2025-2026 Respiratory Season Vaccine Planning:

Toolkit for States

The fall 2025 respiratory season is approaching at a time of significant vaccine policy changes and uncertainty, particularly for COVID-19 vaccines. State officials, including public health, Medicaid, and insurance leaders, continue to play a critical role in protecting people against flu, RSV, and COVID-19 through clarity, confidence, and access.

The Common Health Coalition developed this toolkit to empower state health officials to navigate what's ahead.

Background on Federal Actions

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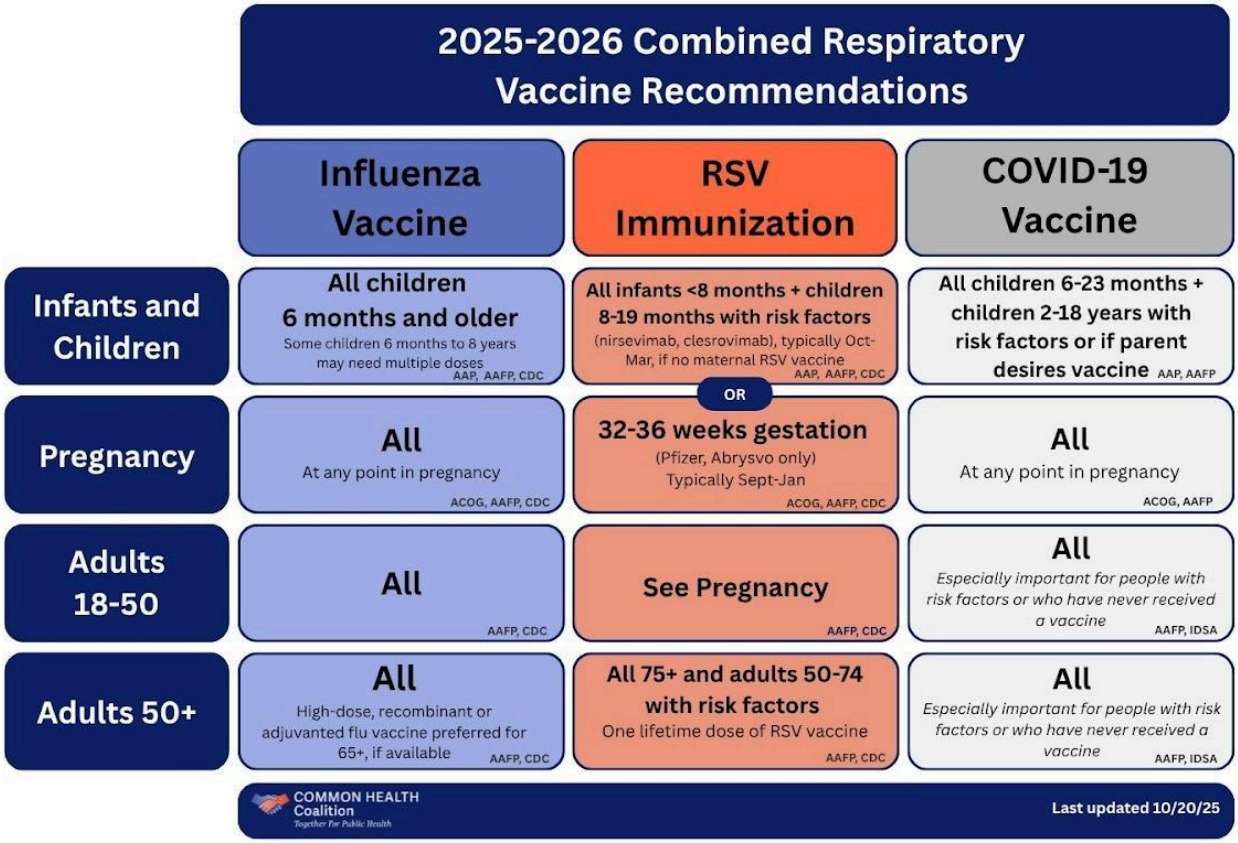
Figure 1: Summary of Current Federal Flu, RSV, and COVID-19 Immunization Recommendations



CHC has developed this resource with detail on the current state of recommendations, by vaccine type 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.

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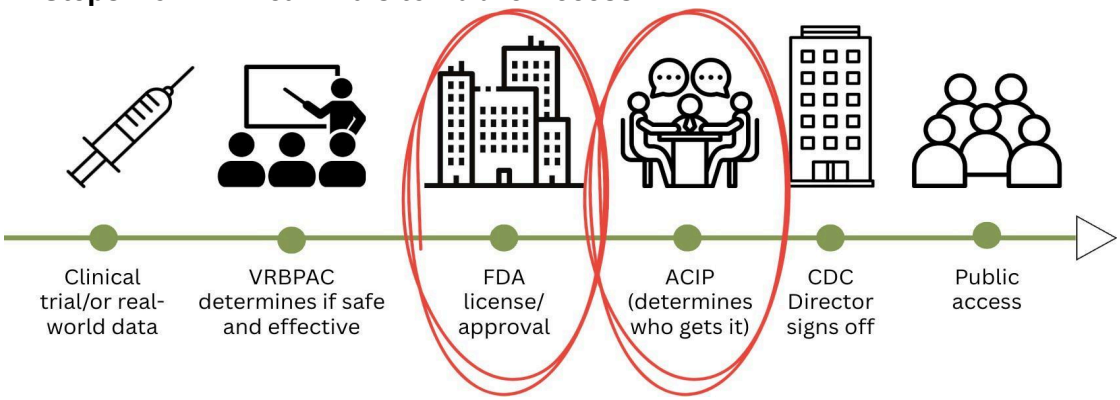
What is considered "high risk" appears undefined by the FDA, but the approved labels reference the CDC Clinical Considerations, which links out to the CDC's reference list for "high risk" conditions. This list encompasses common conditions such as diabetes, a disability, overweight/obesity, or a heart, lung, liver, kidney, cancer, or mental health condition. The list also includes pregnancy. For more information about the label change, see this resource.
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.

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.

In May, CDC updated 2024-2025 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. These recommendations, however, are specific to the 2024-2025 vaccines, ACIP needs to actively issue recommendations for the 2025-2026 COVID-19 vaccines.

Figure 2: Steps from Clinical Trials to Public Access:



How might these changes affect access to COVID-19 vaccines for people in my state?

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These changes and uncertainties are likely to create confusion – not only for patients trying to access COVID-19 vaccines, but also for the providers who administer them and the payers responsible for covering them.

There are three key implications for these changes: provider scope of practice, provider liability, and vaccine coverage, each described in more detail below.

Vaccine Access – Scope of Practice

Scope of practice authority for pharmacists nationwide to prescribe and administer COVID-19 vaccines was granted under the PREP Act Declaration, but only in line with ACIP recommendations.

Each state takes a different approach to defining what is permissible, but most existing state laws tie scope of practice to a combination of ACIP Due to the discrepancy between the narrowed FDA label and ACIP recommendations, pharmacies, where 90% of adult COVID-19 vaccines were administered in past years, could be limited in their ability to prescribe and administer vaccines to certain "off-label" populations this year absent state actions to protect access.

Additional Detail: 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. Broadly, physicians can prescribe and administer COVID-19 vaccines on or off-label.

The federal Public Readiness and Emergency Preparedness ("PREP") Act Declaration 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. In state law, pharmacist scope of practice is also often tied to ACIP recommendations, CDC guidelines, or FDA labels. More information about how administration

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of vaccines may be affected by federal policy changes, including issues around provider liability, can be found in CHC's Provider Toolkit.

Vaccine Access – Liability protections for providers

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

Additional Detail: 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 unsettled whether the PREP Act Declaration(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 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." A physician may choose to administer a COVID-19 vaccine off-label, and 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 specifically protected by the PREP Act.

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.

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Vaccine Coverage Without Cost Sharing

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 choose to cover more than these requirements.

Additional detail:
In June 2025, AHIP and ACHP affirmed commitment to continued vaccine access and affordability, and the AMA and 79 medical associations called for coverage of vaccines without cost sharing for patients.

In September 2025, AHIP affirmed commitment of its member plans to cover recommended vaccines until the end of 2026.

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.

What States Can Do to Support Continued Access

Actions States Can Take

- ❑ Support patients seeking respiratory season vaccines
- ❑ Ensure that providers can administer vaccines to those who want them
- ❑ Maintain health coverage for vaccines with no cost sharing
- ❑ Ensure access to vaccines even if they are no longer covered through Vaccines for Children (VFC) and Section 317

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Support patients seeking respiratory season vaccines:

- ☐ **Communicate clearly** about who is eligible for vaccines and where they can get vaccinated.
- ☐ **Direct providers and the public to speciality society recommendations**
- ☐ **Focus on those who are most at risk** for severe disease so they understand how, where, and when to get vaccinated as soon as they are able to do so.
- ☐ **Work with state-based organizations** and business groups on health to communicate directly to patients and their providers, particularly those at highest risk, about all three vaccines
- ☐ **Use communications tools** such as those found in the Vaccine Resource Hub and through Immunize.org to create materials or access those already created by others

Ensure that clinicians can administer vaccines (especially COVID-19) this respiratory virus season by:

- ☐ **Partner with state medical and hospital associations to communicate clearly** about physicians' continued ability to provide vaccines "off-label" as needed to patients that request them, and related state-based liability protections for off-label prescribing.
- ☐ **Identify and communicate scope of practice requirements in your state's laws for pharmacists and other non-physician vaccine prescribers and administrators** to determine how these requirements could be impacted by federal changes. For more information, see this helpful resource from the National Alliance of State Pharmacy Associations.
- ☐ **Enact policies to ensure pharmacists and other non-physician providers can prescribe and administer vaccines**, even in situations where they are administered "off-label," including actions already taken by states, detailed here.
  - ☐ Updating state regulations directing Departments of Health to consider endorsing vaccine recommendations from medical societies (e.g. recent Colorado legislation) in addition to those by federal bodies (e.g., ACIP/CDC)
  - ☐ Explore opportunities for flexibilities in state law/regulations, including ways to go beyond FDA approved or ACIP recommended vaccines; such as bills and executive orders enacted by Maryland, New York, and others
- ☐ **Develop standing orders pursuant to executive orders/emergency declarations to allow for expanded scope of practice at state and local levels:**
  - ☐ Immunize.org offers standing order templates (examples of state vaccine standing orders include Indiana, Alabama, and Oregon)

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- ☐ **Develop and/or distribute template attestation forms** for use in pharmacies or clinics on high-risk conditions.
- ☐ **Convene state clinical organizations and state-based immunization committees** to understand and address shared plans and concerns around continued access, state-based scope of practice issues, and liability questions. .
- ☐ **Facilitate collaborations between pharmacies and provider organizations**—such as hospital associations—to ensure patients seeking vaccination receive a smooth referral to a qualified provider who can prescribe and administer the vaccine. This is particularly critical if pharmacists in your state are restricted from administering off-label vaccines due to scope-of-practice limitations.
- ☐ **Convene long-term care, congregate settings, and employer groups** in advance of respiratory virus season to ensure they have access to vaccines for high-risk individuals, including supporting coverage and purchasing concerns.
- ☐ **Work with partners across jurisdictions** to share communications content and materials for previous respiratory season campaigns

Maintain health coverage for vaccines with no cost sharing:

The federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements for children and youth under the age of 21 covered under Medicaid require that all medically necessary vaccines be covered. For other populations covered under Medicaid, vaccine coverage may be linked to ACIP recommendations.

State Medicaid programs may also cover additional vaccines beyond ACIP or CDC recommendations, subject to their State Plans. Cost sharing is prohibited for all services to Medicaid-enrolled children under age 18.

- ☐ **States should review their State Plans** to determine whether and how they are able to 1) cover vaccines outside of the ACIP recommendations, and 2) cover vaccines for off-label use as needed. Depending on the State Plan language, a state may be able to maintain coverage based on prior, more expansive ACIP recommendations without the need for a State Plan Amendment.
- ☐ **States should refer to specialty society recommendations,** including those developed by the American Academy of Pediatrics, to inform clinical guidelines for vaccines for children and youth.
- ☐ **States should partner with Medicaid managed care organizations** to encourage

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communications to providers about coverage and to members on where they can receive vaccines this respiratory virus season; and/or conduct direct member communications if their Medicaid program does not include managed care organizations.

- ☐ **States can look to organizations like ASTHO** for additional resources and toolkits on maximizing vaccine access through Medicaid.

Federal vaccine coverage mandates are tied to the ACIP recommendations, but insurers can choose to go beyond ACIP recommendations. A full analysis of how coverage of vaccines may be affected by federal policy changes can be found in CHC's coverage analysis.

Example actions:

- ☐ **States can encourage payers and employers to cover** respiratory vaccines in line with past years, beyond what is required by any changes to the mandates, with no cost sharing for members who want one.
- ☐ **States can pass legislation to protect coverage of vaccines**. For example, Colorado passed a bill to protect insurance coverage for preventive health care in the event of federal policy changes. Maine recently empowered its state health department to determine which vaccines should be available through a universal vaccination program, rather than tying requirements to ACIP.
- ☐ **States can set an example** for large employers by maintaining coverage for vaccines for all employees through state employee health plans.
- ☐ **States may mandate additional benefits** for Qualified Health Plans, which provide Marketplace coverage; states must fund the cost of any additional benefits.

Ensure access to respiratory season vaccines even if they are no longer covered through Vaccines for Children (VFC) and Section 317:

There has been no announcement of changes to VFC or Section 317 funding at this time. However, VFC federal funding and Section 317 grant funding are not available for non-CDC recommended uses of vaccines, and VFC updates its listing of available vaccines to conform with the CDC schedules. States are able to add protections for vaccine funding by:

- ☐ **States may continue to purchase vaccines** using state funds if they want to purchase vaccines for non-CDC recommended uses.
- ☐ **States may explore universal purchasing** of vaccines which enable state health

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agencies to bulk purchase vaccines and distribute them to providers. For example, New Hampshire funds its universal purchase program through a cooperative approach involving health insurers, providers, state agencies.

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Continued value of seasonal vaccines:

COVID-19, RSV, and flu vaccines 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-19 vaccine, and 40-70% additional protection against hospitalizations and ICU stays.

Beyond respiratory season vaccines:

Proactively addressing access concerns for fall respiratory season will strengthen state infrastructure for potential changes to routine vaccinations.

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 across the state health system.

Sincerely,
The Common Health Coalition

APPENDICES

- Provider Toolkit
- Payer Toolkit
- State tracker
- 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

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Children and Youth.pdf
- 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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