



2025 – 2026

BOARD OF DIRECTORS

PRESIDENT

Ronald G. Nahass, MD, MHCM, FIDSA
ID Care
Hillsborough, NJ

PRESIDENT-ELECT

Wendy S. Armstrong, MD, FIDSA
University of Colorado School of Medicine
Aurora, CO

VICE PRESIDENT

Maximo O. Brito, MD, MPH, FIDSA
University of Illinois at Chicago
Chicago, IL

SECRETARY

Erin M. Bonura, MD, FIDSA
Oregon Health & Science University
Portland, OR

TREASURER

Rana Chakraborty, MD, PhD, FIDSA
University of Miami
Miami, FL

IMMEDIATE PAST PRESIDENT

Tina Q. Tan, MD, FIDSA
Lurie Children's Hospital
Chicago, IL

DIRECTORS

David M. Aronoff, MD, FIDSA
Indiana University
Indianapolis, IN

Adarsh Bhimraj, MD, FIDSA

Houston Methodist Hospital
Houston, TX

Michelle S. Cespedes, MD, MS

HIVMA Representative
Icahn School of Medicine at Mount Sinai
New York, NY

Matifadza Hlatshwayo Davis, MD, MPH, FIDSA

St. Louis, MO

Robin H. Dretler, MD, FIDSA

Georgia Metro Infectious
Disease Consultants
Atlanta, GA

Kami Kim, MD, FIDSA

University of South Florida
Tampa, FL

Anurag Malani, MD, FIDSA

Trinity Health Michigan
Ann Arbor, MI

Upinder Singh, MD, FIDSA

University of Iowa
Iowa City, IA

Heather Yun, MD, FIDSA

South Texas Veterans Health Care System
San Antonio, TX

CHIEF EXECUTIVE OFFICER

Jeanne Marrazzo, MD, MPH, FIDSA

4040 Wilson Blvd.
Suite 300
Arlington, VA 22203

info@idsociety.org

703.299.0200

IDSOCIETY.ORG

September 18, 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
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Docket No. HHS-OS-2026-0332

Dear Ms. Goss:

The Infectious Diseases Society of America (IDSA) provides the following comments in response to the **Request for Information (RFI): Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making**.

IDSA is a community of 13,000-plus physicians, scientists and public health experts working together to solve humanity's smallest and greatest challenges, from tiny microbes to major outbreaks. Vaccination is one of the most critical tools to prevent infectious diseases, reduce the severity of illness and stop outbreaks. On behalf of IDSA's members and the patients and communities they serve, we provide these comments on federal vaccine recommendations. Federal vaccine recommendations must be made by qualified individuals who have been thoroughly vetted and appointed through standard processes, developed through rigorous and transparent methodologies, and grounded in the best available scientific information. These basic tenets have been violated repeatedly over the past year. Restoration of these principles is essential to preserving vaccine access, allowing clinicians to offer high-quality care, and empowering patients and families to make informed decisions.

Federal vaccine recommendation framework and categories

Changing vaccine recommendation categories could reduce vaccine uptake even if legal coverage requirements remain unchanged. The three categories established in Executive Order (EO) 14420 of Aug. 10, 2026, "Delivering Gold Standard Childhood Vaccine Recommendations for Americans," and referenced in this RFI — "routine," "risk-based" and "shared clinical decision-making (SCDM)" — may mistakenly suggest to patients and families that the vaccines differ substantially. In fact, vaccines across all three categories have strong safety, efficacy and benefit profiles supported by years of surveillance data. They have achieved high uptake, caused adverse events only rarely, and substantially reduced serious disease.

Making abrupt changes in vaccine recommendations in the absence of scientific data creates confusion and doubt in the public, patients, families and clinicians. The categories listed in the RFI and EO contribute to confusion among health professionals and families because they do not accurately describe how vaccines are administered in the U.S. health system. Clinicians routinely tailor conversations about vaccines — including those that are currently widely recommended, administered and considered "routine" — to individual needs and health status of the patients under their care, no matter their health status.

The configuration of vaccine categories may lead health professionals and families to believe that a patient-clinician partnership is only relevant for the third tier of vaccines (SCDM), not for the other two. In fact, this is not true, and a conversation about benefits and potential risks should happen prior to **any** vaccination being given — and routinely does. To the extent such conversations are not occurring, HHS should work with clinicians to expand their capacity for these conversations by strengthening the primary care and infectious diseases workforce, improving reimbursement for vaccine consultation and administration, and providing evidence-based communications tools and support.

A key role of pediatricians and other health care professionals who administer vaccines to children is to ensure that families understand the benefits and risks prior to vaccination. **Informed consent is a legal requirement and a foundational principle of medical ethics.**

For children who are too young to consent, their parent(s) or guardian(s) must be fully informed about and give input to their child's treatment plan, including permission for vaccination. IDSA objects to the current category "risk-based" because it downplays the severity of common vaccine-preventable diseases that can cause serious illness even among children without underlying health conditions. Categories of vaccines should be based on scientific evidence and not give an untrue impression that some vaccines are more safe, effective or beneficial than others unless that is actually borne out by data.

Shared clinical decision-making

As originally construed by CDC, SCDM identifies situations where individual benefit varies significantly due to personal circumstances or health status or where more than one reasonable clinical option exists.¹ Past federal guidance and recommendations developed by experts did not intend for this designation to be used for routine childhood vaccines where decades of surveillance data exist.

HHS and/or CDC guidance should provide **publicly shared, credible scientific evidence** showing that vaccinations listed under SCDM are not recommended for everyone in a particular age group or everyone in an identifiable risk group.² HHS has not shared credible scientific evidence that the vaccines in their new SCDM category (hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza and COVID-19) should **only** be recommended for people in a particular risk group, and **this designation should not be used for these vaccines unless and until this evidence is provided.** There is significant evidence demonstrating tremendous benefits from routine administration of these vaccines, for example: Routine rotavirus vaccination averted an average annual 280,000 clinic visits, 62,000 emergency department visits and 45,000 hospitalizations for U.S. children under 5.³ Since the universal hepatitis B vaccine birth administration began in 1991, hepatitis B cases dropped by 99% among children and adolescents.⁴ A review of meningococcal vaccine found that without its rollout, incidence of this life-threatening disease would have been 59% higher.⁵ Data shows that influenza vaccination is 80% effective at preventing pediatric flu deaths.⁶ Further, the RFI suggests alternative category labels including "conditional recommendation" or "recommendation based on individualized assessment." These carry the same challenge of suggesting that vaccines are only safe, effective or beneficial for people in a certain category and insinuating a higher level of risk associated with vaccines than is supported by evidence. We also dispute the designation "recommendation based on individual assessment" because it may suggest that individual assessment is not done by clinicians for other vaccines, which is inaccurate.

Once there is adequate data that has been rigorously reviewed by legitimate experts for a category change, a vaccine should not be moved to a different category until immunization information systems have integrated the change, clinical decision support tools are updated, provider guidance has been disseminated, payers have issued coverage instructions, and vaccine supply and distribution systems are prepared. These administrative steps are crucial to minimize confusion and ensure that individuals who would still benefit from the vaccine receive it.

The RFI asks for suggestions on educating the public and provider community that SCDM-recommended vaccines are covered by insurance per the Affordable Care Act. Communications professionals at CDC with subject matter expertise in vaccines are best suited to work on disseminating this information, in collaboration with CMS, medical societies and other stakeholders. As outlined in the RFI, decision aids, provider training, documentation standards, coverage clarifications and category-specific communication materials would all be helpful tools for clinicians. HHS and CDC should invest in the communications workforce and provide appropriate educational resources in order to ensure clinicians have what they need to counsel patients.

Potential additional or modified categories

IDSA opposes adding additional categories of vaccines, as this will cause confusion among health professionals and families and could further decrease childhood immunization rates, which are already declining. Current measles, mumps and rubella vaccination rates decreased during the 2025-2026 school year during the same time period that trust in federal government sources of information declined among many families with school-aged children and HHS made significant changes in vaccine policy.^{7, 8} Depressed MMR vaccination rates are fueling record-breaking measles outbreaks in several states, with 8% of those individuals with measles requiring hospitalization.⁹ Any changes to vaccine categories should decrease confusion, not increase it.

IDSA opposes recommending new categories, such as "recommended with qualification" or "shared clinical decision-making with qualification." This phrasing could suggest that a clinician lacks confidence in the vaccine or there is higher

risk associated with being vaccinated than of contracting the disease the vaccine is meant to prevent. There is no data for currently recommended vaccines that would justify use of such a category.

In addition, **IDSA opposes making modifications to timing and frequency of vaccine administration from the federal level.** Federal vaccine recommendations provide age-related recommendations for children that are based upon the best available scientific data that has been rigorously reviewed by experts, and these recommendations are suitable for the vast majority of children. Deviations in timing and frequency of vaccines can create serious gaps in protection from disease. In limited instances when timing and frequency of vaccination may deviate from the recommended schedule, such changes are best determined by health professionals in collaboration with patients and families.

Considerations in setting recommendations

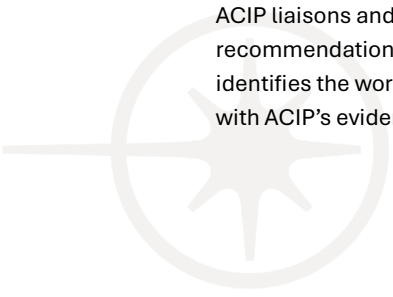
To establish federal vaccine recommendations, **IDSA recommends that the longstanding process of making vaccine recommendations through the Advisory Committee on Immunization Practices (ACIP) be reinstated, with new members who have the necessary scientific qualifications, and are vetted and appointed in accordance with federal law.** ACIP has developed vaccine recommendations to guide clinicians for more than 60 years and, until recent changes, was widely respected and relied upon by clinicians, public health professionals, patients, families and insurers. Alignment and coordination at the national level based on scientific evidence is important for consistency and to provide adequate protection against infectious diseases across the nation.

Without the involvement of a credible group of health care and vaccine experts on ACIP, insurance coverage of vaccines and equitable access to vaccines across socioeconomic groups may be threatened. Additionally, many state policies rely heavily on ACIP recommendations. Without a durable ACIP process to make science-backed vaccine recommendations, we may see additional variation in school-entry requirements across states, inconsistent Medicaid coverage rules and different insurance interpretations leading to unequal access. These variations will leave an increasing number of individuals and communities more vulnerable to vaccine-preventable diseases. There is no scientific justification for such an outcome.

In response to recommendations from the Institute of Medicine (now the National Academy of Medicine), ACIP created an Evidence-Based Recommendations Work Group and formally adopted the Grading of Recommendations Assessment, Development and Evaluation framework in 2010 to ensure its vaccine recommendations are based on systematic evidence review and transparent evaluation of benefits and harms, feasibility and variability across populations. Following work by the ACIP Evidence-Based Recommendations Work Group, ACIP adopted the Evidence to Recommendation framework in 2018, adding a structured process to evaluate factors such as the public health problem, benefits and harms, costs, feasibility, stakeholder perspectives and equity before making recommendations.¹⁰

To ensure access to vaccines for those who want them, IDSA makes the following recommendations:

- ACIP must adhere to the systematic, objective and transparent process of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework and the Evidence to Recommendation (EtR) framework.
- ACIP should focus on evidence-based data to review the efficacy of vaccines and utilize existing systems, including the Vaccine Adverse Event Reporting System and Vaccine Safety Datalink, to identify validated safety signals.
- ACIP should preserve the core purpose of GRADE: ensuring that vaccine recommendation deliberations are based on a systematic assessment of the certainty or quality of evidence, and the core purpose of EtR: ensuring that the committee explicitly addresses each decision domain before making a recommendation.
- ACIP should adhere to the systematic, objective and transparent process of GRADE and the EtR framework for decision-making. Any changes in vaccine recommendations should be based on changes in either the disease, evidence learned about the vaccine, or both, and evidence should be publicly available showing the rationale for changes in recommendations.
- Any changes to the ACIP recommendation methodology should be released publicly and developed using input from ACIP liaisons and other stakeholders who represent a breadth of scientific expertise. Any changes to recommendation methodology should be made in a way that is fully documented in public materials, clearly identifies the workgroup or body proposing the change, and explains how the revised process will remain consistent with ACIP's evidence-based standards.



- Medical/professional society liaisons should also be reinstated as workgroup members, and involved in the review of GRADE and EtR, and the decision-making process.
- CDC subject matter experts should be full participants in committee discussions, not only when they are called on to answer questions. Subjective concerns/questions without accompanying significant substantiating data based on rigorous, reproducible and sound methodology should not be put forward for consideration for votes.
- Recommendations that have not been presented with accompanying systematic and objective review (i.e., GRADE and EtR) in a workgroup should not be put forward for votes.
- To ensure credibility and reassure the public about the validity of ACIP decision-making, better enforcement of conflicts of interest, including the perception or possibility of conflicts of interest, is needed. Ideally, members of ACIP would include only people without conflicts of interest of any type, which means excluding individuals who are unduly connected with vaccine manufacturers or who have a history of opposition to vaccines.

Trust and communication

To build trust and advance evidence-based decision-making about vaccination, we need data-driven ways to educate the public and individual patients. Again, trained specialists within CDC are a valuable resource in advising about the best ways to communicate information about vaccines to patients and the general public.

Any changes in vaccine recommendations that are not scientifically justified should not be made. If such changes move forward, they should, at a minimum, include a surveillance plan with predefined thresholds. If reclassification of a vaccine or changes in the federal vaccine framework lead to a decline in uptake, increased disparities, reduced provider engagement or loss of insurance coverage, HHS should reassess its recommendations. Even when changes to vaccine recommendations are supported by sufficient scientific data, surveillance should still be done to ensure that any changes to vaccine uptake and access are aligned with expectations based upon the changed recommendation and that individuals who should still receive the vaccine are doing so.

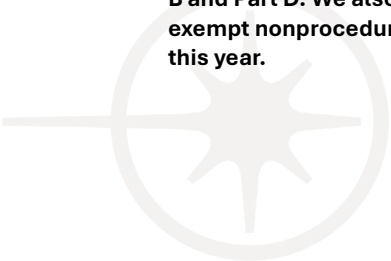
Monitoring of vaccination data should occur at least quarterly during the first year after a new or changed recommendation and should include stratification by:

- Age
- Race and ethnicity
- Insurance status
- Rurality
- State
- Primary language
- Disability
- Medical status (e.g., patients with chronic disease or immunocompromised patients)

Workforce needed to administer vaccines and educate patients and families

To ensure all Americans have access to the health care they need, IDSA highlights the urgent need for a cadre of adult and pediatric infectious diseases specialists and primary care clinicians to assess patient vaccination eligibility, educate patients about benefits and potential harms of vaccines, administer vaccines safely and monitor patients for rare adverse events after vaccine administration. Almost 80% of U.S. counties do not have an ID physician, and rural Americans are less likely to have access to ID physicians than their urban counterparts.¹¹ This is driven in large part by the fact that infectious diseases is the third lowest compensated medical specialty.

To help remedy this shortage, **IDSA calls on the Administration and Congress to work together to reauthorize and fund the Bio-Preparedness Workforce Pilot Program. In addition, IDSA calls on the Centers for Medicare and Medicaid Services to provide reimbursement for physicians who administer vaccines to beneficiaries of Medicare in both Part B and Part D. We also urge CMS to improve reimbursement for infectious diseases physicians and, at a minimum, exempt nonprocedural services such as ID from the cuts to practice expense reimbursement cuts that took effect this year.**



Thank you for the opportunity to advance access to vaccines through this RFI. Please contact Eli Briggs, IDSA director of public policy, at elibriggs@idsociety.org with any questions.

Sincerely,



Ronald G. Nahass, MD, MHCM, FIDSA
President
Infectious Diseases Society of America

¹ Centers for Disease Control and Prevention, ACIP Shared Clinical Decision-Making Recommendations. Accessed from <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html> on August 31, 2026..

² CDC, ACIP Shared Clinical Decision-Making Recommendations. Accessed from <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html> on August 31, 2026.

³ CDC, The Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book), Chapter 19: Rotavirus. Accessed from <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html> on September 2, 2026.

⁴ Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019. *Public Health Reports*®. 2023;0(0). Accessed from <https://journals.sagepub.com/doi/10.1177/00333549231175548> on September 2, 2026.

⁵ Shin T, Wells CR, Shoukat A, et al. Quadrivalent Conjugate Vaccine and Invasive Meningococcal Disease in US Adolescents and Young Adults. *JAMA Netw Open*. 2024;7(11):e2443551. Accessed from <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2825811> on September 2, 2026.

⁶ Jerome S. Leonard, Katie Reinhart, Peng-Jun Lu, Tammy A. Santibanez, Anup Srivastav, Mei-Chuan Hung, Anurag Jain, Alicia Budd, Stacy Huang, Krista Kniss, Ashley M. Price, Erin Burns, Sascha Ellington, Brendan Flannery; Influenza Vaccine Effectiveness Against Pediatric Death in the United States: 2016–2025. *Pediatrics* August 2026; 158 (2): e2026076453. Accessed from <https://publications.aap.org/pediatrics/article-abstract/158/2/e2026076453/208191/Influenza-Vaccine-Effectiveness-Against-Pediatric> on September 2, 2026.

⁷ KFF. “Kindergarten Routine Vaccination Rates Continue to Decline.” Accessed from <https://www.kff.org/medicaid/kindergarten-routine-vaccination-rates-continue-to-decline/> on August 31, 2026.

⁸ KFF. KFF Health Information and Trust Polling Dashboard. Accessed from <https://www.kff.org/public-opinion/kff-polling-on-health-information-and-trust/?entry=trusted-sources-of-health-information-who-the-public-trusts-for-health-information> on August 31, 2026.

⁹ CDC, Measles Cases and Outbreaks. Accessed from <https://www.cdc.gov/measles/data-research/index.html> on September 2, 2026.

¹⁰ CDC, Evidence-based Recommendations for ACIP. Accessed from <https://www.cdc.gov/acip/evidence-based-recommendations/index.html> on September 1, 2026.

¹¹ Rochelle P. Walensky, Daniel P. McQuillen, Sara Shahbazi, et al. *Where Is the ID in COVID-19?*. *Ann Intern Med*.2020;173:587-589. [Epub 3 June 2020]. Accessed from <https://www.acpjournals.org/doi/10.7326/M20-2684> on September 2, 2026.

