September 16, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue 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 American Nurses Association (ANA) appreciates the opportunity to provide input to the Department of Health and Human Services (HHS) on the Request for Information (RFI) regarding Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making. ANA holds that "effective protection of the public health mandates that all individuals receive immunizations against vaccine-preventable diseases according to the best and most current evidence."[1] Collectively, registered nurses (RNs) and advanced practice registered nurses (APRNs) play a large role in immunizations, whether it be getting vaccinated themselves, administering vaccines, counseling patients, or working on vaccine trials and research. As such, we urge HHS to consider our comments on the following elements of the RFI:

- shared clinical decision-making (SCDM) process and terminology,
- preserving access to vaccines,
- informing future vaccine recommendations,
- communicating with providers and patients, and
- restoring trust in vaccines.

ANA represents the interests of the nation's over 5 million RNs through its constituent and state nursing associations, organizational affiliates, and individual members. ANA advances the nursing profession by championing nurses, fostering rigorous standards of nursing practice, promoting safe and ethical work environments, bolstering nurses' health and wellness, and advocating on the healthcare issues that impact both nurses and their patients. ANA seeks to ensure that nurses' voices, interests, and perspectives are represented and heard in policymaking discussions. Our

[1] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

membership consists of both RNs and APRNs—nurse practitioners, clinical nurse specialists, certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs). Nursing is a profession grounded in critical thinking, scientific rigor, and evidence-based practice. Nurses are central to the delivery of high-quality care across many settings and serve in essential direct care, care coordination, research, and administrative leadership roles. Nurses form the backbone of the American health care system, providing and coordinating care, educating patients and the public, and offering counsel and emotional support to patients and their families. As the most trusted profession, nurses play a critical role in treating patients, providing immunization counseling, and influencing health behaviors.[2, 3]

1. HHS should clarify that informed consent, patient education, and meaningful clinical discussion apply across all vaccine recommendations, not just those with a SCDM designation.

HHS solicits comment on whether current immunization recommendation categories create unintended contrast between SCDM and routine recommendations, including implications for consent and assent. As the providers who spend the most time in direct contact with patients and as the most trusted health profession, nurses are well-positioned to assist patients with decisions about their care and offer accurate, truthful, and non-coercive information that empowers their patients to make informed vaccine decisions.[4, 5] Nurses have an ethical obligation to remain educated about vaccines and informed in order to fulfill this responsibility effectively.[6] **A change in recommendation category does not alter these clinical and ethical responsibilities that nurses have consistently carried out; patient education, assessment of understanding, and informed consent remain essential no matter whether a recommendation is routine, risk-based, or based on individualized assessment.** Just because a vaccine has a routine recommendation on the schedule, it does not encourage a nurse to administer a vaccine to a patient if, given the patient's personal medical circumstances, the vaccine is medically contraindicated or poses more significant risks to that patient than benefit potential.

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[2] Brenan, M. (2026, January 12). Nurses continue to lead in honesty and ethics ratings. Gallup. https://news.gallup.com/poll/700736/nurses-continue-lead-honesty-ethics-ratings.aspx
[3] American Nurses Association. (2025, September 12). *Immunization* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf
[4] Butler, R., Monsalve, M., Thomas, G. W., Herman, T., Segre, A. M., Polgreen, P. M., & Suneja, M. (2018). Estimating time physicians and other health care workers spend with patients in an intensive care unit using a sensor network. *The American Journal of Medicine, 131*(8), 972.e9–972.e15. https://doi.org/10.1016/j.amjmed.2018.03.015
[5] Brenan, M. (2026, January 12). Nurses continue to lead in honesty and ethics ratings. Gallup. https://news.gallup.com/poll/700736/nurses-continue-lead-honesty-ethics-ratings.aspx
[6] American Nurses Association. (2025, September 12). *Immunization* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

Vaccination counseling is already an important part of informed consent, relating directly to ANA's *Code of Ethics for Nurses*. Provision 1 affirms nurses' responsibility to promote health, preserve public health, and prevent illness and injury, while Provision 1.4 supports the right to self-determination, for both nurses and patients.[7, 8] ANA acknowledges that when situations arise where a patient's medical choices may compromise the health and welfare of their community, nurses must thoughtfully navigate the pivotal balance between the patient's individual autonomy and the general public welfare.[9] However, this does not change the pre-existing clinical and ethical requirement of educating patients about vaccines, obtaining informed consent, or engaging in vaccine counseling. **Therefore, because of the clinical and ethical requirement of vaccination counseling and informed consent, the term and recommendation status of "shared clinical decision-making" is functionally unnecessary, because every vaccination administered or decision made surrounding vaccines are the result of conversations between patients and their healthcare provider.** Overall, changing immunizations from routinely recommended to SCDM recommendations undermines trust in the patient/provider relationship and responsibility to counsel patients and obtain informed consent. Moreover, changing immunizations to SCDM recommendations can sow distrust in patients regarding the safety and necessity of vaccinations and can create confusion, as well as incorrectly imply a reduced ethical responsibility to get vaccinated. **As such, if evidence demonstrates that a vaccine provides clear benefits for nearly everyone in an age or risk group, it does not need a SCDM designation and should remain a routine recommendation.**

2. HHS must account for the effects of recommendation changes on nursing practice and patient care.

HHS solicits comments on the risks of SCDM as a vaccine recommendation category. ANA members report that recent changes from routine to SCDM recommendations contribute to patient confusion, longer counseling discussions, additional documentation, more administrative work, requests for alternative vaccine administration schedules, and greater clinical complexity when patients request those alternative vaccination schedules. These effects should not be interpreted as evidence that immunization counseling was previously inadequate, but rather, that recommendation changes generate new questions among patients about need, safety, timing, and coverage that nurses and other clinicians must address.

First, moving a vaccine from a routine recommendation to an SCDM designation may create confusion about which vaccines are recommended, when they should be administered, and

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[7] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf
[8] American Nurses Association. (2025). *Provision 1.4: The right to self-determination*. In *2025 Code of ethics for nurses*. Retrieved September 10, 2026, from https://codeofethics.ana.org/provision-1-4
[9] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

whether they remain covered.[10, 11] This concern is especially important amid widespread vaccine misinformation and disinformation. Furthermore, this confusion and general doubt around vaccines is, alongside messaging in Executive Order 14420 that recommends separate medical visits for certain vaccines, fueling patients to delay or space out vaccines.[12, 13] This means that **HHS must communicate more information to providers about vaccine timing for when patients request separated or spaced out vaccines and altered administration schedules, as these split visits or altered schedules have not historically been the norm, especially when current electronic medical record systems (EMRs) are not always designed to clearly track and flag these alternate vaccine administration timelines.** Additionally, split vaccines mean more injections and visits to the provider which can be traumatic for young children. **Combination vaccines were developed for ease of administration (one injection vs. three) as well as to minimize the number of provider visits.** Furthermore, multiple provider visits can be difficult to accommodate due to scheduling for patients and providers, increasing burden and resulting in patients facing barriers due to scheduling, access, and cost per encounter. This can result in increased loss to follow up, which can negatively impact public health, resulting in more spread of infectious disease.

Moreover, SCDM recommendation status increases the amount of time providers spend counseling patients—but not due to prior insufficient immunization counseling. Providers might feel compelled to go far beyond what is typically needed for informed consent and have longer conversations, so as to make sure they are checking the boxes needed and documenting fully and correctly to ensure they meet SDCM requirements to reduce legal risks regarding potential negligence or malpractice claims. Additionally, when vaccines have historically had a routine recommendation and are suddenly switched to SCDM, it can generate mistrust and create confusion for patients, thus requiring significantly longer vaccine counseling to address any newfound doubts or misinformation regarding a vaccine. Furthermore, ANA members have shared that more of their patients are spacing out vaccines than ever before, requiring multiple clinic visits, more administrative work, additional insurance paperwork, and thus more time. Some of our APRNs have also communicated that with current doubt in vaccines, and more requests to split up

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[10] Annenberg Public Policy Center. (2026, January 5). *ASAPH shared clinical decision-making items: Topline results* [Survey report]. University of Pennsylvania. https://www.annenbergpublicpolicycenter.org/wp-content/uploads/aw26-do05-topline-v2.pdf

[11] Annenberg Public Policy Center. (2026, January 5). *CDC urges "shared decision-making" on some childhood vaccines; many unclear about what that means*. https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/

[12] Exec. Order No. 14,420, Delivering Gold Standard Childhood Vaccine Recommendations for Americans (Aug. 10, 2026), https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans/.

[13] Kearney, A., Montero, A., Valdes, I., Hamel, L., & Kirzinger, A. (2025, October 10). *KFF/The Washington Post survey of parents*. KFF. https://www.kff.org/public-opinion/kff-the-washington-post-survey-of-parents/

schedules or for certain formulations, they are spending a significant amount of well-visit time explaining to parents which safe vaccinations are available currently and the benefit of one combination shot versus three separate shots.

Additionally, EMRs are typically built around previous immunization recommendations and are not designed to handle split up vaccines or alternative schedules. This creates more work for providers, more room for error, and more loss to follow up, all complicating nursing practice. Providers also struggle to obtain vaccination records and information about split up immunizations if the patient has been vaccinated in an atypical schedule by a different provider. It is very hard to keep track of split vaccinations, and because alternate schedules were not taught during most current providers' nursing schooling, many providers have not been trained in how to handle custom vaccination schedules. For example, the measles, mumps, rubella, and varicella vaccination (MMR+V) has been formally recommended as an option, used by providers, and standard in many clinics since 2006, so providers are not always used to separating MMR vaccination from varicella.[14] However, as live attenuated vaccines, MMR and varicella, when separated, have to be administered four weeks apart, and maintaining these interval rules in EMRs is complex and often has varied, unreliable output.[15, 16] As a result, keeping track of alternate vaccination schedules alone poses administrative complexities and increased room for error when custom designing a new immunization schedule for a patient. When vaccines have been separated but the EMR is not equipped to handle the specific custom vaccine administration schedule, our members have seen instances where live vaccines have been administered in an incorrect window. As such, HHS needs to communicate more information about split up dosing schedules widely and in an easily referenceable format for nurses, and HHS needs to work with EMRs to make sure vaccines and the requested alternative schedules can be properly tracked and recorded as administered.

Overall, the change of vaccination recommendations from routine to SCDM, as well as pushes for single-disease vaccines, are fundamentally changing nursing practice and public behavior. Nurses are navigating increasingly complex vaccine conversations during well-visits, including clarifying SCDM recommendations, addressing vaccine-related questions and mis- and disinformation, and supporting patients in making informed decisions about recommended vaccines. Furthermore, when patients choose to deviate from the vaccine schedule it creates risk of errors since EMRs are not always built to handle vaccination

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[14] Marin, M., Broder, K. R., Temte, J. L., Snider, D. E., & Seward, J. F. (2010). *Use of combination measles, mumps, rubella, and varicella vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recommendations and Reports, 59*(RR-3), 1-12. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5903a1.htm

[15] Centers for Disease Control and Prevention. (2024, July 24). *Timing and spacing of immunobiologics*. Retrieved August 31, 2026, from https://www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html

[16] Centers for Disease Control and Prevention. (2026, August 14). *Clinical Decision Support for Immunization (CDSi)*. Retrieved August 31, 2026, from https://www.cdc.gov/iis/cdsi/index.html

tracking this way, patients are more likely to be lost to follow up during split scheduling, and splitting up vaccines creates safety spacing concerns for live vaccinations.

3. Introducing new vaccine recommendation categories will only create more confusion.

HHS solicits information on whether additional or different vaccine recommendation categories be adopted, such as the following named categories: "recommended, but not during infancy" (or otherwise age-de-emphasized recommendations); "recommended with qualification;" or "shared clinical decision-making with qualification." As previously noted, changes to vaccination recommendations cause confusion. **The more categories that are added, the more confusing vaccination recommendations become for both patients and providers.** Furthermore, by adding "qualifications" it will likely sow even more distrust in vaccines, undermine the patient and provider relationship, and likely result in reduced vaccine utilization. Before creating new categories, HHS should demonstrate that they convey meaningful differences in evidence and expected benefit and that they will not reduce access, coverage, or confidence in vaccination.

4. HHS must ensure that vaccines remain accessible and affordable.

HHS solicits comment on preserving vaccine accessibility and educating about affordability. Not only do changes to vaccine recommendations cause confusion, ANA is concerned that changes to recommendation categories, processes, and structures can affect the accessibility and affordability of vaccines. Although we discourage the potential adoption of new designations such as "recommended, but not during infancy" or "shared clinical decision-making with qualification," **ANA holds that vaccines must continue to be covered by insurance and the Vaccines for Children (VFC) program no matter their recommendation status, as Food and Drug Administration (FDA)-approved vaccinations are safe, effective, and economically beneficial. Currently, a SCDM designation from the Director of the Centers for Disease Control and Prevention (CDC) triggers the same insurance coverage requirement as a routine recommendation under the Affordable Care Act (ACA)—this must continue no matter recommendation status and apply to all formulations and variants.**

Additionally, Executive Actions have initiated an official federal push to transition from combination vaccines to single disease-specific vaccines and more spread-out vaccine schedules.[17, 18, 19] **HHS must take steps to ensure that the current combination vaccines**

[17] Exec. Order No. 14,420, Delivering Gold Standard Childhood Vaccine Recommendations for Americans (Aug. 10, 2026), https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans/.
[18] Memorandum on Aligning United States Core Childhood Vaccine Recommendations With Best Practices from Peer, Developed Countries, Daily Comp. Pres. Doc. No. DCPD202501167 (Dec. 5, 2025), https://www.govinfo.gov/content/pkg/DCPD-202501167/pdf/DCPD-202501167.pdf.
[19] The White House. (2026, May 29). Fact sheet: President Donald J. Trump realigns U.S. core childhood vaccine recommendations with best practices from peer, developed countries.

remain available, accessible, affordable, and covered by insurance and the VFC program. Current ACIP-recommended combination vaccinations, such as tetanus, diphtheria, and acellular pertussis (Tdap) and the measles, mumps, and rubella (MMR) vaccines are proven to be safe and effective and reduce the number of times a child has to be injected with a needle.[20, 21, 22] Even if the government changes the recommendation of a combination vaccine for MMR into separate disease-specific vaccines, it could take a significant amount of time to make individual vaccines for measles, mumps, and rubella available nationwide, as measles, mumps, and rubella vaccine manufacturing cannot be rapidly scaled due to the culturing process and because individual component monovalent vaccine production was discontinued due to manufacturing constraints and limited demand.[23, 24] **Combination vaccines must be available and an affordable option during and after the roll out of separated MMR vaccines to ensure no gaps in access and to allow patients to get the combination vaccine that they are confident is safe and effective in the future, and so as to allow provider offices to be able to continue to stock vaccines for these conditions that do not require potential alternate storage conditions.**

Not only is it important that vaccines with a SCDM recommendation remain accessible and affordable, but both patients and providers must be aware that their vaccines remain covered under the ACA. HHS must clearly and publicly communicate to both patients and providers that vaccines recommended by SCDM recommendations are still required to be covered without cost-sharing through the ACA and under VFC. One way that can inform both providers and patients is a public service campaign, particularly during the Fall respiratory season, that could both remind patients to get vaccinated and let them know that their vaccines remain covered. Additionally, in the past, the CDC has made posters and handouts for clinics available for providers to order for free through CDC Info on Demand. Bringing back CDC Info on Demand, or another way for providers to order free posters and handouts, will allow providers to widely disseminate this

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https://www.whitehouse.gov/fact-sheets/2026/05/fact-sheet-president-donald-j-trump-realigns-u-s-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/

[20] Centers for Disease Control and Prevention. (2025, July 2). *Child and adolescent immunization schedule by age (Addendum updated July 2, 2025): Recommendations for ages 18 years or younger, United States, 2025*. Retrieved August 31, 2026, from https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

[21] Liang, J. L., Tiwari, T., Moro, P., Messonnier, N. E., Reingold, A., Sawyer, M., & Clark, T. A. (2018). *Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*. *MMWR Recommendations and Reports, 67*(RR-2), 1-44. https://doi.org/10.15585/mmwr.rr6702a1

[22] Demicheli, V., Rivetti, A., Debalini, M. G., & Di Pietrantonj, C. (2012). *Vaccines for measles, mumps and rubella in children*. *Cochrane Database of Systematic Reviews*, (2), Article CD004407. https://doi.org/10.1002/14651858.CD004407.pub4

[23] Savoy, M. L. (2026, May). *Measles, mumps, and rubella (MMR) vaccine*. Merck Manual Professional Edition. Retrieved September 8, 2026, from https://www.merckmanuals.com/professional/infectious-diseases/immunization/measles-mumps-and-rubella-mmr-vaccine

[24] Feinberg, M. (2009, October 21). *Monovalent vaccines no longer available for measles, mumps, rubella*[Letter to health care providers]. Merck Vaccines and Infectious Diseases. https://breakspearmedical.com/files/documents/monovalentMessage.pdf

information to patients in their clinics and decrease the amount of time they have to spend answering questions about vaccine coverage. Finally, for providers, CDC could add information regarding these coverage requirements directly on the immunization schedule webpage and printable formats, as well as some talking points for communicating this to patients. This will ensure better visibility and knowledge of coverage requirements, as well as ensure that providers who frequently reference the CDC immunization schedule and website will be aware of how to communicate this with patients.

5. Vaccine recommendations must be based on high-quality data and input from nurses.

HHS solicits information on considerations for evidentiary basis for setting vaccine recommendations, more specifically when weighing individual versus population benefits and in the absence of randomized control trial data. **ANA holds that "vaccination recommendations must be guided by robust scientific evidence, transparent review, and broad stakeholder engagement, including nurses and other frontline health professionals who play an essential role in vaccine education and administration."**[25]

a. Robust Data

ANA believes that immunization recommendations must be guided by robust, peer-reviewed scientific evidence.[26, 27] Peer-reviewed, high-quality data and evidence is necessary to inform recommendations, both on the basis of a vaccine's safety and effectiveness and on the public health impact of recommendations.

Specifically, HHS requests information regarding setting vaccination recommendations in the absence of available randomized control trials (RCTs). Before a vaccine receives FDA approval, it typically undergoes years of testing to prove safety and efficacy and that the benefits outweigh the risks.[28] **However, RCTs are not required for a vaccine to be recommended, and this must**

[25] American Nurses Association. (2025, June 26). American Nurses Association reaffirms support for evidence-based immunizations following CDC panel vote on hepatitis B vaccine. https://www.nursingworld.org/news/news-releases/2025/american-nurses-association-reaffirms-support-for-evidence-based-immunizations-following-cdc-panel-vote-on-hepatitis-b-vaccine/
[26] American Nurses Association. (2025, June 26). American Nurses Association reaffirms support for evidence-based immunizations following CDC panel vote on hepatitis B vaccine. https://www.nursingworld.org/news/news-releases/2025/american-nurses-association-reaffirms-support-for-evidence-based-immunizations-following-cdc-panel-vote-on-hepatitis-b-vaccine/
[27] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf
[28] Centers for Disease Control and Prevention. (2024, August 9). *Developing safe and effective vaccines: The journey of your child's vaccine*. U.S. Department of Health and Human Services. Retrieved August 31, 2026, from https://www.cdc.gov/vaccines-children/about/developing-safe-effective-vaccines.html

continue. For example, the recommendation to vaccinate against tetanus (although now vaccinated through Tdap) is informed by strong observational data in the absence of RCTs.[29]

While RCTs are incredibly useful, they are not the only way to test the safety or efficacy of a vaccine. Both when RCTs are available and when RCTs are unavailable, recommendations should be informed by observational studies, safety monitoring data, disease surveillance reports, and evidence from large health databases or datasets. Furthermore, neither FDA-approval nor HHS recommendations should be contingent on placebo-controlled RCTs specifically when a placebo-controlled RCT would be unethical or unfeasible to conduct, particularly for illnesses for which a safe immunization standard exists. RCTs for new vaccines for which a safe and effective vaccine already exist cannot be controlled against a true placebo arm—that would be unethical, as the standard of care would be withheld from the true placebo arm. In those instances, the control must be the proven intervention. **When RCTs or placebo-controlled RCTs are unfeasible—whether it be due to time-sensitive strain updates, ethics concerns regarding preexisting interventions, public health emergencies, rare diseases, or small target populations—recommendations must be informed by observational data, large datasets, epidemiologic data, noninferiority trials, immunogenicity data, and consultation with clinical, immunological, public health, ethical, and scientific experts.**

b. Stakeholder Input and Transparency

While setting vaccine recommendations, HHS must consult expert nurses and APRNs in the development of immunization recommendations and any subsequent changes. As providers who administer vaccines and provide immunization counselling, expert nurses are well equipped to inform vaccination recommendations based on their knowledge and experience in clinical science, research, and the logistics and realities of vaccination practices. **Nurses can evaluate scientific and clinical evidence and provide important perspectives on the schedule.** Nursing encompasses a wide scope of issues and specialties, making nurses well poised to provide input to HHS on immunizations, for example:

- Pediatric Nurse Practitioners and Neonatal Nurse Practitioners have specialized training on pediatric populations and are witness to the realities of the difficulties that vaccine preventable illnesses can have on infant and childhood growth and development;

- Certified Nurse Midwives and Women's Health Nurse Practitioners are well versed to provide input on immunization recommendations for pregnancy, given their expertise on

[29] Liang, J. L., Tiwari, T., Moro, P., Messonnier, N. E., Reingold, A., Sawyer, M., & Clark, T. A. (2018). *Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*. *MMWR Recommendations and Reports, 67*(RR-2), 1-44. https://doi.org/10.15585/mmwr.rr6702a1

maternal-fetal health and the impact of infectious disease on pregnant women and in fetal outcomes;

- Adult-Gerontology Nurse Practitioners can provide insight on age-related immune changes and the burden of vaccine preventable illness in older adults;

- Psychiatric Mental Health Nurse Practitioners have training in human behaviors, risk perceptions, and decision-making, which can provide perspective in how patients might respond to vaccine recommendations; and

- clinical research nurses have expertise in clinical trial conduct and research ethics, which enables them to provide practical insight into clinical research processes and the evidence generated from clinical trials.

Furthermore, in order to obtain buy-in from patients and providers, HHS must be transparent in which stakeholders have been consulted in informing vaccine recommendations and transparently disclose any data or processes used, or consulted by these experts, in developing vaccination recommendations.

c. Appropriate Comparisons

HHS solicits information regarding teachings from foreign regulatory bodies for vaccines to inform US recommendations, as in line with the Presidential Memorandum on Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries and Executive Order 14407 on Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries. The Memorandum instructed HHS to review vaccine recommendations in "peer, developed countries," while Executive Order 14407 instructed the CDC to align US vaccine recommendations with that scientific evidence and best practices of "peer nations," respectfully.[30, 31] **When looking to "peer countries," HHS must look to countries who are truly peers to the United States in <u>all</u> relevant fields, including health system, similar healthcare workforces, economics, size, population demographics, and relevant health threats.**

While HHS can consult other countries' vaccine recommendations for inspiration, HHS must consider evidence regarding the short-term and long-term outcomes of those systems. HHS

[30] Memorandum on Aligning United States Core Childhood Vaccine Recommendations With Best Practices from Peer, Developed Countries, Daily Comp. Pres. Doc. No. DCPD202501167 (Dec. 5, 2025), https://www.govinfo.gov/content/pkg/DCPD-202501167/pdf/DCPD-202501167.pdf

[31] Exec. Order No. 14,407, Realigning United States Core Childhood Vaccine Recommendations With Best Practices From Peer, Developed Countries, 91 Fed. Reg. 33,575 (June 3, 2026), https://www.federalregister.gov/documents/2026/06/03/2026-11180/realigning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer.

should not adopt another country's schedule, because each country's schedule is based on their own demographics, size, health system, and health threats. Even though the US is frequently compared to Denmark in HHS analysis as a "peer nation," unlike the US, Denmark has a substantially smaller population and operates a tax-funded, universal healthcare system.[32, 33, 34, 35] **Instead of looking to adopt another country's recommendations directly, HHS' vaccination recommendations must be based on US-specific health care systems and population needs**.

d. Health Behavior Research

HHS also seeks information regarding weighing the evidence between the population benefits of vaccination versus individual choice. ANA believes that it is imperative for everyone to receive immunizations for vaccine-preventable diseases, as vaccination is critical for infectious disease prevention and control, even though patients have the right to make individual choices.[36]

Further, HHS must incorporate health behavior research and respond to the impact of societal behaviors when setting disease recommendations and weighing the evidence regarding the population benefits of vaccination versus individual choice. HHS must consider that if a specific immunization is changed from a routine recommendation to SCDM, it can impact human behavior and thus vaccine uptake and how widely a disease might spread. For example, changing a vaccine from routine recommendation to SCDM could instill uncertainty in that vaccine's safety and effectiveness or be misinterpreted by patients as relieving them of their personal responsibility to their community, which could result in lower vaccination rates. If the vaccination rates decrease due to a change in recommendation, the potential for large outbreaks and severe illness grows and can cause greater strain on already overworked health systems. **As such, HHS must consult health behavior research to anticipate and react to human behavior and should set recommendations according to behavioral science. Furthermore, HHS must react to human behavior and change vaccinations from SCDM back to routine recommendation when necessary if a vaccination framework is failing at reducing the spread of infectious disease.**

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[32] Høeg, T. B., & Kulldorff, M. (2026, January 2). *Assessment of the U.S. childhood and adolescent immunization schedule compared to other countries*. U.S. Department of Health and Human Services. https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf

[33] U.S. Census Bureau. (n.d.). *World population clock: Denmark*. Retrieved August 28, 2026, from https://www.census.gov/popclock/world/da

[34] Birk, H. O., Vrangbæk, K., Rudkjøbing, A., Krasnik, A., Eriksen, A., Richardson, E., & Smith Jervelund, S. (2024). Denmark: Health system review. Health Systems in Transition, 26(1), i–152. European Observatory on Health Systems and Policies. https://iris.who.int/server/api/core/bitstreams/b0992867-dee5-45fa-80b6-1e008fd353c0/content

[35] Congressional Research Service. (2026, March 30). U.S. health care coverage and spending (IF10830, Version 20). Congress.gov. https://www.congress.gov/crs_external_products/IF/PDF/IF10830/IF10830.20.pdf

[36] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

6. HHS must rebuild the public's confidence in immunization.

HHS solicits comments on how to rebuild public confidence in immunizations. In order to rebuild public trust in immunizations and public health, HHS must provide resources for providers, listen to nursing input, engage in transparency, and take steps to address mis- and dis-information.

First, as the most trusted profession, nurses are one of the most important sources to patients for high-quality, tailored information about vaccinations. **HHS should leverage this trusted relationship and provide additional educational resources for nurses and APRNs regarding how to have conversations with vaccine-hesitant patients.** Additionally, HHS should continue to leverage this trust relationship by using nurses in public health and public service announcement campaigns, including about changes to the vaccine schedule, for addressing mis- or dis-information, and reminding the public to get vaccinated.

It is imperative that HHS work to address the mis- and dis-information about vaccines circulating right now. Mis- and dis-information are dangerous and heavily influence patients' and parents' decision-making regarding vaccines. Nurses regularly have to address this circulating mis- and dis-information regarding vaccines.[37] While the daily need to address mis- and dis-information regarding vaccines underscores the importance of immunization counseling, addressing misinformation also poses a large time commitment that can take up a significant amount of time of already short well-patient visits. The time it takes to address misinformation could be significantly reduced if HHS built trust with patients and parents on the immunization recommendation process through transparency.

Although patients might not want to always adhere to immunization recommendations, the ACIP develops vaccine recommendations in order to control disease in the United States, so patients and providers must understand why robust federal vaccination recommendations might be needed and what has informed the process.[38] Engaging in transparency helps ensure that vaccine recommendations are based on rigorous scientific standards and have acknowledged the clinical perspective. Demonstrating what robust science is informing these recommendations helps build trust in vaccination safety and recommendations among both nurses and patients, by showing the rationale behind why each vaccine is recommended in a certain way. Moreover, a transparent process helps clinicians know what steps and research have gone into the recommendation process and thus makes it easier for nurses to explain why patients should trust these

[37] Limaye, R. J., Opel, D. J., Dempsey, A., Ellingson, M. K., Spina, C. I., Salmon, D. A., Dudley, M. Z., & O'Leary, S. T. (2021). *Communicating with vaccine-hesitant parents: A narrative review*. *Academic Pediatrics, 21*(4 Suppl.), S24-S29. https://doi.org/10.1016/j.acap.2021.01.018

[38] National Center for Immunization and Respiratory Diseases, & United States Advisory Committee on Immunization Practices. (2024, June 28). *ACIP recommendations*. Centers for Disease Control and Prevention. Retrieved August 31, 2026, from https://stacks.cdc.gov/view/cdc/158304/cdc_158304_DS1.pdf

recommendations. In order to engage in this transparency, HHS should publicly provide what data informs these recommendations and make sure that the discussions surrounding this are public and have buy-in from clinicians, including through the ongoing public streaming of Advisory Council for Immunization Practices (ACIP) meetings when they resume and allowing liaisons from clinician groups to attend, speak, testify, or ask questions at ACIP meetings where appropriate. Additionally, HHS must return to allowing liaisons to participate in ACIP working groups again and share their expertise. Further, standing committees of experts, as formed by ACIP, must help transparently keep federal recommendations in line with the latest scientific data.

7. HHS must ensure that SCDM terminology does not undermine nurses' clinical expertise.

HHS solicits information regarding recommendation category adequacy and potential future categories. Any vaccination recommendations in both practice and title must not undermine clinicians' clinical expertise. While patients do have the autonomy to make their own medical decisions regarding consenting to a recommended vaccination, most patients do not have clinical, epidemiological, or immunological expertise. Nurses and APRNs still have the clinical judgement required to inform patients on the vaccines best suited for the individual patient.

While patients can and often do educate themselves about vaccines on their own, they should not be expected to conduct and interpret research before talking with their provider. Assigning vaccine recommendation designations like "shared clinical decision-making" implies that a patient has clinical expertise, and this may mislead patients on the amount of medical knowledge and clinical training required when it comes to making the best medical decisions for a patient. Furthermore, phrases like "individual clinical decision-making" remove the provider entirely from the title and may also give patients false agency into feeling as though they do not need to listen to the expertise of their provider. Additionally, as discussed earlier, nurses have a medical, ethical, and professional obligation to counsel their patients on vaccines and obtain informed consent, so the term "shared clinical decision-making" is unnecessary. **As such, vaccine recommendations, both in practice and name, must not undermine a clinician's education, judgement, and authority.**

8. Vaccine mandates for healthcare workers are an effective tool to help protect the nursing workforce.

HHS solicits input on the evidence surrounding the effects of mandates or compulsory vaccination approaches on public trust, vaccine confidence, and long-run vaccination behavior. **The federal vaccine recommendations are solely recommendations, not official federal mandates.** When it comes to vaccination mandates for healthcare workers, many states do not have legislation requiring providers to get vaccinated, so the responsibility for making policies about vaccines falls on hospitals and other healthcare facilities to both develop and enforce their own provider vaccination policies. These approaches can either be voluntary or officially mandated, such as how

it is often a prerequisite of employment in healthcare facilities to be vaccinated against highly communicable diseases and how employees are required to obtain annual influenza immunizations.

Even though mandatory immunization programs may be disliked, they are typically much more effective than voluntary immunization programs. For example, during the 2022-2023 flu season, only 75.9% of providers received their annual flu vaccine.[39] However, during the 2018-19 influenza season, 98% of providers who were subject to workplace vaccination requirements received their annual flu vaccine. [40] This striking difference in vaccination rate supports ANA's position that mandatory immunization programs for providers are necessary when voluntary programs fail to protect the health of the public and providers. [41] Furthermore, mandatory vaccination programs are still designed to safely employ providers for whom vaccination would be medically contraindicated, as typically all providers for whom a vaccination would be medically contraindicated can receive a vaccination exemption that meets standard criteria alongside formal documentation from an appropriate authority that details the condition that compels the request. If a nurse is medically exempt from vaccination, the healthcare facility will have the discretion to determine what steps, if any, unvaccinated RNs must take to reduce the risk of transmitting disease to patients, while complying with all local, state and national regulations.[42] **As such, facility-based mandatory vaccination requirements for providers are an effective way to ensure vaccination compliance in a healthcare setting when voluntary vaccination programs are insufficient.**

[39] Centers for Disease Control and Prevention. (2025, February 4). FluVaxView. Influenza vaccination coverage among health care personnel — United States, 2022–23 influenza season [WebContent]. Retrieved August 29, 2025 from https://www.cdc.gov/fluvaxview/coverage-by-season/health-care-personnel-2022-2023.html#:~:text=Overall%2C%2075.9%25%20of%20HCP%20reported%20having%20received%20an%20influenza%20vaccination,0.05)%20(Table%201

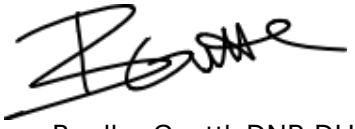
[40] Centers for Disease Control and Prevention. (2020, November 2). *Increase influenza vaccination coverage among your health care personnel: How to increase your facility's influenza vaccination rates*. U.S. Department of Health and Human Services. Retrieved September 2, 2026, from https://archive.cdc.gov/www_cdc_gov/flu/toolkit/long-term-care/plan.htm

[41] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

[42] American Nurses Association. (2025, September 12). *Immunizations* [Position statement]. https://www.nursingworld.org/globalassets/docs/ana/immunization-position-statement.pdf

We appreciate the opportunity to submit these comments and look forward to continued engagement with HHS. Please contact Tim Nanof, Executive Vice President, Policy and Government Affairs at ANA, at (301) 628-5166 or Tim.Nanof@ana.org, with any questions.

Sincerely,



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