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September 18, 2026

Robert F. Kennedy, Jr
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Docket No. HHS-OS-2026-0332: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Dear Secretary Kennedy:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Department of Health and Human Services (HHS) for the opportunity to provide input to the Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making. APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to create a safer world through the prevention of infection.

General Comments

APIC represents IPs who manage the operational consequences of vaccine-preventable disease in hospitals, ambulatory practices, long-term care, and other healthcare settings. Our members conduct the exposure investigations, contact tracing, post-exposure prophylaxis, staff furloughs, cohorting, and unit closures that follow a single measles, pertussis, or varicella exposure in a healthcare facility. We comment from that operational vantage point.

When vaccine-preventable diseases are transmitted in healthcare settings, they reach patients who cannot be protected by vaccination — neonates, transplant and oncology patients, and those with primary or acquired immunodeficiency. Any policy change that reduces population-level coverage transfers risk directly to these vulnerable patients and to the facilities that care for them.

The President's Executive Order implies that its recommendations reducing the number of required vaccines provide more information and options for parents making immunization decisions for their children. However, informed consent already occurs at the point of care through required CDC Vaccine Information Statements and clinician counseling that educate parents on the benefits of the vaccine along with any potential side effects. Recategorizing well-established vaccines does not add information; it removes a clear clinical recommendation and replaces it with ambiguity. Decades of scientific evidence shows that our vaccines are safe and effective, and high rates of immunization protect both individuals and the community from disease outbreaks.

Section B: Potential Additional or Modified Categories and Timing and Frequency Recommendations

5. What can be learned from the recommendation structures of peer bodies abroad, such as global or international health bodies of peer regulatory bodies?

The President's Executive Order stating "the United States currently recommends more childhood vaccines than any peer nation, including more than twice as many vaccine doses as some European nations" is misleading to the public. The United States' recommended childhood and adolescent vaccinations cover approximately 16 diseases, which is generally consistent with other industrialized nations. Most of those countries recommend protection against 11-15 diseases, with Denmark as a notable exception. The United States should not compare itself to a small country with a homogenous population that has access to universal healthcare and lower burden of certain diseases. For example, Denmark does not universally vaccinate newborns for hepatitis B; however, their disease burden is lower with 1.9 chronic hepatitis B cases per 100,000 population.[1] In contrast, up to 2.4 million people in the United States are estimated to have hepatitis B, and about 50% are unaware of their infection. In the United States the birth dose of hepatitis B vaccine serves as an important safety net protecting infants from potential household or community exposure.[2,3] Differences such as these demonstrate the need for careful evaluation when comparing recommendations between countries.

7. If categories remain the same, what modifications to timing and frequency of vaccine administration or guidance on administering vaccines individually versus at a single visit would help parents and clinicians understand that a vaccine is recommended while affording flexibility in timing of administration?

The proposed childhood vaccine updates are confusing, misleading, and put more burden on busy families who now have to go to more doctor visits for administrations that have been made more complicated, labor intensive, and hard for kids who now have to get more

shots. Separate visits do not change the number of antigens a child receives — only the number of opportunities to miss a dose. Missed opportunities are among the best-documented drivers of under-vaccination in the United States, and each additional visit adds transportation, childcare, missed work, and cost-sharing barriers while extending the interval of susceptibility.

Section C: Shared Clinical Decision-Making: Meaning, Risks, and Benefits

11. What are the risks of an SCDM category, including confusion, reduced access or uptake, and time burdens in practice, and what evidence supports them?

When it comes to childhood immunizations, shared clinical decision-making should be used with caution. The vaccines that the EO proposes to include under this category may mislead parents/guardians into believing that these diseases pose little risk and diminishes the importance of vaccination in protecting public health. Using the influenza vaccination included in this category as an example:

- Children younger than 5 years old, especially younger than 2, are at higher risk of developing serious flu complications. Immunization reduces their risk of hospitalization or death if they become ill.
- Children infected with the flu can also spread the virus to vulnerable family members. Immunization helps reduce household spread and spread within the community.[4]

Section E: Trust and Communication

17. What communication practices should accompany vaccine recommendations so that they earn and keep public trust, and what lessons from COVID–19-era communication should inform them?

Communications regarding vaccine recommendations should be based on the available scientific evidence and emphasize vaccine efficacy and safety. Conveying accurate information is important to improve public confidence in vaccines and increase public trust. Communications from HHS, CDC, etc., and their leaders should remain consistent and promote the benefit of the recommended vaccine. The COVID-19 pandemic highlighted the need for federal agencies to develop effective strategies to counter vaccine misinformation, which can rapidly proliferate through social media.

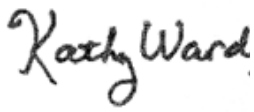
Additionally, changes to long-standing vaccine recommendations that have proven to be safe and effective over many decades should include truthful explanations of the need for the changes. For example, although the Executive Order mandates separating the combined measles, mumps, rubella (MMR) vaccine into three single-disease shots administered at separate medical visits, no published evidence demonstrates a safety benefit to separating administration of the MMR vaccine into separate shots, and no U.S.-licensed monovalent measles, mumps, or rubella vaccines exist. The manufacturer has confirmed both points and noted that using individual components increases injections and may result in delayed or missed immunizations. Claims of new supporting evidence have not been validated. Separation would convert two injections into six at a time when U.S. measles activity is at its highest level in more than three decades.[5,6]

18. How should the Department measure whether a recommendation framework is succeeding, and what data should be collected and published for that purpose?
APIC strongly supports defined, published metrics with a confirmed review cycle (identified with the approval of the Executive Order). We recommend the Department collect and publish, at minimum:

- Vaccine-specific coverage by age range and stratified by category
- Missed-opportunity rates and on-time series completion
- Incidence, hospitalization, ICU admission, and mortality for each vaccine-preventable disease
- Outbreak frequency, size, and duration
- Healthcare-associated transmission events and associated exposure investigations

APIC appreciates the opportunity to respond to the request for information, and we look forward to working with HHS to ensure that childhood vaccine recommendations continue to meet the goal of providing accurate information to protect all children and their communities from transmission of vaccine-preventable diseases.

Sincerely,



Kathy Ward, RN, BSN, MPH, FAPIC, CIC
2026 APIC President

[1] Ministry of Health and Ecclesiastical Affairs of Denmark. “Annual Report on Hepatitis B in Denmark, 2024,” *Statens Serum Institut*. December 23, 2025. Accessed 9/16/26 at https://en.ssi.dk/surveillance-and-preparedness/surveillance-in-denmark/annual-reports-on-disease-incidence/h/hepatitis-b-2024.

[2] U.S. Centers for Disease Control and Prevention. “Hepatitis B Birth Dose Vaccination: Report to the Advisory Committee for Immunization Practices, September 18, 2025. Accessed September 16, 2026 at https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/02-langer-hep-b-508.pdf

[3] Ulrich, A., Fleming, D., et.al. “Universal Hepatitis B Vaccination at Birth: Safety, Effectiveness, and Public Health Impact.” December 2, 2025. *Vaccine Integrity Project and University of Minnesota Center for Infectious Disease Research and Policy (CIDRAP),* Accessed September 16, 2026 at https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hepatitis%20B%20Vaccination%20at%20Birth%202Dec2025.pdf

[4] U.S. Centers for Disease Control and Prevention. “Flu and Children” web page. Accessed September 9, 2026 at https://www.cdc.gov/flu/highrisk/children.html.

[5] Maman, K., Zöllner, Y., Greco, D., Duru, G., Sendyona, S., & Remy, V. (2015). The value of childhood combination vaccines: From beliefs to evidence. *Human Vaccines & Immunotherapeutics*, *11*(9), 2132–2141. Accessed September 16, 2026 at https://doi.org/10.1080/21645515.2015.1044180.

[6] Dodd D. Benefits of combination vaccines: effective vaccination on a simplified schedule. Am J Manag Care. 2003 Jan;9(1 Suppl):S6-12. PMID: 12564784.