Respiratory Season Vaccine FAQs

Navigate by Topic Area

This respiratory season is unusually complex, particularly for COVID-19 vaccines, due to shifting federal policies, delays in vaccine recommendations, and changing eligibility criteria. This will potentially result in reduced access to vaccines, operational challenges for vaccine providers, and public confusion. Vaccines access—especially for those at highest risk—saves lives and keeps hospitals and emergency departments from being overwhelmed by preventable illness. This FAQ document is intended to help health and public health leaders navigate uncertainty for the 2025-26 respiratory virus season.

This document will be updated regularly. Please don't hesitate to reach out with questions, comments, and suggestions on how this iterative FAQ document can better serve decision makers and practitioners across the health system.

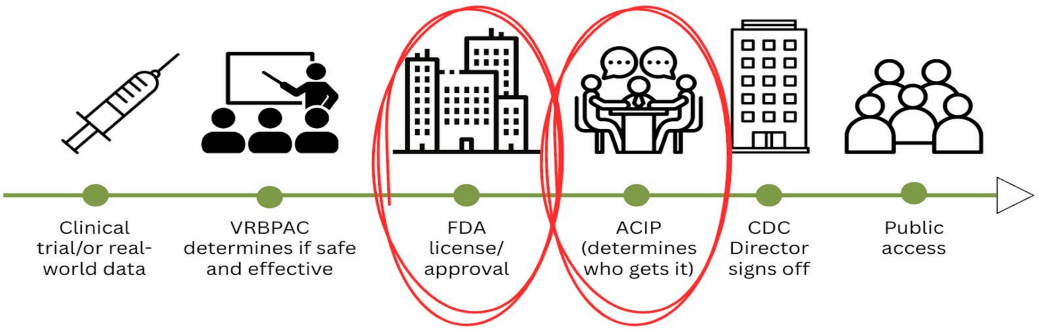
Respiratory Virus Federal Guidance and Changes for 2025 Season

1. What federal bodies provide recommendations for respiratory vaccines?

For a vaccine in development by manufacturers to reach patients, the federal government must coordinate several steps for the fall respiratory season *(see Figure 1 below)*. This includes three key bodies within the US Department of Health and Human Services (HHS):

- US Food and Drug Administration (FDA): Approves and authorizes vaccines for use and determines their labels.
- Advisory Council on Immunization Practices (ACIP): A panel of experts recommends how vaccines should be used.
- US Centers for Disease Control and Prevention (CDC): Accepts ACIP recommendations and adds them to the Immunization Schedule, which determines a number of things, including state policies and minimum coverage requirements under federal law.

Figure 1: Steps from Clinical Trials to Public Access (c/o Your Local Epidemiologist)



2. When does the federal government typically make recommendations?

Each fall, approvals and recommendations are required for the latest strain of respiratory vaccines. Last season, regulatory clarity emerged by June (ACIP) and August (FDA) for respiratory vaccines.

In August, 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.

ACIP made recommendations on influenza and RSV in June, which the CDC adopted in early August. However, ACIP hasn't yet acted on COVID-19 vaccines.

3. What are the latest federal decisions on flu, RSV, and COVID-19 vaccines? And how do they compare to last year?

Immunizations for flu and RSV are expected to be delivered to clinics in late-August/early-September, similar to previous years.

Federal flu vaccine and RSV immunization guidance is largely similar to past years, with minor changes:

- **Flu:** Similar to prior years, ACIP recommended and CDC confirmed that **everyone aged 6 months and older receive a flu vaccine**. In an update from prior years, ACIP recommended and HHS confirmed exclusive use of thimerosal-free influenza vaccines. Thimerosal is in multidose vaccines, which only accounted for ~4% of vaccines administered last year.
- **RSV:** Immunizations for RSV are recommended for **infants, children at high-risk for**

RSV, pregnant people, and high-risk adults 50+, and adults 75+. The CDC extended RSV immunization recommendations to those ages 50-74 who are at high-risk for severe RSV (vs. 60-74 last year). This year, an additional monoclonal antibody (Clesrovimab) is recommended by ACIP and CDC for infants up to 8 months old.

Medical specialty society guidance on flu and RSV immunizations can be found here.

- **COVID-19:** On August 27, 2025, the FDA approved 2025-26 COVID-19 vaccines with indications *only* for adults 65+ and people ages 6 months to 64 years old with conditions that put them at high risk for severe COVID-19. This is a narrowing of the label from previous years, where it was approved for anyone over the age of 6 months.
    - The criteria for whether someone is at high-risk of severe COVID-19 has not changed at this time, and in fact covers many Americans.
    - In May, the CDC updated 2024-25 recommendations to include shared clinical decision-making for COVID-19 vaccinations for healthy children & youth aged 6 months to 17 years and to remove the recommendation for COVID-19 shots for healthy, pregnant women.

CHC has developed a tool to support providers and payers in understanding the latest federal respiratory vaccine recommendations, which you can find here.

Implications of Federal Action / Inaction

1. How do the FDA label changes and ACIP recommendations (or lack thereof) impact the process for getting vaccines to patients?

Changes to the FDA label for COVID-19 vaccines may make it harder for large swaths of the population to receive those vaccines. For example, a 30-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 COVID-19 vaccine "off-label."

Further, delay of key ACIP recommendations compresses the timeframe for all stakeholders, including coverage determinations, provider readiness, and public messaging *(see Figure 3 below).* For example, ACIP recommendations affect minimum insurer coverage requirements and subsequently may influence how many vaccines (and of which brand or formulation) providers order.

ACIP's recommendations must be approved by the CDC Director or Health and Human Services Secretary to be included in the CDC's Immunization Schedules. ACIP has not yet made recommendations for COVID-19 vaccines for the 2025-26 season. Without clear recommendations from ACIP nor professional medical societies on COVID-19 vaccines, payers may delay clear communications about coverage without cost sharing, and providers may delay

their orders and administration, in turn delaying availability for patients in late summer and early fall.

2. How do ACIP recommendations affect coverage of vaccines without cost-sharing?

ACIP recommendations create the basis of minimum coverage requirements, meaning insurers are required to cover scheduled vaccines at no cost to members ("without cost-sharing"). Payers can always choose to cover more than these requirements. In June, AHIP, the trade association representing the health insurance industry, and the Alliance for Community Health Plans (ACHP) published statements that insurers remain committed to vaccine access and affordability, and the American Medical Association (AMA) and 79 other medical societies published a statement calling for continued access without cost sharing.

Medicare Part B coverage of vaccines and coverage for children enrolled in Medicaid is not tied to ACIP recommendations. See the Appendix, or this coverage analysis resource, for more information on how federal recommendations may affect coverage this respiratory virus season.

3. Does FDA approval and labelling affect insurance coverage of vaccines?

Minimum coverage requirements for insurers are **not** linked to FDA licenses or labels. FDA approval and labelling does have implications for provider scope of practice and liability — see these scenario tables for more information on these issues for the COVID-19 vaccine.

4. Without clear COVID-19 vaccine recommendations from ACIP, how should providers think about ordering vaccines?

Ordering and offering flu, COVID-19 and RSV vaccines, particularly in clinics and pharmacies — the most-frequented places patients get vaccinated — is one of the most important ways to ensure vaccine access nationally. Common Health Coalition put together a provider toolkit to help guide providers who prescribe and administer COVID-19, flu and RSV vaccines.-19, flu and RSV vaccines.

5. Can patients still request vaccines if the patient is not part of the population for which the FDA has approved the vaccine for that season?

Yes, patients should continue to talk to their health care provider about access to vaccines. For example, given the FDA label changes for 2025-26 COVID-19 vaccines, if a patient is not 65 or older and does not have a high-risk condition, they can still get the vaccine but will need to find a provider to prescribe and administer the vaccine "off-label". "Off label" prescribing happens when a vaccine or medication is prescribed for a condition, dosage or patient population that has not been approved by the FDA specifically for that indication.

Flu vaccines

1. Who will be most impacted by the thimerosal decision and ordering?

Certain vaccine providers, such as long-term care facilities and carceral settings (e.g., prisons/jails), tend to rely more on multi-dose flu vaccines (MDVs, a single vial that contains vaccines for multiple patients) because they require less storage space. Experts anticipate there will be little impact on patients from HHS formally rescinding the endorsement of those shots.

COVID-19 Vaccines

1. What is the impact of the FDA label change for 2025-26 COVID-19 vaccines?

For more information on the FDA label change for COVID-19 vaccines, see this resource. Changes to the FDA label may make it harder for large swaths of the population to receive COVID-19 vaccines. For example, a 10-year-old who doesn't meet criteria for high-risk conditions will need to find a provider to prescribe and administer the vaccine "off-label".

Prescription & Administration of COVID-19 Vaccines

- **Physicians** are broadly able to prescribe and administer vaccines off-label.
- **Other providers such as pharmacists and nurses**, off-label administration depends on state scope of practice rules which varies by state, but is generally tied to FDA label, ACIP recommendations, and/or CDC guidance.
    - Pharmacists administered ~90% of COVID-19 vaccines in past years. Restrictions on their ability to administer vaccines may cause disruption relative to the prior year's distribution channels.

Providers can look to clinical guidelines, peer-reviewed studies, and specialty society recommendations, such as those published by the American Academy of Pediatrics, for guidance on the evidence-based standard of care. Providers' comfort in administering vaccines off-label will require clear communication from employers, state medical associations and specialty groups to ensure understanding about off-label protections and risks.

Coverage

The FDA label change does not have an effect on vaccine coverage. ACIP (not FDA) recommendations set minimum coverage requirements, but payers can always cover more than this minimum.

High-Risk Conditions

The criteria for whether someone is at high-risk of severe COVID-19 has not changed, and in fact covers many Americans.

2. Are there liability protections for providers that administer a vaccine off-label?

Physicians will still be able to prescribe and administer vaccines, regardless of them being "off label," as they do for other off-label medications. Their comfort level with doing so will ultimately rely on clear communication from their employers, state medical associations, and specialty groups to ensure there is understanding about physicians' off-label protections.

Pharmacists, nurses, and other non-physicians will likely be impacted by changes to the FDA label, the vaccine license, or updates to ACIP. 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. CHC has developed a resource on what COVID-19 liability rules could look like under different scenarios.

3. Is there liability risk for payers to cover a vaccine off-label?

There is no substantial risk for payers to cover vaccines off-label. Payers typically have limited liability exposure for clinical decisions, which are made independently by licensed providers.

For plans covered by Employee Retirement Income Security Act (ERISA), which set minimum standards for most voluntarily established retirement and health plans, ERISA's broad preemption provision generally bars state law claims—including personal injury claims—that "relate to" the administration of the plan. Courts have consistently held that decisions about what a plan covers fall within the scope of ERISA preemption. As such, litigation arising from a plan's decision to cover or not cover a vaccine based on federal guidance would likely be preempted.

4. If ACIP recommendations align with the FDA label changes, will providers still be able to administer the vaccine to populations outside of the recommended populations?

If the COVID-19 vaccine for the 2025-26 respiratory season is not recommended by ACIP for certain populations, those populations may still receive the vaccine based on the judgment of their health care provider.

The Public Readiness and Emergency Preparedness ("PREP") Act Declaration, initially published in 2020, allows pharmacists, pharmacy technicians, and pharmacy interns to administer COVID-19 and flu vaccinations, even if not permitted under state law, but **only if** in compliance with the ACIP/CDC recommendations. This means if ACIP changes recommendations for COVID-19 vaccines to only high-risk adults and children, then pharmacists, pharmacy technicians, and pharmacy interns may not provide the COVID-19 vaccine off-label (for example, to a 50 year old with no high risk conditions who comes to a pharmacy asking for a COVID-19 vaccine), unless permitted to do so under state law. In state law, pharmacist scope of practice is also often tied to ACIP recommendations, CDC guidelines, or FDA labels.

5. If ACIP recommendations align with the FDA label changes, will patients be able to access it without cost-sharing?

Federal law requires no-cost coverage in commercial plans and some Medicaid plans only for vaccines on the CDC's Immunization Schedules, but health plans, including Medicaid programs and commercial insurance, can choose to cover additional vaccines beyond that baseline. Health plans can choose to cover, without cost-sharing, COVID-19 vaccines delivered off-label. Further, Medicare Advantage and Medicaid coverage for children is not limited to CDC/ACIP recommendations.

The Vaccines for Children (VFC) program only covers vaccines in the CDC immunization schedules, which typically incorporate ACIP recommendations. Providers cannot use VFC-supplied vaccine or VFC funding to administer the shot for children who are not included in ACIP recommendations. For more information on VFC coverage of respiratory vaccines, see CHC's explainer on the program.

6. What do the announced HHS changes to recommendations for COVID-19 vaccination for pregnant people mean for coverage?

Federal law requires no-cost coverage *only* for vaccines on the CDC's Immunization Schedules, but health plans including Medicaid programs and commercial insurance can choose to cover additional vaccines beyond that baseline. Medicare Part B, including Medicare Advantage, covers the COVID-19 vaccines without cost for all Medicare enrollees. Given ambiguity around ACIP recommendations for COVID-19 vaccination for pregnant people, insurers may choose to continue covering the vaccine for this population. Please refer to this regulatory brief for more information on what these changes could mean for payers.

7. What does the HHS COVID-19 vaccine recommendation for pregnant people mean for who can administer vaccines?

The revised COVID-19 vaccine recommendation for pregnant people, made by the CDC in May, has not followed the formal ACIP recommendation process. This change does not impact most providers but may affect vaccine administration by pharmacists and other vaccinators like nurses in clinics and health systems who rely on state standing orders.

Pharmacies have historically been a key vaccine access point with up to 90% of adults getting their COVID-19 vaccine in a pharmacy. Please refer to this regulatory brief for more information on how this change may impact which providers can administer the vaccine.

8. What do the recommendations for "shared decision making" for child/adolescent COVID-19 vaccines mean for providers?

This change doesn't impact vaccine coverage for these populations but may affect vaccine administration by pharmacists. Please refer to this regulatory brief for more information on what these changes could mean for providers.

9. What impact will the label change and ACIP recommendations have on FMAP for states?

If a state's SPA allows for vaccine coverage beyond ACIP recommendations, expenditures remain eligible for the state's regular FMAP. The anticipated impact is on the 1-percentage-point enhanced FMAP available under Section 4106 of the Affordable Care Act, which applies to certain preventive services, including ACIP-recommended adult vaccines. If ACIP narrows its recommendation, the enhanced FMAP applies only to vaccines and administration fees that remain within the scope of that narrower recommendation. Coverage beyond ACIP may continue, but at the regular FMAP rate.

An FDA label change by itself does not alter FMAP. However, a narrowed FDA label may result in more off-label prescribing or administration. Unless ACIP modifies its recommendations in parallel, FMAP treatment remains unchanged.