Explainer: COVID-19 Vaccine FDA Label Change

What is the FDA COVID-19 vaccine label and what changed?

Each respiratory virus season, the FDA approves updated seasonal COVID-19 vaccines based on the agency's determination that its benefits outweigh its known and potential risks for the intended population. The FDA-approved drug label includes the indications for use, including the disease and population. It is typical for this to occur at the end of August, when the FDA also inspects products to ensure they are safe to use.

On August 27, 2025, the FDA approved 2025-26 COVID-19 vaccines with indications *only* for adults 65+ and people 6 months to 64 years old with conditions that put them at high risk for severe illness. This is a narrowing of the label from previous years, where it was approved for everyone over the age of 6 months. Linked here are approvals for Pfizer, Moderna, and Novavax COVID-19 vaccines.

What is considered "high risk" appears undefined by the FDA, but the approved labels reference the CDC Clinical Considerations, which links out to the CDC's reference list for "high risk" conditions. Over 200 million Americans are estimated to be at high risk based on this list, which encompasses common conditions such as diabetes, a disability, overweight/obesity, or a heart, lung, liver, kidney, cancer, or mental health condition. The list also includes pregnancy.

There is robust evidence that COVID-19 vaccines continue to provide additional protection against illness and death in populations beyond these high risk groups, as reflected in past years' labels.

What do these changes mean for COVID-19 vaccine access?

For patients who meet the "on label" indications:
People who meet the more restrictive label indications should be able to receive vaccines in ways similar to past years – through a pharmacist, physician, nurse, or other healthcare provider.

For those with high-risk conditions, Moderna's SPIKEVAX is approved for those **6 months and older**, Pfizer's COMIRNATY COVID-19 vaccine for those **5 years and older**, and Novavax's NUVAXOVID for those **12 years and older**. All 3 vaccines are approved for those **65 and older**.

For patients who do not meet the "on label" indications:
These changes to the FDA label may make it harder for many people to receive COVID-19 vaccines. For example, a healthy 30-year-old (who doesn't meet the high-risk conditions) will need to find a provider to prescribe and administer the vaccine "off-label." In many states, pharmacists are not able to administer off-label vaccines, and some pharmacies may ask patients to attest that they meet the "on label" indications.

> **Physicians** will still be able to prescribe and administer vaccines, including "off label," as they do for other off-label medications. As with any care they provide, physicians can use clinical guidelines, like those published by their professional societies (e.g., AAP and

ACOG), to help them follow standards of care. Clear guidance from health systems and state medical associations can also support physician clinical decision making and explain protections for off-label prescribing.

Pharmacists, nurses, and other non-physicians will likely be more restricted by the new FDA approvals or Advisory Committee on Immunization Practices (ACIP) recommendations. Scope of practice and liability protections vary widely from state to state, but most states link ability to administer COVID-19 vaccines to ACIP recommendations and/or FDA label via state laws or regs. In past years, pharmacists have administered ~90% of COVID-19 vaccines, so restrictions on their ability to administer vaccines to all patients who want them will significantly limit vaccine access.

Off-label prescribing is a common practice; AHRQ estimates that one in five medications are prescribed off-label. The FDA label change may impact the additional liability immunity provided by the PREP Act for use of COVID-19 vaccines. Even without this additional liability protection, providers are covered by the same professional liability standards that apply to their other medical decisions, where reliance on evidence-based guidelines (e.g., AAP and ACOG) can provide strong support that the standard of care has been met.

Insurance coverage:
The FDA label change does not have a direct effect on whether or how health plans cover vaccines. Most minimum coverage requirements are tied to ACIP recommendations rather than FDA licensing/labeling, and payers have broad flexibility to follow the evidence and cover more than this minimum.

How does this relate to the ACIP recommendations for COVID-19 vaccines?

FDA labeling is just one step in the process for federal bodies to approve and recommend seasonal vaccines. ACIP has not yet made recommendations for 2025-2026 updated COVID-19 vaccines.

ACIP recommendations for COVID-19 vaccines from the prior year do not apply to the next year. ACIP must affirmatively issue recommendations each year. ACIP is expected to meet in September, though a date has not been set for the meeting. The CDC generally adopts ACIP recommendations into the Immunization Schedule shortly thereafter. Because the ACIP recommendations are expected to be issued later than most years, vaccines will arrive in clinics and pharmacies before ACIP recommendations are made.

What should my organization do in response?

Providers, payers, states, and patients all play a role in ensuring that anyone who wants a COVID-19 vaccine this season can get one. To preserve access:

- **Providers** can review recommendations from medical societies on COVID-19 vaccines; review state scope of practice rules around prescribing and administering vaccines, including off-label use; and order vaccines for the upcoming respiratory season if they have not already done so. Additional detail here.

- **Payers** can cover COVID-19 vaccines with no cost sharing, in line with past years; ACIP (not FDA) recommendations are tied to minimum coverage requirements, but payers have flexibility to cover more than this minimum. Additional detail here.
- **States** can encourage the public to get vaccinated and use policy tools to preserve provider (including pharmacist) ability to administer COVID-19 vaccines, and preserve funding for vaccines through VFC and other programs. Additional detail here.
- **Patients** can discuss vaccine questions with their health care provider and health insurance plan to understand their options for vaccine access, including their options for off-label administration.

The importance of vaccine access this respiratory virus season

Vaccines remain the best tool to prevent severe illness, hospitalizations, and death from respiratory viruses. The more restrictive FDA label approvals for 2025-2026 COVID-19 vaccines may make it harder for many people to get the COVID-19 vaccine. Providers, payers, states, and other health sector stakeholders can work together to prioritize providing COVID-19, flu and RSV vaccines to people who want them, with particular focus on people who are at the highest risk, including people 65 and older and those with underlying conditions.

For additional analyses and toolkits, please visit “Vaccine Resources” on the Common Health Coalition website.