

September 2025 ACIP Meeting: COVID-19 Vaccine Updates for Health Leaders

On September 19, 2025, the Advisory Committee on Immunization Practices (ACIP) voted on updated recommendations on COVID-19, Measles, Mumps, Rubella, and Varicella (MMRV), and Hepatitis B. These recommendations should allow people, 6 months and older, who want a COVID-19 vaccine to get one. Below are the key takeaways for health leaders and the populations they serve, particularly as they relate to COVID-19 vaccine access across the US. **Note: HHS must sign off before the recommendations are formally adopted.**

What was the recommendation for COVID-19 vaccines?

On September 19, 2025, ACIP unanimously <u>recommended</u> that vaccination for COVID-19 be determined by individuals – in consultation with a health care provider – for everyone aged 6 months and older. ACIP explicitly voted against requiring prescriptions.

What does this recommendation mean in practice?

COVID-19 vaccines remain recommended for individuals 6 months and older under "individual decision-making," known more commonly as "shared clinical decision-making." This recommendation includes both people who are included in the FDA label approved in August 2025 (individuals with high-risk conditions and individuals 65 and older) as well as people who would receive the vaccine off-label (e.g., an otherwise healthy 10 year old or 50 year old who does not have a high-risk condition).

What is Shared Clinical Decision Making?

Shared clinical decision-making means vaccinations are informed by an individual decision process with a health care provider about the benefits and risks of vaccination. These types of discussions already occur often between patients and their doctor or pharmacist for routine vaccinations, including those with shared clinical decision-making, like meningococcal B vaccination in adolescents and young adults or HPV vaccination in some older adults. A clinician's recommendation for vaccination continues to be <u>among the most important predictors</u> for a patient choosing to get vaccinated, particularly for patients at higher risk of severe outcomes.

What about pharmacists? Importantly, <u>CDC</u> recognizes pharmacists as health care providers for the purposes of shared clinical decision-making. In fact, pharmacists already practice this for many vaccines administered in pharmacies – they have training, expertise, and experience to have these clinician-patient discussions on vaccine benefits and risks.

Will the COVID Vaccines be covered/paid for?

Yes. Insurance coverage for vaccines recommended by ACIP is required by law in Medicare, and across most private plans. Additionally, prior to the release of the ACIP recommendation, the trade association AHIP affirmed that its member plans would cover COVID-19 vaccines with no cost sharing.

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The Vaccines for Children (VFC) Program, which provides vaccines for Medicaid-insured children, is required to cover all ACIP-recommended vaccines; additional clarity about ordering is anticipated following formal HHS approval of the ACIP recommendation.

What does this mean for state by state access?

Once the ACIP recommendation is approved, COVID-19 vaccines should be broadly accessible for people who want the vaccine, though there are still some nuances that remain to be resolved.

The ACIP recommendation includes both people who are included in the FDA label approved in <u>August 2025</u> (individuals with high-risk conditions and individuals 65 and older) as well as people who would receive the vaccine "off-label." <u>Most states</u> have historically linked policies related to vaccine scope of practice authority, insurance coverage, and state public health recommendations to ACIP recommendations, so shared clinical decision-making should facilitate access in these states.

Some states place limits on vaccine administration in pharmacies to adults or persons over a certain age, or administration according to the FDA label. Individual states should assess their rules and regulations around vaccines to determine whether further action is necessary to ensure access is free from barriers and scope-of-practice issues from this discrepancy, particularly if they have policies linked to FDA approval criteria.

Is it uncommon for the FDA licensure and ACIP recommendations to differ?

FDA licensure and ACIP recommendations usually align, but not always. The FDA bases its vaccine approvals on data submitted by manufacturers, which set the official label and package insert. ACIP, on the other hand, looks beyond the manufacturer's data. It also considers real-world studies, population-level benefits, cost-effectiveness, and post-licensure safety information.

There have been at least 20 discrepancies between ACIP recommendations and FDA licensed indications <u>identified</u> between 2000 and 2014. One notable example was Tdap vaccination: for about ten years, ACIP recommended Tdap use in situations that went beyond the FDA label, and providers followed ACIP guidance, giving the vaccine off-label.

What are other barriers to vaccination?

Some providers are unfamiliar with shared clinical decision-making, and will likely need education and support from public health, health systems and medical society leadership. And shared clinical decision-making may add time to appointments. Additionally, not everyone has access to a health care provider.

For additional analyses and toolkits, please visit "Vaccine Resources" on the <u>Common Health</u> <u>Coalition website.</u>

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