

Regulatory Brief: Shared Clinical Decision-Making Recommendation
COVID-19 Vaccine for Children and Youth

Overview: This regulatory brief summarizes how the FDA approval changes for the 2025-26 COVID-19 vaccines and the CDC recommendation for “shared clinical decision-making” of the 2024-25 COVID-19 vaccine for children and youth affects coverage and administration of the vaccine.

Effective May 29, 2025, the Centers for Disease Control & Prevention (CDC) revised the 2024-2025 COVID-19 vaccine recommendations in its Immunization Schedules for [adults](#) and for [children & adolescents](#). CDC had previously recommended “routine use” of the COVID-19 vaccine for children and youth aged 6 months to 17 years (neither pregnant nor immunocompromised). CDC now recommends “shared clinical decision-making” for use of the COVID-19 vaccine in this population. Specifically, for healthy children and youth, the updated Immunization Schedule says: “Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.”

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. For more information about the label change, see this [resource](#).

Changes to the FDA label may make it harder for children and youth to receive COVID-19 vaccines. For example, a 14-year-old who doesn’t meet criteria for high-risk conditions but wants to get vaccinated will need to find a provider to prescribe and administer the vaccine “off-label”.

Are the CDC recommendations made in May still in force, given the FDA label has excluded healthy children?

Yes, the CDC recommendations remain in effect. These recommendations, however, are specific to the 2024-2025 vaccines, ACIP needs to actively issue recommendations for the 2025-2026 COVID-19 vaccines.

If a provider administers a COVID-19 vaccine off-label to a child over 6 months of age, are there considerations distinct from off-label administration to any other person?

No, physicians may prescribe or administer FDA-approved vaccines off-label to children and youth, just as they can for other populations and with FDA-approved drugs and biologics. Off-label prescribing is legal and common for physicians in the US, [and according to AHRQ](#), one in five prescriptions written today are for off-label use.

When prescribing and administering COVID-19 vaccines off-label, physicians and other providers may not have specific liability protections under the PREP Act because it is currently unsettled whether the law (which provides broad immunity from liability when COVID-19 vaccines are used “*pursuant to the FDA license*”) also applies to off-label use.

Given FDA label changes, if a healthy 14-year-old patient’s guardian asks their primary care provider for the 2025-26 COVID-19 vaccine, the physician may choose to administer it “off-label” if deemed medically necessary. In doing so, the physician would be protected by the same professional liability standards that apply to other “off-label” medical decisions in their practice, but may not be additionally protected by the PREP Act.

What does this mean for coverage of COVID-19 vaccines for children and youth?

- For most populations, federal law requires no-cost coverage for vaccines recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP). This applies to all categories of ACIP recommendations, including those that are specified as based on shared clinical decision-making. Therefore, this change in recommendation does not result in a change in coverage.

What does this mean for who can administer COVID-19 vaccines to children and youth?

- Pharmacists are entitled to prescribe and administer COVID-19 vaccine consistent with CDC recommendations and pharmacy interns or technicians are permitted to administer COVID-19 vaccine consistent with CDC recommendations, pursuant to the 12th Amendment to the COVID-19 PREP Act Declaration, 89 Fed. Reg. 99875 (Dec. 11, 2024). This temporary federal preemption of state pharmacy law expires on December 31, 2029. *Id.* at 99877.
- The PREP Act Declaration applies only to routine childhood vaccines, COVID vaccine, and flu vaccine, when ordered and administered consistent with the CDC Immunization Schedules. (RSV vaccine for adults is not covered by the PREP Act declaration, so pharmacist prescribing and administration will depend on state law.)

About the Common Health Coalition (CHC)

Founded in 2023, the Common Health Coalition (CHC) brings together leading health organizations in pursuit of a reimagined health system, one in which the nation's healthcare and public health systems no longer work in parallel, but hand in hand, with better health for all as the common goal. The Coalition encompasses 300+ members across the country. CHC is working with providers, payers, public health agencies, and other key actors to develop and implement a coordinated strategy for the continued coverage, access, and uptake of COVID-19 and flu vaccines and RSV immunizations. Focusing on the fall respiratory season, CHC is building consensus on industry best practices for vaccine access, analyzing and navigating the evolving coverage and regulatory landscape, and developing tools that promote a shared understanding of key issues and impacts across all stakeholders.

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