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 changes and 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 federal policy changes and delayed decisions regarding COVID-19 vaccines. To help providers navigate what's ahead, the Common Health Coalition developed this toolkit.

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
info@commonhealthcoalition.org

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What Should Providers Do Now?

Providers should continue to support broad 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.

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

- ☐ Prioritize encouraging individuals with high risk conditions - particularly those 65 years and older — to get vaccinated against COVID-19, flu, and RSV.
- ☐ Follow specialty society recommendations, including the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists, the Infectious Disease Society of America, and the American Academy of Family Physicians.
- ☐ Develop clear guidance and tools for providers to communicate the state of respiratory vaccines and the value of continued uptake with patients.
- ☐ Partner with state health authorities to support the protection of pharmacists and other non-physician providers to administer COVID-19 vaccines off-label or in scenarios broader than may be recommended by the CDC; as a number of states have already done.

Answers To Your Questions

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

Immunizations for flu and RSV are expected to be delivered to clinics in late-August or 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.

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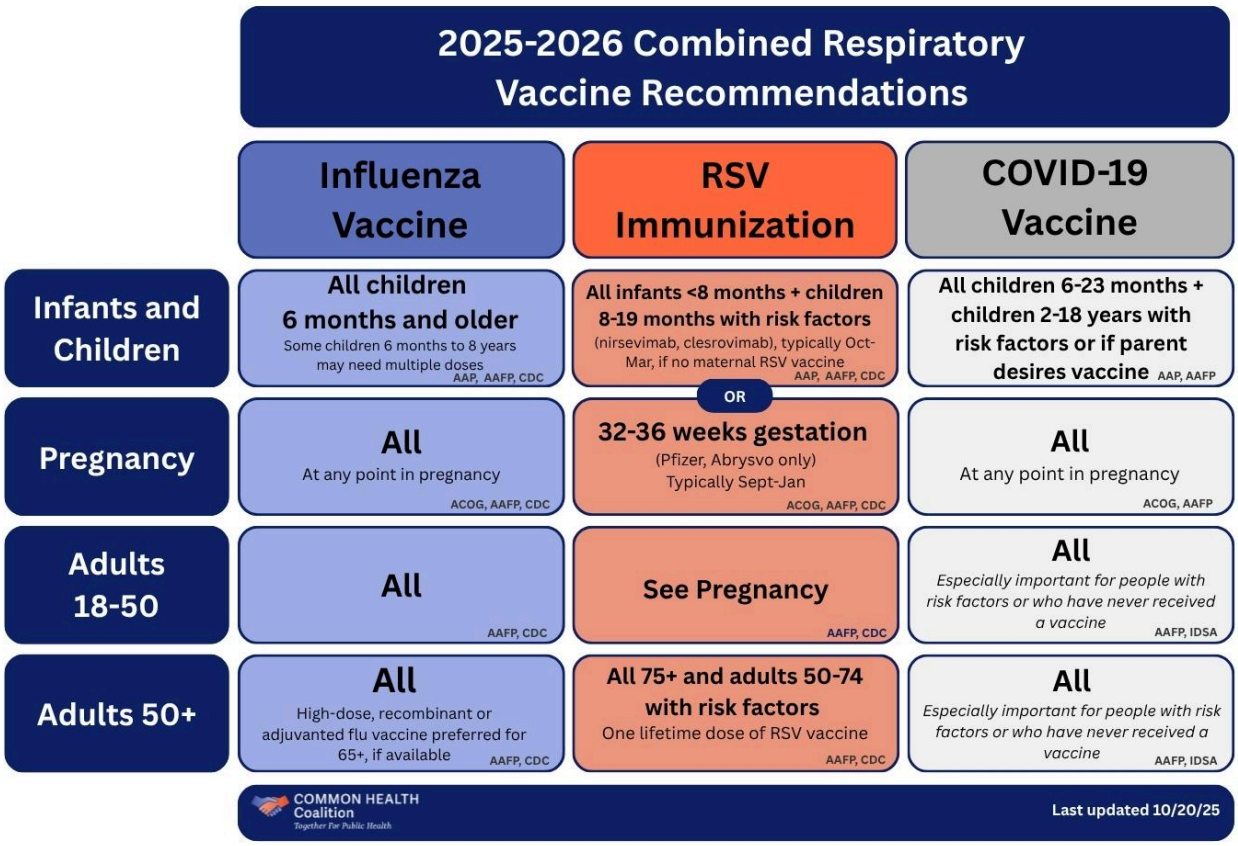
Figure 1: Summary of Current Federal Flu, RSV, and COVID-19 Immunization Recommendations



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

What are the big changes and unknowns?

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.

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On September 19, 2025, ACIP recommended COVID-19 vaccines for individuals 6 months of age and older, under "shared clinical decision making" (also referred to as "individual decision making). ACIP explicitly voted against requiring prescriptions. On October 6, HHS announced that the ACIP recommendations were approved by the Acting CDC Director.

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).

Providers may opt to follow professional society recommendations for these vaccines, and a number of states have linked professional society recommendations to their vaccine laws and protocols.

Figure 2: Steps from Clinical Trials to Public Access:

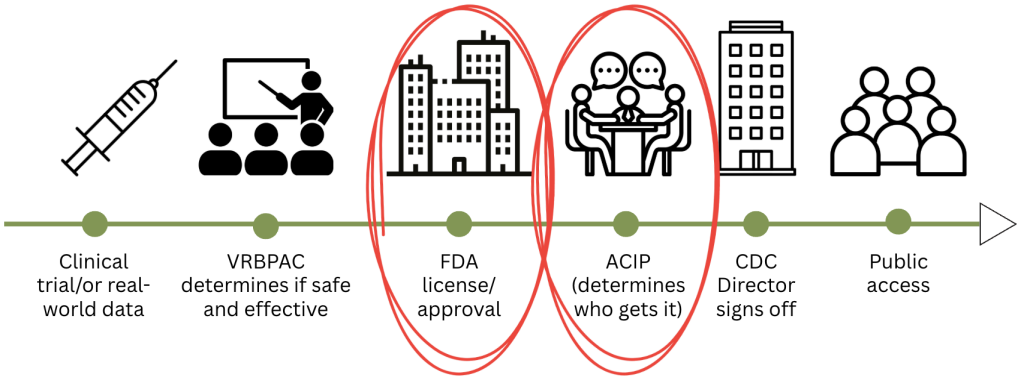

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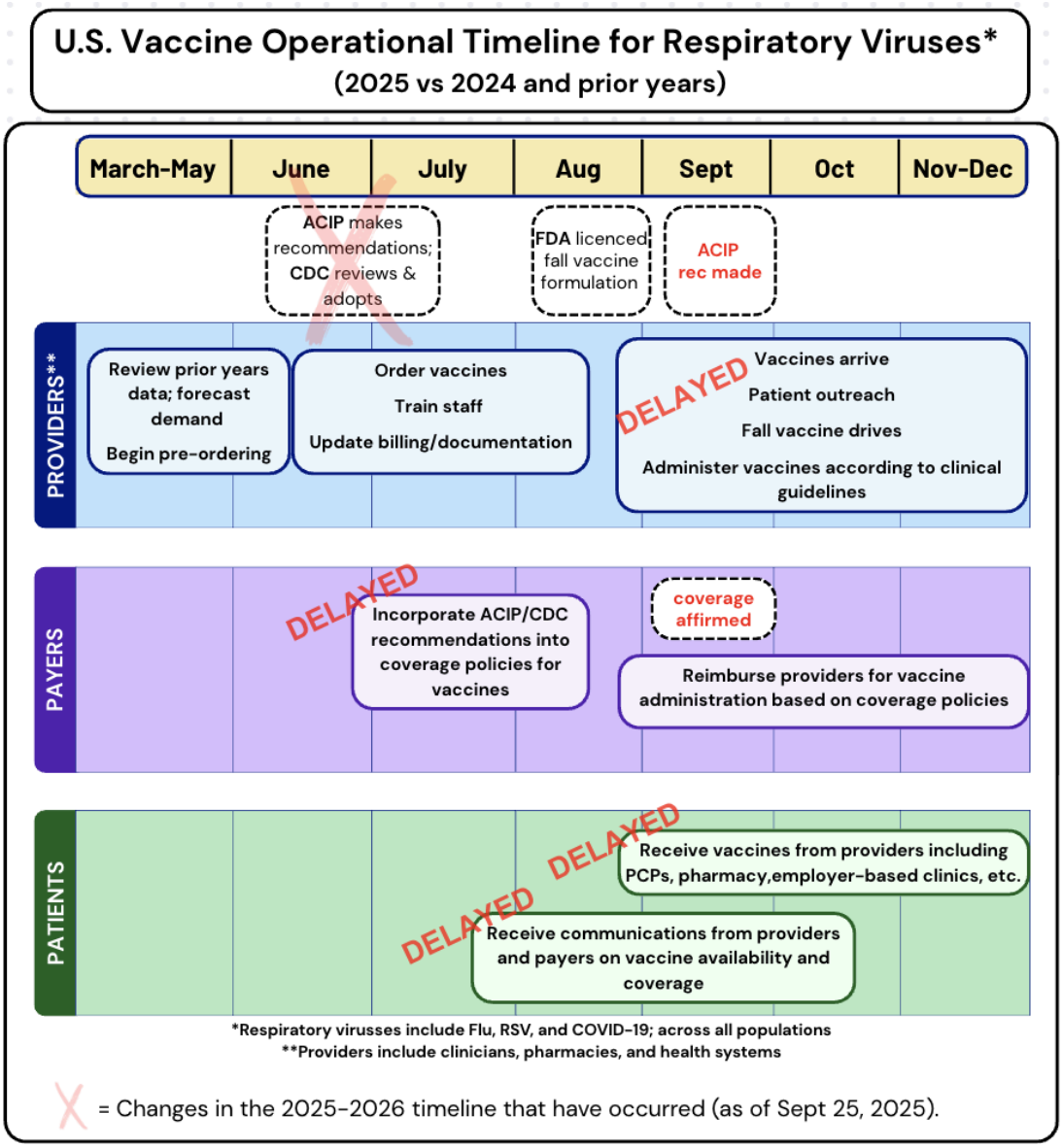
Figure 3: Typical Timeline to Operationalize Vaccines (link)



Despite these changes and unknowns, providers and payers — AMA and 79 medical societies, AHIP and the Alliance of Community Health Plans continue to support vaccine access, affordability and coverage.

This resource has additional detail on the typical timeline for U.S. Respiratory Vaccines from clinical trial to public access.

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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 standing orders, some of which may have direct links to FDA licenses and approvals. For an current status of state-by-state actions, reference this tracker.

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.

- In past years, ~90% of adult COVID-19 vaccines were administered in pharmacies.
- The Public Readiness and Emergency Preparedness ("PREP") Act Declaration,[1] 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 be able to 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.

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

Will providers have liability protections when administering COVID-19 vaccines?

Providers are granted liability protections for vaccine prescription and administration from a variety of regulations, specific to each vaccine. Updates to the FDA label or license of a vaccine or updates to ACIP recommendations may impact protections granted to providers and their willingness to prescribe or administer certain vaccines.

Physicians may prescribe or administer FDA-approved vaccines off-label, just as they can with other 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

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[1] The Public Readiness and Emergency Preparedness Act (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 12th Amendment to the Declaration for Medical Countermeasures Against COVID-19, issued by HHS and published on December 11, 2024 (89 Fed. Reg. 99875).

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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.

For instance, given FDA label changes for 2025-26 COVID-19 vaccines, if a healthy 30-year old patient asks their primary care physician for the vaccine, the physician may choose to administer it off-label. However, 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 scenario tables and background on the vaccine injury compensation program.

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, and as recently announced by AHIP and ACHP, most payers in the US have affirmed the coverage of these vaccines with no cost sharing. See CHC's analysis of current vaccine coverage by payer and scenario tables for what COVID-19 vaccine coverage could look like under different scenarios for different patient populations.

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 COVID-19 Scenario Modeling Hub, the RSV Scenario Modeling Hub, and the Flu Scenario Modeling Hub 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.

In 2024-25, COVID-19 vaccines continued to provide 30%-40% additional protection against urgent care visits, regardless of age, compared to people who did not get the Covid vaccine, and 40%-70% additional protection against hospitalizations and ICU stays.

APPENDICES

- State actions map
- 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
- Vaccines for Children One-Pager

- **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

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- 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.

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