ADULT VACCINE ACCESS COALITION

September 20, 2026

Ms. Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation (ASPE)
Department of Health and Human Services
200 Independence Ave SW,
Washington, DC 20201.

Docket No. HHS–OS–2026–0332

Dear Ms. Goss:

As participants and partners of the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to comment on the Department of Health and Human Services (HHS) *Request for Information (RFI): Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making.*

Specifically, AVAC:

- Urge HHS to instruct the Director of the CDC to make publicly available the report required under the 21st Century CURES Act (P.L. 114-225) and any recommendations on improving the consistency of the GRADE and EtR processes.
- Urges HHS to remain staunchly committed to ensuring that any American who wishes to receive a vaccine that is approved and licensed by the FDA and is recommended for them by a licensed clinician can continue to do so.
- Encourage HHS to clearly reiterate its unequivocal commitment to vaccine access and coverage at no cost for Americans across the life course.

AVAC's broad membership consists of over eighty organizational leaders in health and public health that are committed to addressing the range of barriers to adult immunization and to raising awareness of the importance of adult immunization.

AVAC works towards common legislative and regulatory solutions that will improve and enhance access to adult immunization across the health care system. Our priorities and objectives are driven by a consensus process with the goal of enabling a range of stakeholders to have a voice in the effort to improve access and utilization of adult immunizations. Ensuring that clinicians, individuals and communities and have the tools and resources they need as it relates to clear and consistent vaccine information to safeguard health and protect against avoidable illness remains a top AVAC priority.

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Despite the well-known benefits of immunizations, roughly 50,000 adults die from vaccine preventable diseases annually, with 3 out of 4 adults missing at least one recommended vaccine. Outbreaks of common vaccine-preventable conditions, such as influenza and pneumococcal, continue to take a toll on lives and wellbeing of thousands of adults each year.

Scientific evidence should be the foundation and primary driver of vaccine recommendations.

It is important to note that the federal government has developed and refined a framework that provides for consistent consideration of the available evidence, convenes subject matter experts to review, deliberate, and offer recommendations (not requirements or mandates) based on the evidence for regional, state and local public health jurisdictions to consider for the protection of their residents from birth through end of life. Agencies and advisory committees under the purview of HHS play important roles in reviewing safety and effectiveness of new vaccines and treatments for intended populations.

Initially, the Food and Drug Administration (FDA) must determine whether products under review meet specific standards of clinical benefit outweighing potential harms for intended groups. Once that review is complete and if that threshold is met, the FDA approves the product for sale. Since vaccines are used at the population level, the story does not end there.

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) reviews the scientific and clinical evidence while also factoring in individual and population-level data around benefit versus harm, costs and other relevant factors in designing recommendations that guide which populations should or should not receive certain vaccines.

ACIP also provides recommendations on what intervals should vaccines be given to ensure maximum individual and population protection and benefit while minimizing potential individual and population level harm from a vaccine.

The ACIP vaccine evidence review process is based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach and the Evidence to Recommendations framework.[1] The GRADE approach was developed in 2000 to provide a consistent, rigorous, and transparent way to review scientific evidence to produce better health outcomes. According to the GRADE working group, this approach has been endorsed or is used by over 120 organizations across 20 nations.[2] International collaborative efforts have also led to the development of “evidence-to-decision" frameworks for various clinical areas, including vaccines.[3]

The RFI notes, "commentators, including current and former Federal officials, have cautioned that recommendations extending beyond the strength of the underlying evidence can carry costs to institutional credibility." Indeed, broad recommendations based on limited

evidence and data during a global pandemic presented unique challenges and learnings that are important to acknowledge. However, it is important to note that vaccines produced, recommended and administered under an emergency use authorization (EUA) have subsequently undergone extensive additional clinical testing, review and evaluation.

Use of the GRADE approach and EtR framework by ACIP was recognized and highlighted by Congress over a decade ago. Specifically, the 21st Century CURES Act (P.L. 114-255) directed ACIP to ensure a more predictable and timely review of new, FDA-approved vaccines, which also included a review of the ACIP workgroups and vaccine recommendation development process to ensure that it was both transparent and consistent. As such, **AVAC urges HHS to instruct the Director of the CDC to bring a level of transparency to the results of this review and any recommendations on improving the consistency of the GRADE and EtR processes by making them publicly available.**

The RFI seeks public comment on a number of important topics, including: the adequacy of the current categories (routine, risk-based and shared-clinical decision making/individual-based decision-making) that are used to delineate vaccine recommendations and their implications for parental permission and individual consent. The RFI also raises the potential for additional or modified categories as well as timing and frequency recommendations; the meaning, risks and benefits of shared clinical decision-making; and considerations in setting recommendations. To be clear, all of these are important and valid questions.

However, it is also important to acknowledge the stark truth: infectious diseases do not respect geographic boundaries, political affiliations, religious beliefs, or perceptions of individual autonomy. Americans look to our leaders, including the Federal Government, to guide and protect our nation from the range of natural and man-made threats we face. Clinicians, health care payers, individuals and families seek clarity and desire confidence that recommendations are not built on individual or organizational biases but truly reflect the best available evidence and carefully balance the individual and societal benefits against the potential risks. **We urge HHS to rely upon well-established frameworks and deliberative approaches to evaluating scientific and medical evidence that are flexible to meet the specific condition or situation yet durable and consistent in the recommendation outcomes they produce.**

The National Vaccine Advisory Committee's (NVAC) Standards for Adult Immunization Practice advise clinicians to assess the vaccination status of patients at all clinical encounters; utilize a jurisdiction's immunization information system (IIS) to view patients' prior vaccinations to support vaccine needs assessment; clearly recommend needed vaccines; and, offer needed vaccines or refer patients to another provider for vaccination. **AVAC urges HHS to support this dialogue and process between patient and clinician at a medical encounter, and to remain staunchly committed to ensuring that any American who wishes to receive a vaccine that is approved and licensed by the FDA and is recommended for them by a licensed clinician can continue to do so, regardless of where they live or seek health care. Furthermore, as HHS considers the**

responses to the important questions set forth in this RFI, we urge HHS to ensure that vaccines remain accessible at no cost.

We appreciate the opportunity to share this perspective. We would be grateful for your consideration of these comments, and through the RFI process, we **encourage HHS to clearly reiterate its unequivocal commitment to vaccine access at no cost for Americans across the life course.** Please contact an AVAC Coalition Manager at info@adultvaccinesnow.org if you wish to further discuss our comments. To learn more about the work of AVAC, visit www.adultvaccinesnow.org.

Sincerely,

Alliance for Aging Research
American Academy of Family Physicians
American Immunization Registry Association
American Society for Meningitis Prevention
Asian & Pacific Islander American Health Forum
Association of Asian and Pacific Community Health Organizations (AAPCHO)
Big Cities Health Coalition
Emily Stillman Foundation
Gerontological Society of America
Hepatitis B Foundation
Infectious Diseases Society of America
Kimberly Coffey Foundation
National Asian Pacific Center on Aging (NAPCA)
National Association of Community Health Centers
National Foundation for Infectious Diseases
NMAC
National Viral Hepatitis Roundtable (NVHR)
Partnership to Fight Infectious Disease
The AIDS Institute
Trust for America's Health
Vaccinate Your Family
Zero Hour Health