexico Health Alert Network" default phone number for your account used for text messages on the mobile device(s) you register with us.