



September 18, 2026

The Honorable Robert Kennedy
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201
Submitted electronically via Regulations.gov

RE: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Dear Secretary Kennedy:

The American Academy of Nursing (Academy) is pleased to offer the following comments in response to the Department of Health and Human Services' (DHHS) August 24, 2026, request for information on categories used in federal vaccine recommendations and the role of shared clinical decision-making.¹ The Academy is an honorific society and policy organization with more than 3,400 Fellows who represents nursing's most accomplished leaders in policy, research, administration, practice, and academia. Collectively with our Fellows and partners, the Academy aims to create solutions that matter, inspire innovative change that propels transformation, and envision a healthier future for all people.

The Academy has long supported immunization as a critical intervention to reduce the incidence of vaccine-preventable disease and promote healthy lives for all people.^{2,3,4} Declining immunization rates due to vaccine hesitancy, vaccine-related misinformation, as well as coverage, access, and financial barriers⁵ presents a public health crisis. We must reduce the spread and resurgence of vaccine-preventable diseases and prevent higher rates of morbidity and mortality across the lifespan. Before offering our response to the questions posed in the RFI, the Academy believes it must first address the preceding Executive Order (EO), that it references and spurred this inquiry from HHS.

Immunization Schedule Recommendations Must Be Evidence Based and Transparent

The recent Executive Order, *Delivering Gold Standard Childhood Vaccine Recommendations for Americans*⁶ is deeply concerning. Though the EO states that "it is the policy of the United States that the core childhood vaccine recommendations should be aligned with scientific evidence," the recommendations outlined in the EO are not grounded in new or existing research that would present a basis for diverging from current, evidence-based practice by trusted review boards, academies, and scientifically based health organizations. The safety and efficacy of immunizations are vigorously studied and well-established. All vaccines used in the United States are required to go through years of rigorous and extensive safety testing before they are licensed by the US Food

and Drug Administration (FDA). The FDA and the Centers for Disease Control and Prevention (CDC) work with healthcare professionals to monitor the safety of vaccines, including any adverse events, and especially rare events not identified in pre-licensure study trials. There are currently three systems used to monitor the safety of vaccines after they are licensed and used in the US.⁷ Extensive research has consistently demonstrated the safety and efficacy of vaccines as well as the vaccine schedule recommended by the American Academy of Pediatrics (AAP) for children and adolescents.⁸ There has been no new evidence to suggest that the current schedule by AAP or the CDC prior to 2025 of vaccines is unsafe nor warrant a suggestion they are not aligned with scientific evidence. To do so only serves to further confuse the public and continues to sow the dissemination of misinformation on the safety and efficacy of vaccines.

Outbreaks generally occur among unvaccinated communities,⁹ making vaccination a key strategy to promote sustained health and well-being. The United States is already experiencing record breaking measles outbreaks across the country. As of September 11th, the country has over 3,387 cases.¹⁰ This represents a 48% increase over the total number of 2,287 cases for all of 2025. At current immunization rates, it has been predicted that measles could become endemic again in the United States within approximately two decades.¹¹ Immunization is a critical intervention to reduce the incidence of vaccine-preventable diseases. We recommend improving access to vaccines and making vaccination easier for families by minimizing the number of doses and visits required, while ensuring guidance is evidence-based and developed by immunization experts. This is essential for reducing the spread of vaccine-preventable diseases such as measles.

Strain on the Health Care System with Multiple MMR Vaccines

The EO recommends that the measles, mumps, rubella (MMR) vaccine be administered in three separate single-disease shots which are not currently available nor approved for the US market. The Academy recommends DHHS seriously consider the impact such a decision will not only have on public health and vaccine adherence, but also on the economy, access to care, and our health care system. This current proposal to split the MMR vaccine into three doses will mean that patients and their families may be less likely to adhere to the schedule.^{12,13} Completion of a vaccine series was 69% among children receiving at least one combination vaccine versus 50% when the vaccines were given in single doses vaccines.¹⁴ Further, the same study found the timely completion of the vaccine series for children at 24 months was 24% for the group with at least one combination vaccine versus 13% for those with only the single doses throughout the series.¹⁴ This will translate into more time needed for parents and caregivers needing to take time off for work, more in-office health care visits translating into less access, and increased costs on the health care system.¹⁵ This also means the country will experience further and more frequent outbreaks of vaccine preventable diseases such as the current measles outbreak. Also, it is unclear if both public and private health insurance programs will provide coverage for three doses of the MMR vaccine without any new evidence or science that the current single dose has lost efficacy or is unsafe. Coupled with cuts to the Medicaid program from the One Big Beautiful Bill Act (Public Law No: 119-21), the health care system will be unable to sustain the additional strain the proposal for

increased MMR vaccine doses, in-office visits, and health care professionals will be needed. Ultimately, this proposal will lead to declines in vaccine adherence with dangerous implications for public health.

Expressing our significant concerns with the aforementioned EO, the Academy offers the following comments to address the questions posed in the RFI.

B. Potential Additional or Modified Categories and Timing and Frequency Recommendations

The Academy has serious concerns about adding more vaccine categories as outlined in the proposal. Specifically, additional categories beyond the current three categories – recommended mandatory, at-risk, and shared clinical decision-making - currently in use might further confuse clinicians as well as the public. While some vaccine categories like "recommended but not during infancy" are clear, others like the proposed "recommendation with qualification" leaves room for interpretation and could impact both childhood and adult health. The clinician- patient or clinician and family relationship is built on trust and is often the first line of communication when making important health care decisions. Ensuring that clinicians have the most accurate information and clear understanding about the vaccine categories is vital to them engaging and advising their patients.

Moreover, the current categories were built upon the Evidence to Recommendations (EtR) framework, adopted in 2018 by the CDC's Advisory Committee on Immunization Practices (ACIP), and considers the evidence under the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. HHS has stated that "durability of any vaccine recommendation framework depends on the public's trust in the process that produces it." However, the core premise of the rationale focuses on the public's lack of trust during the COVID-19 pandemic in which a novel virus impacted all aspects of daily life in an extreme and unprecedented way. The durability of the EtR framework and GRADE criteria should not be measured against a single and disruptive time in our history. Now, six years from that pandemic, it is hard to compare the COVID-19 vaccine in a similar categorical way as vaccines for diseases like measles or polio that have been implemented for decades. Research takes time, evolves over time, and communications equally progress to represent that evidence, to build public trust over time. Attempting to thread a needle through an extremely contemporary response to a virus the world had little knowledge about is flawed at the premise. Public trust must be built with continued, clarified, and consistent communication.

Additionally, DHHS should also consider the potential impracticality and financial burdens associated with proposed vaccination spacing and splitting recommendations. More categories may not necessarily translate into coverage by public and private insurance creating frustration, delays in care, and impacts on the public's overall protection against viruses. The Academy recommends DHHS focus on ensuring the current categories are clearly defined to lessen confusion for both clinicians, payers, purchasers, and most of all patients and their families.

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

Shared clinical decision-making (SCDM) was developed as a recommendation type when the evidence was insufficient for population-level impact. It was used when there may be a benefit for some individuals to be vaccinated but there is insufficient evidence that there would be broad population benefit within a specific population. As of January 2025, the vaccinations under this category are meningococcal B (MenB), hepatitis B (HepB), human papillomavirus (HPV), pneumococcal conjugate vaccination (PCV20 or PCV21), and additional COVID-19 vaccines for the severely immunocompromise.¹⁶ Each of these vaccines were placed on this list due to the fact that some, but not all individuals may benefit from vaccination for which it is unlikely to have population-level impacts. Segmenting, adding, splitting, or recreating this category does not meet the Administration's aim, and as noted above would create additional confusion, reduce vaccine completion, and increase the risk of vaccine-preventable disease.

The SCDM recommendation type reinforces the clinician-patient relationship and the “decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered.”¹² This is guidance retains the essential connection between the clinician, who has the most relevant information about their patient, and the individual's ultimate choice.

Further, SCDM should also be based on location and local epidemiology of diseases. The current measles outbreak is a recent illustration of how real-time information could help determine when communities need to focus on education and evidence-based interventions to increase vaccine uptake. Incorporating local epidemiology data into vaccine decision-making processes supports shared decision-making discussion between clinicians and patients.

Of significant concern, the shared clinical decision-making recommendation type, as suggested by the Administration, implies that all vaccines should be subject to this category. It is the reason routine immunizations are not under this category. The current measles outbreak is a firm example of why routine immunizations should not be in this category. It also further demonstrates that real-time information could help determine when communities need to focus on education and evidence-based interventions to increase vaccine uptake. Incorporating local epidemiology data into vaccine decision-making processes supports shared decision-making discussion between clinicians and patients. The Academy recommends the department focus on developing an unbiased resource for both clinicians and patients in determining whether the benefits of vaccines outside of the recommended schedule will be beneficial for the patient.

D. Considerations in Setting Recommendations**State and Federal Authority on Vaccination Policy**

Both state and federal governments play a crucial role in vaccine policy. While the government has key federal agencies such as the FDA, CDC, the National Institutes of Health, and others to influence vaccine policy and make recommendations, states are granted the primary responsibility for enacting and enforcing laws to promote the health and welfare of their constituents.¹⁷ Under the 10th Amendment of the US Constitution, the states set vaccine requirements within the community such as through vaccine requirements in schools. The only exception to this is during a declared health emergency. The federal government provides guidance on vaccine schedules and states as well as local entities use this guidance to determine vaccine requirements.

States should be empowered to continue to determine vaccine requirements without interference from the federal government. Federal funding for the CDC is critical for public health initiatives at all levels and particularly at the state and local level, as a substantial portion of the CDC's annual budget is awarded to state and local health departments.¹⁸ This funding helps support wide-ranging disease prevention and control activities including public health surveillance and data collection, dissemination of information, preventative health services such as vaccination, and public health emergency preparedness and response efforts.¹⁸ Faced with decreasing immunization coverage for some diseases and the presence of outbreaks, such as for measles, it is essential to protect and promote federal funding for the CDC to enable prevention and control efforts at the local, state, and national levels. We urge DHHS to abstain from withholding funding for critical state and local public health initiatives when state vaccine requirements go further than federal vaccine recommendations.

Global Implications

Vaccine policy in the US has global implications worldwide. Efforts at the federal level to modify vaccine recommendations in the US to what other countries specifically those in the European Union recommend should not be continued. Doing so without further looking at the vast differences in vaccine policy approach, respective health care systems, and populations would be comparing apples to oranges. Previous statements have stated the US should follow the vaccine recommendations of Denmark. While Denmark recommends vaccines which are not mandatory, they have a universal single payer health care system versus our multi-payer public and private insurance system. Additionally, we have a population of approximately 345 million people versus only six million in Denmark. These are vast differences between both countries. Should an individual in a small county with a universal health system become sick because they chose to not vaccinate, they have access to care whereas in the US this is not the case. Perceived risk does not translate into access in the US and if an individual chooses not to get vaccinated, they are not able to go to school or may miss work.

Immunization is critical for public health promotion and reducing the spread of vaccine-preventable diseases on an individual, community, national, and global level. Furthermore, immunization supports increased global prosperity, reduces burden and cost on health care

systems, and improved health protection across the lifespan. The Academy urges increased action to address barriers to vaccination and expand access to vaccines.

E. Trust and Communication

Health promotion is at the core of nursing care. Nurses have a professional duty to provide evidence-informed education to the public regarding the importance and safety of vaccines to support their decision-making process. In alignment with the American Nurses Association's (ANA) *Code of Ethics for Nurses*, nurses support patients' informed decision-making by providing accurate information, and nurses have a responsibility to combat health misinformation and disinformation.¹⁹

Addressing misinformation and lack of trust are critical steps to promote vaccine uptake. This is especially true following the COVID-19 pandemic. Despite extensive evidence demonstrating the safety and efficacy of vaccines, misinformation about vaccines and mistrust of health care practitioners and institutions continue to spread.²⁰ Misinformation on vaccines can result in vaccine hesitancy, delay, or refusal, making this a key area for clinicians to address to improve vaccine acceptance.²¹ Clinicians remain influential in people's vaccine decision-making processes and clinician recommendations have been shown to be a strong predictor of vaccine acceptance.²² Vaccine preventable diseases can cause complications that affect school attendance and future earning potential. Clinicians have a key role in emphasizing the importance of patients understanding these broader implications.

Additionally, ACIP plays an important role in developing evidence-based recommendations on how to use vaccines to control disease in the United States.²³ Health insurance plans generally cover the cost of vaccines recommended by ACIP.²⁴ It is essential to ensure that ACIP and any other federal entities making vaccine policy and recommendations are comprised of members with robust expertise, research, and experience in vaccination and immunization to guide evidence-based recommendations on vaccine schedules.

The Academy thanks DHHS for the opportunity to provide comments on the RFI on categories used in federal vaccine recommendations and the role of shared clinical decision-making. We stand ready to work with you to provide expertise and shape policy solutions that champion health and well-being, ensuring healthy lives for all people. If we can be of any assistance to you or your staff, please do not hesitate to contact the Academy's Chief Policy Officer, Christine Murphy, at cmurphy@aannet.org or 202-777-1170.

Sincerely,



Debra J. Barksdale, PhD, FNP-BC, FAANP, ANEF, FAAN
President, American Academy of Nursing

-
- ¹ Request for information: Categories used in federal vaccine recommendations and the role of shared Clinical Decision-Making. (2026, August 24). Federal Register. <https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared>
- ² American Academy of Nursing. (2021, July 26). *Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care*. <https://aannet.org/page/covid-19-vaccine-mandate>
- ³ Cohen, F. L., & Larson, E. (1996). Emerging infectious diseases: Nursing responses. *Nursing Outlook*, 44(4), 164–168. [https://doi.org/10.1016/S0029-6554\(96\)80036-4](https://doi.org/10.1016/S0029-6554(96)80036-4)
- ⁴ American Academy of Nursing. (2023). *Meeting's Proceedings: Lessons from the COVID-19 Pandemic: Mobilizing Nursing Leadership to Advance Global Equity*. <https://aannet.org/page/lessons-from-covid-2022>
- ⁵ Hill, H. A., Yankey, D., Elam-Evans, L.D., Mu, Y., Chen, M., Peacock, G., & Singleton, J.A. (2024). Decline in vaccination coverage by age 24 months and vaccination inequities among children born in 2020 and 2021—National immunization survey-child, United States, 2021–2023. *Morbidity and Mortality Weekly Report*, 73. <https://doi.org/10.15585/mmwr.mm7338a3>
- ⁶ House, W. (2026, August 14). *Delivering gold standard childhood vaccine recommendations for Americans*. The White House. <https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans/>
- ⁷ National Foundation for Infectious Diseases. Vaccine Science & Safety (n.d.). Retrieved from <https://www.nfid.org/immunization/vaccine-science-safety/>.
- ⁸ AAP releases recommended childhood and adolescent immunization schedule for 2026. (n.d.). HealthyChildren.org. <https://www.healthychildren.org/English/news/Pages/AAPs-recommended-childhood-and-adolescent-immunization-schedule-for-2026.aspx>
- ⁹ Centers for Disease Control and Prevention. (2025, May 30). *Measles Cases and Outbreaks*. <https://www.cdc.gov/measles/data-research/index.html>
- ¹⁰ John Hopkins University Bloomberg School of Public Health. (n.d.). *Tracking Measles Cases in the U.S.* <https://publichealth.jhu.edu/ivac/resources/us-measles-tracker>
- ¹¹ Kiang, M. V., Bubar, K. M., Maldonado, Y., Hotez, P. J., & Lo, N. C. (2025). Modeling reemergence of vaccine-eliminated infectious diseases under declining vaccination in the US. *JAMA*, 333(24), 2176. <https://doi.org/10.1001/jama.2025.6495>
- ¹² Fan, X., Zhao, Y., Zhang, X., Li, S., Wu, F., Cui, M., Ye, Y., Duoqi, W., Jiang, S., Yuan, J., & Sun, C. (2025). Vaccination burnout impedes the compliance with multiple-dose administration of vaccines. *Scientific Reports*, 15(1), 13269. <https://doi.org/10.1038/s41598-025-97959-4>
- ¹³ Nelson, J. C., Bittner, R. C. L., Bounds, L., Zhao, S., Baggs, J., Donahue, J. G., Hambidge, S. J., Jacobsen, S. J., Klein, N. P., Naleway, A. L., Zangwill, K. M., & Jackson, L. A. (2009). Compliance with Multiple-Dose vaccine schedules among older children, adolescents, and adults: results from a Vaccine Safety DataLink study. *American Journal of Public Health*, 99(S2), S389–S397. <https://doi.org/10.2105/ajph.2008.151332>
- ¹⁴ Kurosky, S. K., Davis, K. L., & Krishnarajah, G. (2017). Effect of combination vaccines on completion and compliance of childhood vaccinations in the United States. *Human Vaccines & Immunotherapeutics*, 13(11), 2494–2502. <https://doi.org/10.1080/21645515.2017.1362515>
- ¹⁵ Di Fusco, M., Vaghela, S., Mateus, C., & Janke, K. (2026). A systematic literature review of methodologies used in economic evaluations of combination vaccines. *Journal of Medical Economics*, 29(1), 740–760. <https://doi.org/10.1080/13696998.2026.2637396>
- ¹⁶ Centers for Disease Control and Prevention. (2025). *ACIP Shared Clinical Decision-Making Recommendations*. <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>
- ¹⁷ Kates, J., & Michaud, J. (2025, August 9). *How HHS, FDA, and CDC can influence U.S. vaccine policy*. KFF. <https://www.kff.org/covid-19/how-hhs-fda-and-cdc-can-influence-u-s-vaccine-policy/>
- ¹⁸ Sekar, K. (2024, July 16). Centers for Disease Control and Prevention (CDC) Funding Overview. Congressional Research Service. <https://www.congress.gov/crs-product/R47207>
- ¹⁹ American Nurses Association. (2025). *Code of Ethics for Nurses*. <https://codeofethics.ana.org/home>

-
- ²⁰ Romer, D., Winneg, K. M., Jamieson, P. E., Brensinger, C., & Jamieson, K. H. (2022). Misinformation about vaccine safety and uptake of COVID-19 vaccines among adults and 5–11-year-olds in the United States. *Vaccine*, 40(45), 6463–6470. <https://doi.org/10.1016/j.vaccine.2022.09.046>
- ²¹ Fisher, A., Mbaeyi, S., & Cohn, A. (2021). Addressing vaccine hesitancy in the age of Covid-19. *Academic Pediatrics*, 21(4), S3–S4. <https://doi.org/10.1016/j.acap.2021.03.013>
- ²² Limaye, R. J., Opel, D. J., Dempsey, A., Ellingson, M., Spina, C., Omer, S. B., Dudley, M. Z., Salmon, D. A., & Leary, S. O. (2021). Communicating with vaccine-hesitant parents: A narrative review. *Academic Pediatrics*, 21(4S), S24–S29. <https://doi.org/10.1016/j.acap.2021.01.018>
- ²³ Centers for Disease Control and Prevention. (2025, May 15). *ACIP Recommendations*. <https://www.cdc.gov/acip/vaccine-recommendations/index.html>
- ²⁴ Centers for Disease Control and Prevention. (2024, July 10). *How to Pay for Vaccines*. <https://www.cdc.gov/vaccines-adults/recommended-vaccines/how-to-pay-adult-vaccines.html>