COMMON HEALTH Coalition
*Together For Public Health*

*Last Updated 8.11.25*

# 2025-2026 Respiratory Season Vaccine Planning:

## *Toolkit for States*

The fall 2025 respiratory season is approaching at a time of significant vaccine policy uncertainty, particularly with 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)?

Flu vaccine and RSV immunization guidance is largely similar to last year, 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.

Vaccines are expected to be delivered to clinics as early as late-August/early-September, similar to previous years.

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

| | 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 get nirsevimab or clesrovimab | **Flu:** No thimerosal-containing vaccines<br><br>**RSV:** Clesrovimab is new |
| **Pregnant Women** | **All** | **32-36 weeks gestation** | **Flu:** No thimerosal-containing vaccines |
| **Adults 18-49** | **All** | **See Pregnant Women** | |
| **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 single lifetime dose | **Flu:** No thimerosal-containing vaccines<br><br>**RSV:** Lowered eligibility age to 50 (from 60 y/o) |

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?

Vaccine licensing and federal **recommendations for the updated 2025-2026 COVID-19 vaccines remain in flux**. Last year, ACIP voted on recommendations for the COVID-19 vaccine in June. This year, ACIP has not yet made a recommendation - shifting the timeline for vaccine planning (see this resource for an operational timeline of vaccines from manufacturing to administration), and has not yet scheduled a meeting for September.

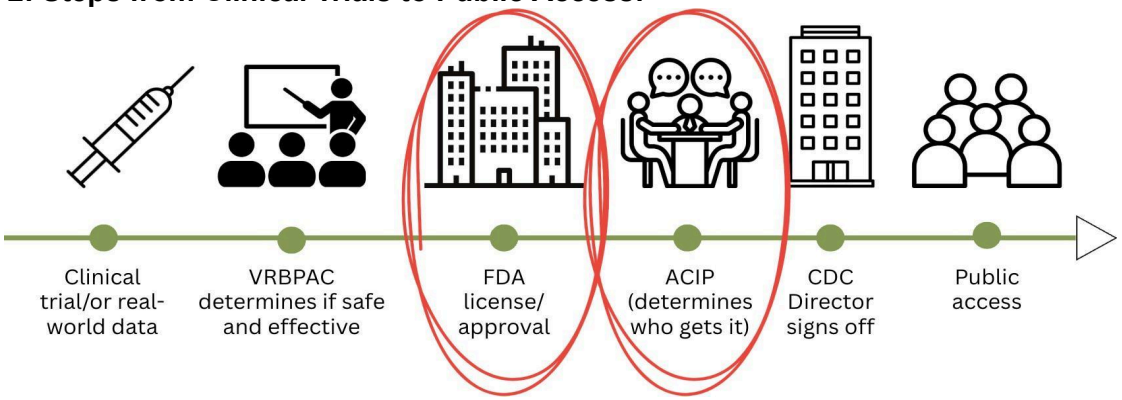
In addition, HHS signaled that this year's COVID-19 vaccines could be labeled by the FDA and recommended by the CDC only for people aged 65+ and people aged 6 months to 64 years old with a high-risk condition. This would mean a 50 year-old without a high-risk condition who

wants a vaccine would need to receive it “off-label” from their provider. Further, what is considered a high-risk condition in this season’s labeling and recommendations is also still unknown, including whether pregnancy will be listed.

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.

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

**Figure 2: Steps from Clinical Trials to Public Access:**




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

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.

If ACIP does not recommend the COVID-19 vaccine for some or all populations, pharmacists' ability to prescribe and administer COVID-19 vaccines will default to their scope of practice as determined by each state's regulations for those populations.

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 recommendations and/or CDC guidance and/or FDA labels. Due to the expected changes, pharmacies, where 90% of adult COVID-19 vaccines were administered last year, could be severely limited in their ability to prescribe and administer vaccines to certain populations this year absent state actions.

*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. This means if ACIP limits its recommendations to only a limited population, then pharmacists, pharmacy technicians, and pharmacy interns could not provide vaccine to non-recommended populations, 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. More information about how administration 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 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.

*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.

For instance, if the FDA label for COVID-19 vaccines approves 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, the physician may choose to administer it "off-label." 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 additionally 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.

**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.

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

## 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 that may go broader than ACIP recommendations
- ☐ Ensure that those who are most at risk for severe disease understand how, where, and when to get vaccinated as soon as they are able to do so.
- ☐ Work with state-based patient organizations and business groups on health to communicate directly to patients and their providers, particularly those at highest risk, about all three vaccines
- ☐ Use 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 providers - including physicians, pharmacists and other non-physician providers - can administer vaccines (especially COVID-19) to anyone who wants one this respiratory virus season include:

- ☐ **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:
  - ☐ 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 issuing a state emergency declaration or order to unlock temporary regulatory flexibilities, including changes to scope of practice authority to go beyond ACIP recommended vaccines. Depending on state emergency declaration requirements, these changes can allow certain health professionals, such as pharmacists, to prescribe or administer vaccines they wouldn't normally be authorized to under standard state law.

  In 2022, NY issued an executive action to expand scope of practice for prescription and administration of the polio vaccine, In 2021, Maryland issued an emergency declaration enabling EMS personnel to administer COVID-19 and flu vaccines.

☐ **Develop standing orders pursuant to emergency declarations/orders 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)

☐ **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 content and materials and reduce overall unnecessary costs.

## 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 clinical guidelines, including those developed by the American Academy of Pediatrics, to inform medical necessity for vaccines for children and youth.
- ☐ States should partner with Medicaid managed care organizations to encourage 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. 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. New York and Massachusetts lawmakers are considering legislation with similar goals of safeguarding coverage of respiratory vaccines. Representatives in Pennsylvania and Michigan are considering introducing similar bills.

- ☐ 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 (which typically adopt ACIP recommendations). In the event that COVID-19 vaccines are no longer covered:

- ☐ 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 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.

## 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.

Last year, 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
- 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
    - 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's founding members are the Alliance of Community Health Plans, AHIP, American Hospital Association, American Medical Association, and Kaiser Permanente. It has since grown to 300+ members. 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, flu, and RSV vaccines. 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.