

Respiratory Season Vaccine Planning

U.S. Vaccine Operational Timeline for Respiratory Viruses

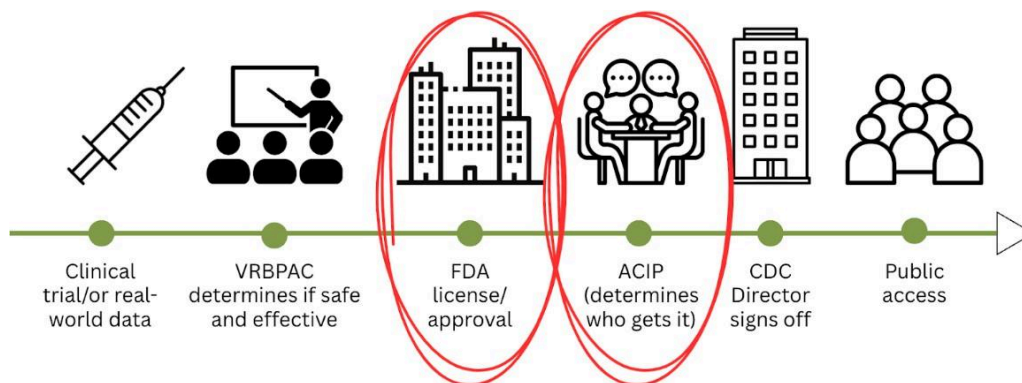
Summary: Providers and payers begin planning for respiratory virus vaccines well in advance of the virus season, including time-sensitive actions, like ordering vaccines. Operational planning begins in the spring and is facilitated by ACIP recommendations in June/early July. Much of this typically hinges on having clinical guidelines established early in the summer.

For a vaccine to reach patients from manufacturers, several steps across the federal government have to be coordinated to streamline the process during the fall respiratory season.

What is happening this year?

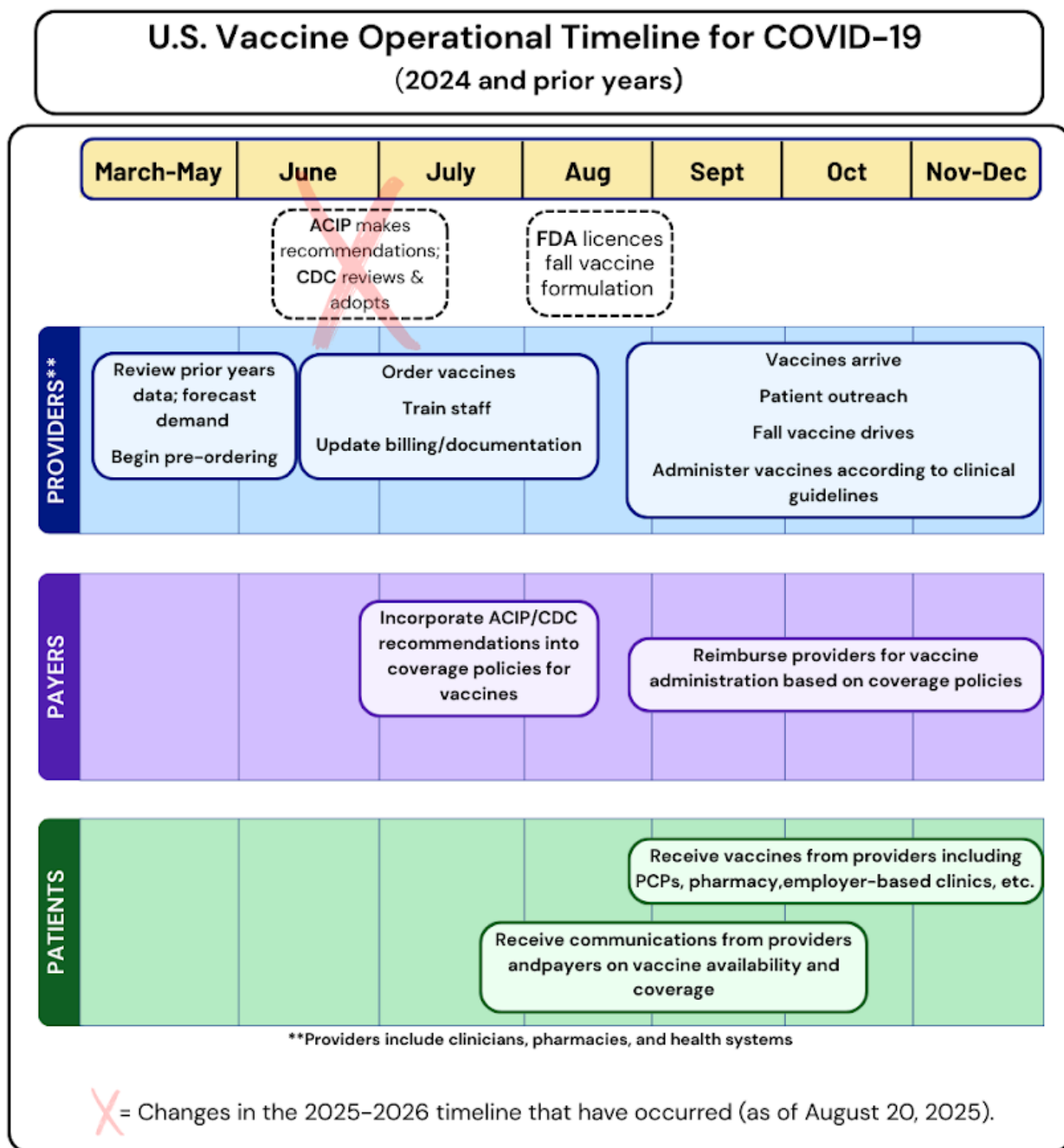
Heading into the 2025-2026 respiratory season, RSV and flu products have taken the usual route, but there are changes to federal policy and areas of continued uncertainty for COVID-19 vaccines:

Figure 1: Steps from Clinical Trials to Public Access:



Source: Your Local Epidemiologist

Figure 2: Typical Timeline to Operationalize Vaccines



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How have the COVID-19 vaccines been licensed and labeled?

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

Who will the COVID-19 vaccines be recommended for? The Advisory Committee on Immunization Practices (ACIP) – an advisory committee to the CDC — has not voted on this season’s COVID-19 vaccine recommendations, though historically they have generally aligned their recommendations with FDA approval decisions. Last year, the ACIP recommendation was made in June, and clinical guidance was issued by CDC in late August.

What are the implications for vaccine access?

As demonstrated in the timelines above (Figures 1 and 2), there is typically a coordinated set of steps that the federal government takes related to COVID-19 vaccines: (1) ACIP makes a recommendation, (2) CDC incorporates the recommendation into the immunization schedule, and then (3) the FDA updates labels for the seasonal vaccines. Given the shifts in timeline that have already occurred there are a few important things for providers to know this 2025-26 respiratory virus season:

- Scope of practice and standing orders vary by state and by type of clinician (MD, pharmacist, RN, etc.) and in many states are tied to ACIP recommendations; provider organizations in each state should support their members in understanding their role in delivering vaccines to different populations.
- Payers can continue to cover COVID-19 vaccines for all populations, even if it is not recommended by ACIP; check with your patient’s insurance plan to check if there is cost-sharing for a vaccine

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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