COMMON HEALTH Coalition
Together For Public Health

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2025-2026 Respiratory Season Vaccine Planning:
Scenario Planning Toolkit for Payers

Dear Partner,

The fall 2025 respiratory season is approaching at a time of significant vaccine policy uncertainty. While access to flu and RSV shots is relatively stable, COVID-19 vaccines are in flux, shaped by potential changes to FDA approvals and ACIP recommendations. For payers, these dynamics increase the risk of potential disruptions in coverage policies and, ultimately, patient access.

To help payers navigate what's ahead, the Common Health Coalition has developed this **Scenario Planning Toolkit** for payers. This packet includes:

- A visual roadmap of the vaccine ecosystem from recommendation to reimbursement
- Scenario-based memos outlining potential outcomes for COVID-19
- Summaries of regulatory and legal implications by payer type
- Actionable guidance and checklists for your internal teams and downstream partners

You can:

- ☐ Use this toolkit to guide operational and benefit planning
- ☐ Share this toolkit with colleagues and partners to help answer their questions

We're here to help ensure a smooth, coordinated, and equitable vaccine rollout this season. Please don't hesitate to reach out with questions, comments, and suggestions on how we can make this iterative toolkit better serve decisionmakers and practitioners across the health system.

Sincerely,

The Common Health Coalition

EXECUTIVE SUMMARY

The 2025–26 respiratory season is shaping up to be unusually complex, particularly for COVID-19 vaccines. A combination of delayed federal decisions and shifting regulatory signals is creating ambiguity and planning uncertainty for health insurers and health plans ("payers") and other actors in the health care system. This could result in gaps in vaccine access, operational bottlenecks, and patient confusion.

To maintain vaccine access, payers should consider preparing for multiple scenarios and continuing broader coverage than may be required to minimize disruptions.

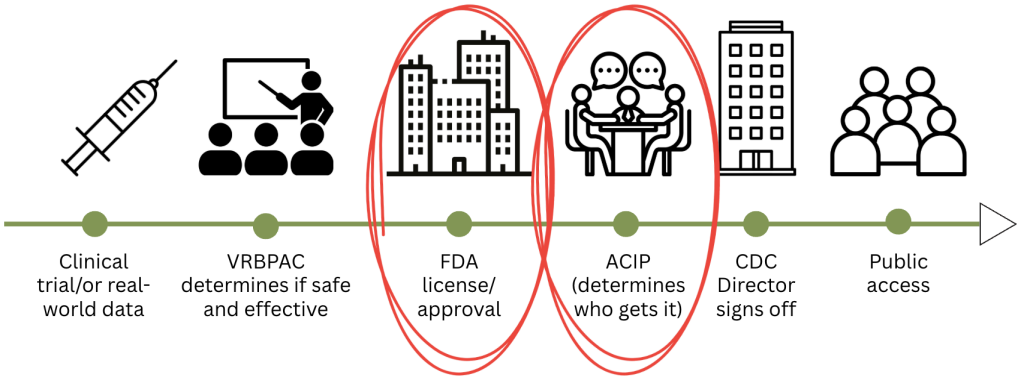
With some exception, influenza vaccine and RSV immunization coverage requirements are generally the same as they were last year, with modest changes. Most notably, HHS approved ACIP's recommendations to transition to thimerosal-free formulations for influenza vaccines, which may influence payer coverage decisions if the recommendation is reflected in the CDC Immunization Schedules.

Questions remain about COVID-19 vaccines — further delineated in scenarios below — which will hinge on actions by ACIP and the CDC (and are not reliant on FDA actions). Regardless, payers can make the choice to cover vaccines with no cost sharing.

Current State of the Coverage Landscape

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.

Figure 1: Steps from Clinical Trials to Public Access:

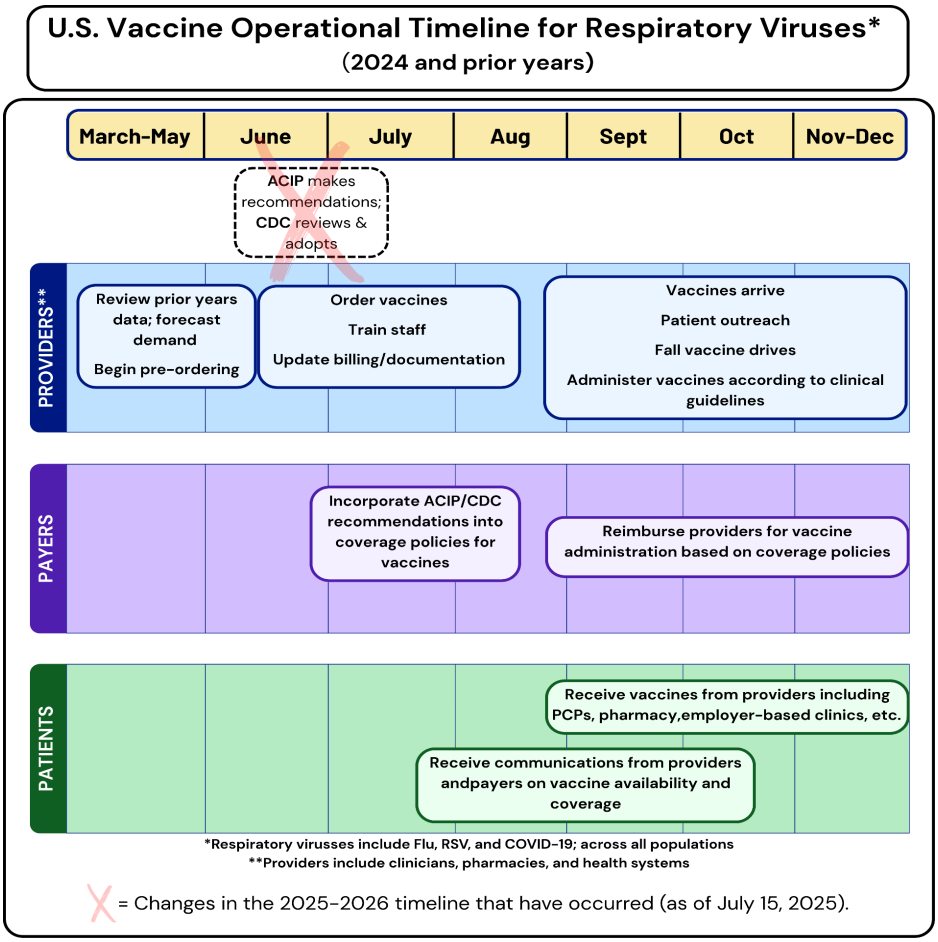


Source: Your Local Epidemiologist

However, heading into the 2025-26 respiratory season, while RSV and flu products have taken the usual route, the U.S. vaccine ecosystem is showing multiple areas of uncertainty for COVID-19 vaccines:

- ***COVID-19*** vaccine licensing and ACIP recommendations remain in limbo, creating legal gray areas for payer coverage. Last season, regulatory clarity emerged by June (ACIP) and August (FDA) (Figure 2, below); this year, as of early August, ACIP hasn't acted, and FDA is showing signs that they may significantly change license terms compared to last year. These delayed key decisions compress the timeframe for all stakeholders, coverage determinations, provider readiness, and public messaging.

Figure 2: Typical Timeline to Operationalize Vaccines



What we don't yet know about COVID-19 vaccines for this season:

- ***Who will the COVID-19 vaccines be recommended for?*** ACIP — an advisory committee to the CDC — has not voted on this season's COVID-19 vaccine recommendations, though the administration has signaled narrowing the recommendation to only people aged 65+ and people ages 6 months to 64 years old with a high-risk condition. It's still unclear which conditions will be listed as high risk. Last year, the ACIP recommendation was made in June, and the clinical guidance was issued in late August. These actions are directly tied to minimum coverage requirements for payers.

- ***How will the COVID-19 vaccines be licensed and labeled?*** FDA has not yet taken its usual regulatory action for the 2025-26 COVID-19 vaccine. The administration signaled that vaccines may be labeled for a narrower population: only people aged 65+ and people aged 6 months to 64 years old with a high-risk condition. Last year, the FDA's 2024-25 COVID-19 vaccine approvals and authorizations happened in late August and for everyone over the age of 6 months. However, FDA labeling and licensing has no impact on minimum coverage requirements for payers.

Regardless of the unanswered questions, What is similar to prior respiratory seasons (so far)?

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

- **Flu:** Similar to prior years, ACIP recommended everyone age 6 months and older receive a flu vaccine. In an update from prior years, ACIP recommended exclusive use of thimerosal-free influenza vaccines.
    - 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.
    - Vaccine manufacturers have confirmed they have the capacity to replace multi-dose vials, which typically contain thimerosal containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted.
- **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.

Figure 3: 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 **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 **RSV:** Lowered eligibility age to 50 (from 60 y/o)

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

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:

- 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 vaccine, and 40%-70% additional protection against hospitalizations and ICU stays.
- In a study completed by Aetna and Milliman in 2021, it found flu vaccinations (vs. unvaccinated) were approximately ROI neutral when accounting for the cost savings

from avoided ED visits and hospitalizations in the general population. In the high risk population, savings were more pronounced driving savings of $45-$141 per person. While continued access to and coverage for vaccines is good healthcare — it's also good business.

- Infants and older adults continue to be most affected by COVID-19 infections, highlighting the importance of vaccination during pregnancy.
    - COVID-19 vaccination during pregnancy builds antibodies that can help protect the baby. Receiving mRNA COVID-19 vaccines during pregnancy can help protect babies younger than age 6 months from hospitalization due to COVID-19. Most babies hospitalized with COVID-19 were born to pregnant women who were not vaccinated during pregnancy. (Source: CDC - Sept. 2024)
    - In prior seasons, infants could not get the vaccine until they were at least 6 months old.

Recommendation:

For the 2025-26 season, payers should provide coverage with no cost sharing for fall respiratory season vaccines to avoid care gaps, avoid costly interventions for acute illness, and reduce member and provider confusion.

Key takeaways:

- The regulatory uncertainty has created confusion among health care providers and stressed the timeline by which vaccine production, ordering, and administration typically take place.
- Thimerosal-free flu vaccinations and RSV immunizations should still be fully covered for the upcoming respiratory season.
- Minimum coverage requirements are **not** linked to FDA updates — only to ACIP recommendations and the CDC Immunization Schedule. Regardless, a health plan can **always** choose to cover more than they are required. If there is a confusion about what is required, a payer can choose to cover vaccines and the administration thereof.
- Payers should provide coverage with no cost sharing for all fall respiratory vaccines and communicate clearly about this affirmatively to members in order to avoid confusion.

SCENARIO PLANNING

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 payers to know about coverage requirements this 2025-26 respiratory virus season:

- If any of the steps listed above are skipped, it creates a lot of uncertainty about coverage requirements (e.g. If CDC changes the immunization schedule without ACIP making a recommendation);
- Coverage requirements for payers typically depend on the CDC immunization schedule when it's based on an ACIP recommendation;
- Coverage requirements do not depend on FDA labeling.

The upshot for payers — minimum coverage requirements are **not** linked to FDA updates — only to ACIP recommendations and the CDC Immunization Schedule. Regardless, a health plan can **always** choose to cover more than they are required. If there is a confusion about what is required, a payer can choose to cover vaccines and the administration thereof.

Below are five scenarios that outline what *can potentially* happen if the federal government does not follow the typical order of operations and the implications for coverage.

Scenario 1: What if ACIP remains quiet and does not provide recommendations for COVID-19 vaccines?

If ACIP does not make recommendations for 2025-26 COVID-19 vaccines, it would create uncertainty about whether there is a recommendation in effect for the current COVID-19 strain. It is unclear whether CDC updates to the immunization schedules, made without an ACIP recommendation, have a legal impact on the mandated coverage of COVID-19 vaccines.

Implications for Payers: Federal law requires no-cost coverage in commercial health plans *only* for vaccines on the CDC's Immunization Schedules, but health plans, including Medicaid programs and commercial insurance, can choose to cover additional vaccines beyond that

baseline. Medicare Part B, including Medicare Advantage, and Medicaid coverage for children cover the COVID-19 vaccines without cost.

Scenario 2: What if CDC Immunization Schedules are modified so that the 2025-26 COVID-19 vaccine is recommended only for age 65 and older, and high-risk younger adults, but ACIP has not taken action on the 2025-26 vaccine?

The ordinary process is for ACIP to make a recommendation and then CDC to adopt the recommendation in the Immunization Schedules. It is not clear whether changes to the Immunization Schedules that do not originate with ACIP effectively change coverage mandates for commercial health plans.

Implications for Payers: Commercial health plans and Medicaid programs can elect to cover COVID-19 vaccines for additional populations, especially since it may be unclear whether a recommendation made by CDC without ACIP involvement is valid.

Scenario 3: What if the FDA and ACIP/CDC only approve the COVID-19 vaccine for 65+ and high-risk?

Coverage depends on CDC Immunization Schedules, not FDA labeling. Commercial health plans and Medicaid would be required to cover only for the CDC recommended populations. Part B, including Medicare Advantage, and Medicaid coverage for children is not limited to CDC recommended populations. Health care providers who are authorized under state law to prescribe, dispense, and administer such a vaccine can continue to do so even after the FDA restricts the label. However, off-label administration of vaccines may affect provider liability.

For payers there is not a substantial liability risk for covering something off-label. Plans typically have limited liability exposure for clinical decisions, which are made independently by licensed providers. Courts have generally declined to hold insurers responsible for injuries resulting from a provider's exercise of medical judgment, particularly when the insurer's role is limited to financing the service and does not control or interfere with the provider's medical judgment.

Implications for Payers: Payers can elect to cover for populations beyond the minimum required under the ACIP recommendations.The liability risk of a plan or insurer to cover a vaccine off-label is not substantial.

Scenario 4: What if the FDA approves the vaccine for 65+ and high-risk people and CDC does not recommend the COVID-19 vaccine for anyone?

In this scenario, if someone is under the age of 65 and does not have a high-risk condition, they could still receive the COVID-19 vaccine if they want the vaccine and if their health care provider advises that the vaccine is appropriate for them. This situation would be considered an "off-label" use of the vaccine, which is when a vaccine is used in a way other than those described on the FDA-approved label. Health care providers who are authorized under state law to prescribe, dispense, and administer such a vaccine can continue to do so even after the FDA restricts the label. However, off-label administration of vaccines may affect provider liability.

Implications for Payers: Federal law requires no-cost coverage *only* for vaccines on the CDC's Immunization Schedules, but health plans, including Medicaid programs and commercial insurance, can choose to cover additional vaccines beyond that baseline. Health plans can choose to cover, without cost-sharing, COVID-19 vaccines delivered off-label. Further, Medicare Advantage and Medicaid coverage for children is not limited to CDC/ACIP recommendations.

Scenario 5: What if pregnant people are not specifically called out as an eligible group under "high-risk" for the COVID-19 vaccine?

If the CDC does not include guidance on whether pregnancy is a high-risk condition for COVID-19 vaccines, it does not mean that pregnant individuals are unable to receive the COVID-19 vaccine. Pregnant individuals can continue to receive COVID-19 vaccines in coordination with their health care provider, which may be considered an off-label use of the vaccine if the individual does not have other risk factors.

Implications for Payers: Insurers may continue to provide coverage for COVID-19 vaccines for pregnant people, both ensuring access for this higher-risk population and in light of uncertainty absent formal ACIP action. Federal law requires no-cost coverage *only* for vaccines on the CDC's Immunization Schedules, but health plans, including Medicaid programs and commercial insurance, can choose to cover additional vaccines beyond that baseline.

Scenario 6: What if restrictions limit the ability of certain health care providers to administer vaccines?

Changes to either FDA labeling or CDC schedules may limit the ability of certain health care providers — including pharmacists or those operating under standing orders in hospitals — to prescribe, dispense, and administer vaccines (to the extent that they are not independently authorized to do so under state law). Pharmacies or drug stores were the most common settings for flu (48%), updated COVID-19 (71.5%), and RSV immunizations (81.7%).

Implications for Payers: If these providers are no longer authorized to dispense and administer vaccines, payers will likely have to update their processes to review and update their claims systems accordingly.

ACTION CHECKLIST FOR PAYERS

- ☐ Proceed in alignment with past years for RSV immunizations and flu vaccines, for which recommendations remain largely unchanged from last year.
- ☐ Monitor ACIP/CDC updates on COVID-19 licensures and recommendations.
- ☐ Consider maintaining broad coverage without cost sharing for all vaccine types, including for at-risk groups (e.g., pregnant people).
- ☐ Communicate clearly with provider networks about your current coverage and reimbursement policies for COVID-19 and flu vaccines, and RSV immunizations.

APPENDICES

- 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 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.