

2025-2026 Respiratory Season Vaccine Planning: Toolkit for Health Care Providers

Dear Partner,

The fall 2025 respiratory season is approaching at a time of significant vaccine policy uncertainty. Providers — including physicians, pharmacists, nurses, hospitals, long-term care facilities, and other clinical settings — continue to play a critical role in protecting patients against flu, RSV, and COVID-19. Their role this season will be even more important given confusion around vaccines, especially COVID-19 vaccines.

To help providers navigate what's ahead, the Common Health Coalition developed this toolkit.

What Should Providers Do Now?

Providers should continue to support strong access to respiratory virus vaccines so all populations can receive appropriate vaccines based on the strongest evidence. Ordering and offering flu and COVID-19 vaccines and RSV immunizations, particularly in clinics and pharmacies — the most-frequented places patients get vaccinated — is one of the most important ways to ensure vaccine access nationally. Providers can now order these vaccines and should use the best available data on anticipated uptake of the vaccine. CDC published this page for last year's vaccine season that may be useful for finding information about ordering vaccines this year.

Medical societies, health systems, pharmacies, and provider organizations can support their affiliated clinicians by:

Launching campaigns that encourage individuals with high risk conditions - particular those 65 years and older to get vaccinated against COVID 19 fly and PSV

Launching campaigns that encourage individuals with high risk conditions - particularly
those 65 years and older — to get vaccinated against COVID-19, flu, and RSV.
Revisiting this toolkit for updates, including those around FDA and ACIP/CDC updates
on COVID-19 licensures and recommendations.
Monitoring individual specialty societies as they produce timely and coordinated clinical
recommendations in August for children, adults, and older adults for COVID-19
vaccinations using the latest science and evidence.
Sharing these scenario planning resources across your networks to ensure providers
and partners have the latest on vaccine licensing and recommendations, provider
liability, scope of practice, and vaccine coverage considerations.

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Asking members and clinicians what they need to be able to protect their patients this respiratory season, particularly those at highest risk for severe outcomes from respiratory illness.
Developing clear guidance and tools for providers to communicate the state of respiratory vaccines and the value of continued uptake with patients.
Considering partnership with your state health authority to issue a standing order or directive authorizing pharmacists and other providers to administer COVID-19 vaccines off label or in scenarios broader than may be recommended by the CDC.

Answers To Your Questions

1. What is similar to prior respiratory seasons (so far)?

Flu vaccine and RSV guidance is largely similar to last year, with minor changes:

- <u>Flu</u>: Similar to prior years, ACIP recommended everyone age 6 months and older receive a flu vaccine. In an update from prior years, ACIP recommended <u>exclusive use</u> of thimerosal-free influenza vaccines. <u>HHS accepted these recommendations on July 22</u>.
 - Thimerosal is in multidose vaccines, which only accounted for ~4% of vaccines administered last year.
 - Practices that typically rely on thimerosal containing vaccines will need to consider other flu vaccine formulation options.
- RSV: Immunizations continue to be recommended for infants, children at high-risk for RSV, pregnant people, and adults 75+. The CDC extended the RSV immunization recommendation 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 available and recommended for infants up to 8 months old. CDC accepted these recommendations on Aug. 5.

Figure 1: Summary of current flu vaccine and RSV immunization recommendations

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	Influenza	RSV	What has changed
Infants and Children	6mo-17 years Some children 6 months through 4 years may need multiple doses	All infants <8 months and children 8-19 months with risk factors should	Flu: No thimerosal-containing vaccines RSV: Clesrovimab is new
Pregnant Women	All	I 37-36 WARKS DESTATION	Flu: No thimerosal-containing
Adults 18-49	All	See Pregnant Women	vaccines Vomen
Adults 50+	All High dose, recombinant, or adjuvanted preferred for 65+, if available	All adults 75+ and adults 50 through 74 years with risk factors should get a	

This <u>resource</u> has detail on the current state of recommendations, by vaccine and patient population.

2. What are the big changes and unknowns?

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Vaccine licensing and federal **recommendations for the updated 2025-26 COVID-19 vaccines remain in flux**. Last year, ACIP voted on recommendations for the COVID-19 vaccine in June. This year, they have yet to make a recommendation — shifting the timeline for vaccine planning. HHS <u>signaled</u> that this year's COVID-19 vaccines could be labeled by the FDA and recommended by the CDC only for people aged 65+ and people aged 6 months to 64 years old with a high-risk condition this year. What is considered a <u>high-risk condition</u> in this season's labeling and recommendations is also still unknown, including whether pregnancy will be listed.

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. Further, ACIP has not yet made any recommendations about the COVID-19 vaccines for the 2025-26 season. These changes could have direct implications for minimum coverage requirements for payers, liability protections for providers, and scope of practice laws that give pharmacists in certain states the authority to prescribe or administer vaccines.

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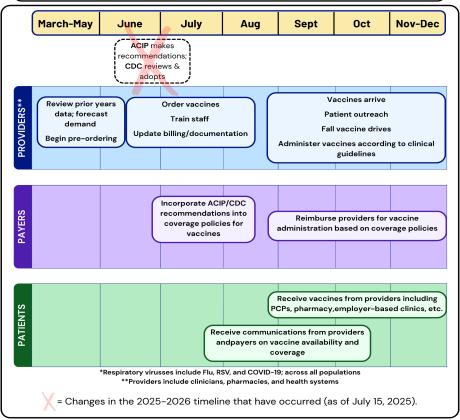
Figure 2: Steps from Clinical Trials to Public Access:



Source: Your Local Epidemiologist

Figure 3: Typical Timeline to Operationalize Vaccines

U.S. Vaccine Operational Timeline for Respiratory Viruses*
(2024 and prior years)



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Despite these changes and unknowns, providers and payers — including 80 medical societies, <u>AHIP</u> and the <u>Alliance of Community Health Plans</u> continue to support vaccine access, affordability and coverage.

This <u>resource</u> has additional detail on the typical timeline for U.S. Respiratory Vaccines from clinical trial to public access. See below for additional guidance on these topics.

3. Which providers will be able to prescribe and administer COVID-19 vaccines?

The authority to prescribe and administer vaccines varies by clinician type and is typically determined by the state laws governing scope of practice and <u>standing orders</u>. Broadly, physicians have the ability to prescribe and administer COVID-19 vaccines on or off label; see below for liability considerations. Advanced practice practitioners and nurses should check their state specific laws to ensure they can meet the scope of practice requirements which may be tied to ACIP recommendation, CDC guidance and / or FDA licenses.

Pharmacists play a central role in vaccination.

- Last year, ~90% of adult COVID-19 vaccines were administered in pharmacies.
- The <u>Public Readiness and Emergency Preparedness</u> ("<u>PREP"</u>) <u>Act Declaration</u>, 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 could 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, <u>pharmacist scope of practice</u> is also often tied to ACIP recommendations, CDC guidelines, or FDA labels.

For detailed information on pharmacist scope of practice considerations across various ACIP recommendation scenarios and patient populations, please refer to CHC's scenario tables.

¹ The <u>Public Readiness and Emergency Preparedness Act</u> (PREP Act), enacted in 2005, authorizes the Secretary of the Department of Health and Human Services (HHS) to issue declarations that provide liability immunity for the use of medical countermeasures during public health emergencies. In this document, the term "PREP Act Declaration" refers specifically to the <u>12th Amendment to the Declaration for Medical Countermeasures Against COVID-19</u>, issued by HHS and published on December 11, 2024 (89 Fed. Reg. 99875).

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4. Will providers have <u>liability protections</u> when administering COVID-19 vaccines?

Physicians may prescribe or administer FDA-approved vaccines off-label, just as they can with other FDA-approved drug and biologics. However, it is currently unsettled whether the HHS declaration under the PREP Act, which provides broad immunity from liability when COVID-19 vaccines are used "pursuant to the FDA license," also applies to off-label use. When administering a vaccine off-label, providers (including physicians, pharmacists, and other clinicians) may be subject to the same professional liability standards that apply to most other medical decisions.

For instance, if the FDA label for COVID-19 vaccines recommends the vaccine only for individuals 65+ or individuals with high risk conditions and a healthy 30-year old patient asks their primary care physician for the vaccine, and the physician administers the vaccine off-label to the patient, the physician may not have liability immunity under the PREP Act, but would instead be subject to the same professional liability standards as other "off-label" medical interventions they conduct.

For detailed information on what COVID-19 vaccine liability rules could look like under different recommendation scenarios for different patient populations, see CHC's <u>scenario tables</u> and <u>background on the vaccine injury compensation program</u>.

5. Will providers be reimbursed for COVID-19 vaccines?

Minimum coverage requirements for insurers are **not** linked to FDA licenses or labels, but rather to ACIP recommendations and the CDC Immunization Schedule. Payers can always choose to cover more than these requirements. See <u>CHC's analysis of current vaccine coverage by payer</u> and <u>scenario tables</u> for what COVID-19 vaccine coverage could look like under different scenarios for different patient populations.

Note, that in June 2025, <u>AHIP</u> and the <u>Alliance of Community Health Plans</u> affirmed their commitment to continued and affordable access to vaccines for the respiratory virus season.

Continued value of seasonal vaccines:

COVID-19 and flu vaccines and RSV immunizations remain the safest, most effective way to protect patients, ease the strain on hospital systems, and reduce healthcare costs:

The <u>COVID-19 Scenario Modeling Hub</u>, the <u>RSV Scenario Modeling Hub</u>, and the <u>Flu Scenario Modeling Hub</u> aggregate data from multiple academic modeling teams to monitor virus circulation, forecast disease burden, and inform public health preparedness. Their ongoing projections underscore the urgency of efforts to promote timely and equitable access to vaccines ahead of each respiratory virus season.



Last year, COVID-19 vaccines continued to provide <u>30%-40%</u> additional protection against urgent care visits, regardless of age, compared to people who did not get the Covid vaccine, and <u>40%-70%</u> additional protection against hospitalizations and ICU stays.

We're here to help work toward a smooth, coordinated, and equitable vaccine rollout this season. We hope you can use this toolkit to guide operational planning, share it with your colleagues and partners.

Please don't hesitate to reach out with questions, comments, and suggestions on how we can make this iterative toolkit better serve decision makers and practitioners across the health system.

Sincerely,

The Common Health Coalition



APPENDICES

- Provider Operational Timeline Respiratory Vaccines.pdf
- Current Coverage Requirements By Virus and Payer Line of Business Analysis.pdf
- Vaccine Recommendation Updates ACIP & CDC.pdf
- Vaccine Injury Compensation Program Notes.pdf
- Provider Liability, Coverage, and Scope Scenario Tables.pdf
- Regulatory briefs
 - Coverage and Administration of COVID-19 Vaccine for Pregnant People.pdf
 - Shared Clinical Decision-Making Recommendation COVID-19 Vaccine for Children and Youth.pdf
 - o Coverage and Administration of Flu Vaccines with Thimerosal.pdf

ABOUT US

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.