Off-label use of COVID-19 vaccines was once discouraged but has become common amid new guidelines

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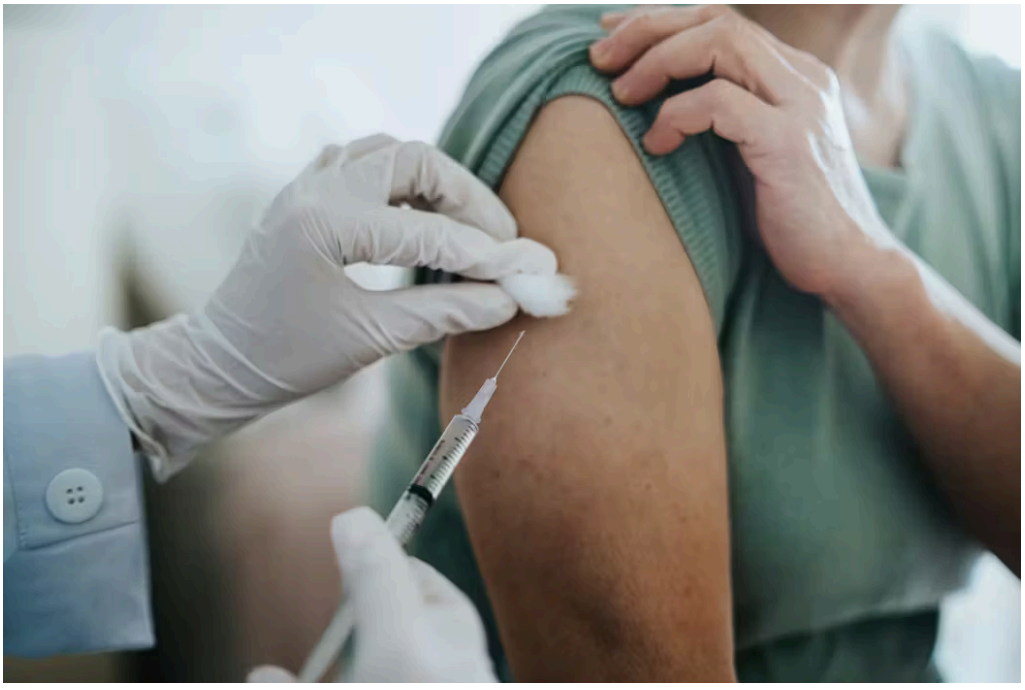

Getting a COVID-19 vaccine is trickier now than in years past, but still possible.

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Following the federal government's changes to COVID-19 vaccine eligibility and recommendations in 2025, many people are wondering whether they can get COVID-19 vaccines for themselves or their children.

In May 2025, the U.S. Food and Drug Administration limited eligibility for updated COVID-19 vaccines to people ages 65 years and up and to those under 65 with a "high-risk" condition. In September, the Centers for Disease Control and Prevention adopted an "individualized decision-making" approach to COVID-19 vaccination instead of broadly recommending the vaccines.

It's not just the public that is confused. Many physicians and pharmacists also have questions about whether and how they can administer COVID-19 vaccines.

As philosophers with expertise in bioethics and legal philosophy, we have been following the ethical and regulatory landscape for COVID-19 vaccines since they first became available in late 2020.

In the fall of 2025 that landscape looks a bit different in light of the new guidelines. While it is causing understandable confusion, most people who want to get a COVID-19 vaccine can do so. Broad access is possible, in part, through what in health care is called "off-label use."

"Off-label" refers to using an FDA-approved product for a different purpose, or with a different population, than that for which it received approval. Off-label prescriptions are common in health care, particularly in pediatrics.

COVID-19 vaccines from 2020-2025

People likely recall that COVID-19 vaccines were developed faster than any vaccine had been previously, thanks to efforts such as the U.S. government's Operation Warp Speed. Initially limited in supply, the vaccines first became available through "emergency use authorization" in December 2020, with health care workers among the first prioritized by the government to receive them.

In August 2021, the FDA fully approved the first COVID-19 vaccine for people ages 16 and up. Following this, younger children started to become eligible for COVID-19 vaccines. From 2022 through summer 2025, COVID-19 vaccines were available to everyone 6 months and older in doctors' offices or pharmacies, mostly free of charge, albeit with disparities in access due to an individual's age, geographic location or vaccine costs.

But in May 2025, the new FDA and CDC leadership appointed by the Trump administration started to change their agencies' positions on COVID-19 vaccines. Such regulatory changes affect who is considered eligible for the vaccines and whether public and private insurers must provide coverage. Meanwhile, state laws influence the ability of pharmacists, who frequently provide routine vaccinations, to administer COVID-19 vaccines.

Understanding the role of federal agencies such as the FDA and the CDC, as well as medical professional organizations and guidelines, can help untangle the complicated picture for access to COVID-19 vaccines.

2025 changes to FDA and CDC guidance

It's helpful to understand the process through which vaccines become approved and endorsed by government agencies in the U.S.

First, the FDA approves drugs and other biologic products such as vaccines for specific uses, in specific age groups – in this case, to prevent people from getting COVID-19 or, if they do get it, to reduce the severity of their symptoms.

Next, the CDC recommends products that the FDA has approved or authorized. These recommendations have a different regulatory function than the initial FDA decisions. The CDC issues public health guidelines for which vaccines people should receive and which ones public and private insurance must cover. In some states, the CDC's recommendations also affect whether pharmacies can administer vaccines.

Until September 2025, when the CDC shifted its stance, the agency broadly recommended COVID-19 vaccines for everyone 6 months of age and older, regardless of their underlying conditions. These recommendations supported public health and ensured that public and private insurance covered 100% of the cost of these vaccines as preventive health care.

Medical and CDC recommendations

Despite the FDA's updated eligibility criteria and the CDC's revised guidance, medical professional organizations have continued to broadly recommend COVID-19 vaccines.

In August, the American Academy of Pediatrics issued its own vaccine schedule. In addition to kids who meet FDA eligibility due to heightened risk, the organization recommends that all children between 6 months and 2 years old be vaccinated against COVID-19, as well as any child whose parent or guardian wants them to be vaccinated.

When the Advisory Committee on Immunization Practices, or ACIP – the committee that advises the CDC on vaccine policy – met in mid-September, it voted to recommend that anyone 6 months and older can get a COVID-19 vaccine according to "individual-based decision-making." The committee also voted to require continued funding of COVID-19 vaccines through private and public health insurance and the Vaccines for Children program that provides free vaccines to children who are Medicaid eligible, uninsured or underinsured. In October, the interim CDC director adopted the ACIP recommendations as the formal guidance from the CDC for the 2025-2026 COVID-19 vaccines.

These recommendations from the CDC and medical professional organizations are difficult to square with the FDA labeling changes for COVID-19 vaccines. The CDC is recommending that people make individual decisions with their medical providers about COVID-19 vaccination, regardless of their eligibility through FDA approval.

This is possible because anyone who doesn't meet FDA eligibility can get a COVID-19 vaccine through off-label use.

The American College of Obstetricians and Gynecologists still recommends that people who are pregnant get the COVID-19 vaccine.

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Off-label use of COVID-19 vaccines

Using COVID-19 vaccines off-label means administering them for the same purpose but to a wider population than those who are FDA-eligible. In 2021 the CDC prohibited the off-label use of COVID-19 vaccines purchased by the federal government. This was an unusual move and is no longer the case.

While uncommon, off-label vaccination is sometimes recommended. One example is off-label vaccination against measles, mumps and rubella, or MMR, for children under 12 months old who plan to travel to areas where measles is not eradicated, or are exposed to a disease outbreak.

Moreover, the CDC's 2025-2026 COVID-19 vaccine recommendations remove certain barriers that typically accompany off-label use.

For example, products used off-label are not always covered by insurance. Many private insurers already committed to covering COVID-19 vaccines as preventive care for the 2025-2026 vaccine season. The recommendations from ACIP and the CDC subsequently guaranteed that private and public health insurance plans would continue to cover COVID-19 vaccines in full. This includes COVID-19 vaccines under the Vaccines for Children program that purchases vaccines for approximately half of U.S. children.

Off-label use of a product is ethically and legally permissible if a physician believes its benefits outweigh its risks for their patient. But the CDC's recommendation for individual decision-making may also lessen clinicians' worries about liability. So might the guidance from the American Academy of Pediatrics, as well as the American College of Obstetricians and Gynecologists' vaccine recommendations that anyone who is pregnant should get an updated COVID-19 vaccine during pregnancy.

Off-label use is typically done via a doctor's prescription. Yet many COVID-19 vaccines are administered in pharmacies. Getting vaccinated in a pharmacy is especially helpful for people without primary care doctors or the time or money for a clinic visit. Many states have taken steps to remove barriers to obtaining off-label COVID-19 vaccines at pharmacies. The CDC's October 2025 recommendations for individual decision-making also enable COVID-19 vaccination by pharmacists.

For people who would like to be vaccinated against COVID-19, knowing how off-label use fits into current regulations may be helpful for understanding their access to vaccines this respiratory virus season, and medical treatment in general.

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