



Department of Health and Human Services
Centers for Disease Control and Prevention
Docket No. CDC-2025-0024

June 25-26, 2025 ACIP Meeting Notice

[Federal Register :: Meeting of the Advisory Committee on Immunization Practices](#)

The Shapiro Administration, on behalf of the Commonwealth of Pennsylvania, appreciates the opportunity to submit public comment for the Advisory Committee on Immunization Practices (ACIP) meeting scheduled for June 25, 2025. We thank ACIP for its leadership and science-based recommendations during the April 2025 meeting. At the upcoming June meeting, ACIP members will vote on influenza vaccines containing thimerosal and respiratory syncytial virus (RSV) immunizations for maternal and pediatric audiences, as well as RSV immunizations for the Vaccines for Children (VFC) program, and will discuss the Measles, Mumps, Rubella, Varicella (MMR-V) vaccination recommendation in children younger than 5 years.

The Pennsylvania Department of Health (PA DOH) and the Pennsylvania Insurance Department strongly urge ACIP to recommend all vaccines listed for discussion on the June agenda and urge the Centers for Disease Control and Prevention (CDC) and Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. to approve and implement them without delay. We further urge ACIP to uphold the integrity of the immunization schedule by opposing any rollback of current vaccine recommendations, which would jeopardize decades of progress in protecting public health.

PA disease burden and vaccination rates for diseases listed for ACIP meeting

ACIP has a unique responsibility within the federal government to recommend the vaccinations used to protect the public health of our nation. While our country is not a monolith, our Commonwealth, like our sister states, has faced the same burden of the diseases for which you are about to consider vaccinations.

Influenza

In Pennsylvania, influenza vaccination coverage is monitored through dose administration data:

- 2022–2023 season: 3.73 million influenza vaccine doses were administered
- 2023–2024 season: 3.37 million doses
- 2024–2025 season to date: 3.34 million doses

This downward trend represents a roughly 2.7% population-level decline over two years. During the current season, Pennsylvania saw a single-week peak of 28,991 influenza cases—the highest in several years. Case monitoring confirms this trend:

- Influenza A cases have reached over 208,000, surpassing previous seasons
- Influenza B cases, while down from last year's spike, remain elevated compared to 2022–2023

This rise in cases puts significant pressure on Pennsylvania's hospitals and emergency departments. Vaccination is the most effective way to prevent illness and reduce emergency visits and hospitalizations. Weakening influenza recommendations would erode progress and increase preventable suffering. Maintaining consistent and clear vaccination guidance is critical for both protecting public health in Pennsylvania and preserving patient confidence in science-based vaccines.

RSV

RSV remains a serious threat to both older adults and newborns and infants, causing significant illness, hospitalizations, and deaths each year. Until recently, no RSV immunizations were available beyond limited monoclonal antibody use in premature infants. In just the past two years, the development of maternal and adult RSV vaccines and infant monoclonal antibodies has been a major public health advancement.

Pennsylvania data shows strong uptake and need:

- Adults 60+: nearly 600,000 RSV vaccine doses administered
- Pregnant individuals (ages 15–50): 24,000 doses, with the current season's uptake nearly three times higher than the previous year
- Children under 19 months: nearly 100,000 monoclonal antibody doses, more than double last season

Despite these gains, RSV continues to cause high disease counts in Pennsylvania:

- RSV case counts declined from 58,297 (2022–2023) to 48,101 (2024–2025 to date)
- Seasonal rates remain elevated: 448.35 (2022–2023) to 369.93 (2024–2025 to date) per 100,000 population

Hospitalization rates are especially high among young children and older adults. RSV often leads to ICU admissions, long hospital stays, and high costs. A retrospective PA analysis using 2000–2023 Healthcare Cost Containment Council data found:

- 94,884 RSV-associated hospitalizations, with annual rates between 287 and 8,034
- Children aged 0–4 years had the highest burden: 435 hospitalizations per 100,000 population

Post-implementation monitoring in the U.S. and abroad shows that RSV immunization, especially with Nirsevimab, reduces hospitalizations by up to 90% in infants and by ~50% overall. No deaths have been reported among Nirsevimab recipients, and serious adverse events match those in unvaccinated groups. CDC and ACIP should continue to recommend RSV products for the 2025–2026 season and approve their inclusion in the immunization schedule. VFC availability is critical to ensure all families—regardless of income—can access protection ahead of the fall respiratory season.

Measles

Measles cases are nearing a 25-year high in the United States, threatening the elimination status the country achieved in 2000. As of June 12, 2025, cases have been reported in 35 jurisdictions, including Pennsylvania. The recent resurgence—including the tragic deaths of two children—underscores the consequences of declining vaccination rates and the importance of maintaining herd immunity.

In Pennsylvania, measles cases have increased steadily over the past three years. While no cases were reported in 2022, the number rose to nine in 2023 and four in 2024. Alarming, 15 cases have already been reported in 2025. This upward trend reinforces the urgent need to ensure children are vaccinated against this highly contagious and preventable disease.

Vaccine Access Protection

Ensuring broad and equitable access to pediatric vaccines is essential to protecting the health of our children and the communities in which they live. Vaccines are one of the most effective tools we have to prevent serious illness, hospitalization, and long-term health complications among infants, children, and adolescents. Any barriers to accessing these life-saving immunizations—whether logistical, financial, or policy-related—pose a direct threat to public health and disproportionately impact our most vulnerable families.

On May 20, 2025, the FDA published a [journal article](#) stating that for individuals ages 6 months to 65 without risk factors for severe COVID-19, randomized controlled trials evaluating clinical outcomes would now be required before approving Biologics License Applications. This shift in guidance bypassed standard advisory committee review and public discussion. Compounding the confusion, HHS Secretary Kennedy subsequently announced the removal of COVID-19 vaccine recommendations for healthy children and pregnant women—again without ACIP consultation or formal advisory input.

These sudden changes disregard established processes and undermine the role of science-based deliberation in national vaccine policy. Removing recommendations outside of an established process also raises the risk of coverage gaps and public hesitancy.

COVID-19, along with RSV, influenza, and HPV, remains a preventable cause of serious illness in children. Since its introduction, the COVID-19 vaccine has been rigorously monitored for safety and effectiveness. Both the CDC and the American Academy of Pediatrics (AAP) continue to recommend routine COVID-19 vaccination for children and adolescents. The AAP emphasizes that.¹

- COVID-19 vaccination is critical to protecting children from acute illness and long-term effects such as MIS-C and long COVID
- Vaccines are safe and effective across all pediatric age groups
- Routine immunization supports broader public health goals, including reducing school absenteeism and family burden

CDC data reinforces this guidance: half of all children hospitalized with COVID-19 had no underlying medical conditions, demonstrating that healthy children are still at risk. Yet vaccine uptake remains low²:

- 6% of children ages 6 months–4 years
- 13% of children ages 5–11
- 18% of adolescents ages 12–17
- 23% of adults

¹ Committee on Infectious Diseases; COVID-19 Vaccines in Infants, Children, and

Adolescents. *Pediatrics* August 2022; 150 (3): e2022058700. 10.1542/peds.2022-058700

² <https://publications.aap.org/aapnews/news/29373/CDC-recommends-updated-COVID-19-vaccines-for>

These low rates reflect rising vaccine hesitancy, fueled in part by inconsistent guidance. Policy changes made without clear, evidence-based justification further undermine parental confidence and reduce the likelihood that families will seek out vaccines—even when available.

It is also important to note that no state requires COVID-19 vaccination for school or childcare entry, meaning the decision to vaccinate children remains entirely with parents and their healthcare providers. Removing the vaccine from the schedule or undermining its recommendation effectively strips away that choice—by disincentivizing insurers from covering it and creating barriers to provider delivery.

The Shapiro Administration stands firmly committed to protecting every child’s right to protection from preventable diseases and calls on ACIP, CDC, and HHS leadership to uphold their duty to safeguard children’s health. We strongly urge the ACIP to support continued recommendations for all pediatric vaccines under review at the June 2025 meeting, and to reaffirm the immunization schedule as a critical, science-based tool for promoting health equity and disease prevention.

Consequences of Delay

If ACIP fails to recommend the aforementioned vaccines for adult and pediatric use, or worse, recommends the removal of previously approved vaccines from the current vaccination schedule, the consequences will be far-reaching and severe, with harm that may be both immediate and enduring.

Risks to Insurance Coverage

Insurance companies across the country, including in Pennsylvania, will no longer be required to cover these vaccines as routine preventive care with no cost-sharing. Routine vaccines are likely to become subject to cost-sharing under a person’s health insurance policy or dropped from coverage altogether. This shift would create new financial and administrative barriers for families, especially those with limited resources who are enrolled in high-deductible plans. The added cost would likely serve as a deterrent for people wanting to stay up-to-date on their vaccinations for fear of the out-of-pocket cost, leading many to delay or forgo altogether important immunizations out of concern for the cost.

The rising cost of health care will not be stemmed by the removal of the listed vaccines as preventive care. On the contrary, lower vaccination rates lead to increased transmission of illness, more frequent and severe outbreaks, and an overall sicker population that is more likely to utilize their health benefits. This will increase long-term medical spending, burden public health infrastructure, and increase insurance costs for all.

Risks to Access

It is critical that ACIP continue to support the recommendation of pediatric vaccinations, and that the CDC, or HHS in its place, swiftly approve these recommendations to maintain access for children and their families. Many children receive their immunizations through programs like the VFC program. In the 2024-2025 respiratory season, PA DOH's Immunizations’ team distributed 260,000 doses of the influenza vaccine and 27,000 doses of Nirsevimab to Pennsylvania providers for VFC in record time. However, the VFC program cannot include new vaccines without CDC approval. Without that formal step, even vaccines that ACIP has deemed safe and effective cannot be distributed or administered through public programs—creating an unnecessary and potentially harmful gap in access for those uninsured or underinsured. To prevent this, it is essential that ACIP recommend *all* vaccines listed on its June agenda, ensuring that no

critical immunizations are left in limbo and that all children, regardless of income or insurance status, have access to the full range of protection.

Delays in approval by the CDC also create confusion and uncertainty for health care providers, who cannot begin offering newly recommended vaccines without CDC's final endorsement and related billing guidance. This limits provider readiness and disrupts planning during key immunization periods such as back-to-school or respiratory virus season. Moreover, access delays disproportionately impact families in underserved and low-income communities who depend most heavily on public health programs.

Risks to Disease Transmission

When vaccines are not promptly approved and made available following ACIP recommendations, children remain vulnerable to preventable infectious diseases during critical exposure periods—such as the start of the school year or seasonal surges in respiratory illnesses. Pennsylvania's current Communicable and Noncommunicable Disease [regulations](#) refers to ACIP recommendations for immunization requirements for children in childcare group settings. Delays in vaccine approval for highly contagious diseases can severely disrupt childcare environments, undermining their operations and compromising the consistent care and well-being of children.

Influenza and RSV are also a leading cause of missed childcare, particularly among infants and toddlers. When children become ill, working parents are often required to remain home, leading to lost income, increased employer burden, and childcare instability. These consequences disproportionately affect low-income families without paid leave protections.³

The longer the delay, the more likely it is that cases of vaccine-preventable diseases will increase—particularly among children who are not yet immunized and in high-risk settings such as schools and childcare centers.

Economic Risks

Nationally, the economic burden of adult influenza is estimated at \$11.2 billion per year, due to direct medical costs and productivity losses from missed work. Reductions in vaccination uptake threaten not only public health but also economic stability for families and employers.⁴

A delay in adopting the ACIP vaccine recommendations pose significant economic consequences, particularly given the state's role as a national hub for biomedical innovations. GlaxoSmithKline (GSK), one of the world's largest biopharmaceutical companies, maintains its U.S. headquarters in Philadelphia, and operates several major facilities spanning the state. Notably, an estimated one in four vaccines administered in the United States are supplied by GSK's Marietta location in Lancaster County. With Governor Shapiro's support, GSK plans to invest up to \$800 million to expand research, development, and manufacturing capacity at this site—an initiative projected to create at least 200 new jobs and retain over 4,600 existing positions. Merck also manufactures and packages many of its vaccines in its West Point, PA, location and

³ <https://pmc.ncbi.nlm.nih.gov/articles/PMC5410714/>

⁴ <https://pmc.ncbi.nlm.nih.gov/articles/PMC8983919/>

also conducts vital vaccine research and development at this site. Pennsylvania is also home to some of the other leading biopharmaceutical companies, including Sanofi, AstraZeneca, and Eli Lilly.

Failure to promptly update federal vaccine standards would force biomedical companies operating within Pennsylvania to navigate a fragmented landscape, incurring higher operational costs in order to maintain alignment between state requirements and unclear federal standards. As a result, these added complexities and costs could drive these companies to change their business practices in less efficient ways, placing them at a competitive disadvantage and undermining the state's attractiveness for investment and innovation. In the long term, such inefficiencies could stifle Pennsylvania's economic growth and diminish its leadership in the biomedical sector.

Conclusion

Protecting the health and well-being of Pennsylvanians is a top priority for the Shapiro Administration. Delays in the acceptance and implementation of vaccine recommendations—particularly those endorsed by the scientific and medical experts of ACIP—can have immediate and detrimental consequences for communities across our Commonwealth. As ACIP deliberates on the June 2025 agenda, we urge the committee to continue to recommend the safe and effective vaccinations that are listed for consideration, continue to uphold the integrity of the vaccination schedule by ensuring thoughtful recommendation of vaccinations that protect children, their families, and our communities, and swift approval by the CDC/HHS of ACIP's recommendations to ensure timely coverage and access for all. Upholding this process will safeguard public health, reduce preventable disease, and reinforce public trust in the nation's immunization system.

Sincerely,



Michael Humphreys
Pennsylvania Insurance Commissioner



Debra Bogen, MD, FAAP
Pennsylvania Secretary of Health