American Lung Association.

September 18, 2026

The Honorable Robert F. Kennedy Jr.
Secretary
Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making [HHS-OS-2026-0332]

Dear Secretary Kennedy:

The American Lung Association appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Request for Information regarding categories used in federal immunization recommendations and the role of shared clinical decision-making.

The American Lung Association is the nation's oldest voluntary public health organization and represents the more than 34 million people in the United States living with lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Vaccines are critical for protecting public health and remain one of the most effective tools to protect people from serious illnesses, hospitalization and death. This is especially true for people with serious health conditions, including lung disease, who are at increased risk of severe illness from vaccine-preventable diseases. The Lung Association is committed to raising public awareness of infectious respiratory diseases and immunization through education that counters misinformation and supports informed health decisions, as well as advocacy for policies that protect cost-free coverage of vaccines, remove barriers to vaccination and improve immunization rates.

Recent public health trends underscore the importance of sustained efforts to support immunization and protect access to vaccines. Measles cases currently are at a 35-year high,[1] and the 2024-25 flu season was the most severe in over a decade.[2] Additionally, vaccination rates for these conditions are declining.[3,4] Changing immunization categories or recommendations without a transparent, evidence-based process creates confusion, undermines public trust and creates new barriers to accessing vaccines, which will result in lower vaccination rates and increase the risk of spread of vaccine-preventable diseases.

The Lung Association urges HHS to maintain the established evidence-based process underlying federal immunization recommendations to ensure that any changes to vaccine categories or recommendations are made through a transparent, scientifically rigorous process informed by expert review.

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The United States has a longstanding, congressionally established process for developing immunization recommendations through the Advisory Committee on Immunization Practices (ACIP), which uses the Evidence-to-Recommendations (EtR) framework and GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach. These evidence-based frameworks provide a structured, transparent foundation for evaluating the certainty of evidence, disease burden, benefits and risks, feasibility and other factors before recommendations are made to the Centers for Disease Control and Prevention (CDC). Public meetings, open scientific discussions and regular reassessment of recommendations ensure accountability and promote public trust in ACIP's evidence-based recommendations.

The recommendations made by ACIP have critical implications for vaccine access, affecting which vaccines must be covered by most public and private insurers. Most private insurers are required to provide coverage for ACIP-recommended vaccines, as are Medicare Part D and state Medicaid programs. The Vaccines for Children program, which makes vaccines available to children who might not have access, is also required to provide ACIP-recommended vaccines at no cost.

When changes to immunization recommendations or categories are made without following the rigorous evidence-to-recommendations process, the public health consequences can be grave. Even minor changes in vaccine recommendations can lead to a reduction or elimination of coverage for a particular vaccine, driving up the vaccine's cost for patients and leading to uncertainty and confusion about which vaccines are covered and how effective they are, despite the available evidence. In addition, state-based scope of practice rules and pharmacist standing orders are often tied to ACIP recommendations. Altering the recommendations can result in pharmacists and pharmacy technicians no longer able to dispense or administer certain vaccines at the places where the majority of adults receive their respiratory season immunizations.[5,6,7] This can, in turn, lead to a decline in vaccine uptake,[8] which has particularly severe consequences for people with chronic lung disease and others at increased risk of severe illness from vaccine-preventable diseases. Patients who are especially vulnerable to infectious vaccine-preventable diseases rely heavily on broad community vaccination to safely participate in daily life activities such as attending school, working outside the home and seeking medical care.

In January 2026, when CDC announced significant changes to the childhood immunization schedule, including moving routine influenza vaccination for all children to the shared clinical decision-making (SCDM) category, these changes were made without going through the rigorous, scientific review process that has guided U.S. immunization recommendations for decades and in stark contrast to the evidence about the severe burden of influenza on America's health. Data shows that during the 2024-2025 flu season, approximately half of children who died from influenza had an underlying medical condition, and 89% were not fully vaccinated.[9] Flu vaccination is estimated to have prevented up to 360,000 hospitalizations and 39,000 deaths.[10] It is critical that changes to immunization recommendations and categories follow the rigorous evidence-to-recommendations process, grounded in the latest science.

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The Lung Association agrees that rebuilding public confidence in vaccines is an important public health priority. However, the path to greater confidence is a transparent, consistent, evidence-based process that the public can understand and trust. HHS should follow the existing ACIP, EtR and GRADE framework and ensure that changes to immunization recommendations and categories are supported by a public explanation of the evidence and rationale. In addition, HHS should ensure that ACIP follows a transparent process for appointing members, includes members with relevant vaccine and public health expertise, and ensures meaningful participation and collaboration within ACIP work groups. HHS should also invest in education for providers and patients to ensure they have clear information about immunization recommendations and the evidence underlying the recommendations.

Finally, access must remain at the forefront of any discussion of immunization recommendations, and HHS should ensure that recommendation categories do not create new barriers to vaccination for patients. Maintaining a transparent, evidenced-based process is essential to preserving access, minimizing confusion among patients and providers, improving public confidence in immunization recommendations and protecting public health.

Thank you for the opportunity to comment on this important issue.

Sincerely,

American Lung Association

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[4] CDC. (2026, August 17). Vaccination Coverage and Exemptions among Kindergartners. https://www.cdc.gov/schoolvaxview/data/index.html
[5] CDC. (2026, March 25). Influenza Vaccinations Administered in Pharmacies and Physician Medical Offices*, Adults, United States. https://www.cdc.gov/fluvaxview/dashboard/adult-vaccinations-administered.html
[6] CDC. (2026, March 25). Respiratory Syncytial Virus (RSV) Vaccinations Administered in Pharmacies and Physician Medical Offices*, Adults, United States. https://www.cdc.gov/rsvvaxview/dashboard/adult-vaccinations-administered.html
[7] CDC. (2026, March 25). COVID-19 Vaccinations Administered in Pharmacies and Medical Offices*, Adults 18 Years and Older, United States. https://www.cdc.gov/covidvaxview/weekly-dashboard/vaccinations-administered-pharmacies-medical.html
[8] Artiga, S., Ubri, P., Zur, J. (2017). The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings. KFF. https://www.kff.org/medicaid/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/
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[10] CDC. (2026, September 26). Influenza Activity in the United States during the 2024-25 Season and Composition of the 2025-26 Influenza Vaccine. https://www.cdc.gov/flu/whats-new/2025-2026-influenza-activity.html