



September 18, 2026

Ms. Cynthia Goss

Deputy Assistant Secretary for Planning and Evaluation (Health Policy)

U.S. Department of Health & Human Services

200 Independence Avenue, S.W.

Washington, D.C. 20201

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

Submitted via regulations.gov

Dear Ms. Goss:

The Partnership to Fight Infectious Disease (PFID) appreciates the opportunity to respond to the Request for Innovation from the U.S. Department of Health and Human Services (HHS) seeking public input on the categories used in federal vaccine recommendations.

PFID is a coalition of stakeholders working to raise awareness of the threats posed by infectious disease and to advance solutions to address those threats. We acknowledge the significant role federal vaccine recommendations have played in providing clarity for both clinicians and consumers to make evidence-based decisions about vaccination. We also acknowledge the careful processes by which the different recommendation categories have been developed and utilized in the past by the Advisory Committee for Immunization Practices following the evidence to recommendations framework and GRADE methods for evaluating evidence.

Vaccines play a critical and irreplaceable role in public health. Routine childhood vaccinations have prevented an estimated 508 million illnesses and generated an estimated \$540 billion in direct savings and an additional \$2.7 trillion in societal savings. 92% of voters polled by PFID affirmed that personal doctors and family pediatricians are their most trusted source for accurate vaccine guidance and information. PFID wishes to emphasize that protecting the public health gains achieved through vaccination requires policymakers to preserve an evidence-based recommendation framework, maintain access to recommended vaccines, and communicate benefits and risks transparently so

that Americans can make informed decisions in discussions with their trusted healthcare providers.

A. Adequacy of the Current Categories & Process for Their Development

PFID supports the existing vaccine recommendation categories, resulting from rigorous, evidence-based deliberations developed over time by the Advisory Committee on Immunization Practices (ACIP). Sources of public and professional confusion over recommendations did not originate from the existing recommendation categories.

Historically, ACIP has met annually to consider the vaccine recommendation schedule, using frameworks for decision making known as GRADE and EtR. GRADE is a structured methodology for rating the certainty of scientific evidence on specific outcomes, used broadly across public health bodies. That graded evidence then feeds into the Evidence to Recommendations (EtR) framework, which weighs criteria like disease burden, benefit-harm balance, feasibility, and equity in a standardized table before any vote. This created a transparent, traceable link between the evidence and the final recommendation, and was foundational in creating the recommendation categories we have today, which PFID affirms are adequate and clear based on their strong scientific and historical foundation.

While the recommendation categories themselves are clear, recent messaging surrounding categories could lead confusion for both patients and providers. For example, comments about expanding the “shared clinical decision making” recommendations by downgrading universal recommendations reflect faulty assumptions and misplaced concerns that informed consent and provider-patient discussions are not part of every vaccination interaction. In fact, they are. Healthcare professionals are legally and ethically obligated to obtain informed consent as part of patient care. This means individuals must receive information about the benefits and risks and voluntarily agree before receiving any vaccine. Healthcare professionals legally must document that a patient has provided informed consent before administering a vaccine, regardless of the recommendation category.

PFID supports retaining the existing vaccine recommendation categories and urges policymakers to focus on ensuring that their application and communication remain clear, consistent, and grounded in transparent, evidence-based deliberation.

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

We are deeply concerned by proposals that would modify federal vaccine recommendations based on considerations outside the scientific and medical evidence. Adding new categories and caveats does not make recommendations easier to act upon. Instead, it complicates the clarity providers and patients depend on, and risks making vaccination harder to access.

There is no significant evolving scientific evidence behind any change in existing recommendations and recommendation categories. Any changes without evidence to support them will further erode public trust, not enhance it. According to recent polling, 9 in 10 voters say it is important that vaccine recommendations are made by independent medical experts without political influence. Almost 8 in 10 voters believe political influence is affecting scientific decision-making in vaccine policy and 60% are concerned that people who want to get vaccinated will not be able to because of changes in or confusion around vaccine recommendations from the federal government.

Changing recommendation categories carry consequences: the confusion created by such changes can restrict the population who opt into a vaccine and put people at unnecessary risk of illness. Changes based on policy preferences and not scientific evidence also may create risks to coverage and patient access through both private and public insurance and other programs and may restrict access depending on state laws involving vaccine administration and prescription requirements.

Additionally, differences between the U.S. schedule and other countries' schedules do not justify changing the U.S. framework. Such comparisons would have to account for differences in epidemiology, health system structure, population demographics, implementation feasibility, and vaccine access. Our successes in the management and control of vaccine-preventable diseases depend on the robust vaccination recommendations, access, and coverage systems we have tailored over decades to meet the specific needs of U.S. residents and realities of the U.S. system. We should recognize that success and strive to preserve and build upon it.

Adding new or more granular categories furthermore complicate administration in convenient consumer access points, such as pharmacies, where a growing share of vaccination occurs. State laws vary in terms of vaccination access at pharmacies and are often linked to ACIP recommendations. Adding new recommendation categories can have serious real-world repercussions that limit access and choice for millions of Americans. This includes the potential for changes in recommendation categories to affect insurance coverage and no-cost-sharing protections for recommended vaccines, as well as potential eligibility for vaccines through the Vaccines for Children (VFC) program.

To preserve access and choice, PFID urges HHS to keep the current recommendation framework and to avoid adding categorical complexity not driven by clinical evidence of vaccination benefits and risks and disease risks.

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

PFID believes that the Shared Clinical Decision Making (SCDM) recommendation category is sufficient as it stands, due to its historical and scientific foundation. The SCDM category was developed by the ACIP in 2019 as part of its evidence-based framework for situations in which the expected benefits of vaccination may vary meaningfully among individuals. Specifically, the SCDM category identifies vaccines for which an individual patient assessment may be appropriate because the expected benefit varies among eligible individuals and does not represent a lesser judgment about vaccine safety or the scientific evidence supporting vaccination. SCDM was not developed to suggest that vaccination decisions should be based primarily on personal beliefs or that vaccines recommended through this category are somehow less safe or less effective than vaccines receiving other types of recommendations. SCDM allows clinicians and patients to consider the best available scientific evidence alongside individual characteristics relevant to the expected benefits of vaccination. This individualized assessment is the defining purpose of the category, not a determination that science is uncertain or that the vaccine lacks value.

For example, one key utilization of SCDM has been for the HPV vaccine. While routine HPV vaccination is recommended through age 26, ACIP recommends shared clinical decision-making for adults ages 27 through 45 because the potential benefit of vaccination varies based on an individual's likelihood of prior and future HPV exposure.

Accordingly, PFID does not support changes that would diminish or unnecessarily complicate the SCDM category. Instead, we urge HHS to focus on clearly communicating its purpose. Only 22% of people can correctly identify that SCDM means “taking the vaccine may not be a good idea for everyone but would benefit some” according to an Annenberg Public Policy center poll.

Informed consent, patient-provider communication, clinical judgment, and consideration of contraindications and individual circumstances remain fundamental components of patient-clinician discussions with every vaccination regardless of the recommendation category. Likewise, a federal vaccine recommendation is not a mandate. Healthcare professionals and patients routinely discuss the benefits and risks of vaccination, and individuals maintain the ability to ask questions and make informed decisions about their care.

Recasting SCDM primarily around personal beliefs, autonomy, or other non-clinical considerations would defeat the evidence-based rationale for the category. Personal values and preferences appropriately inform conversations between patients and clinicians, as they do throughout medical care, but they were not the central reason ACIP created this recommendation category. Its primary purpose was to address circumstances in which the expected benefit of vaccination differs meaningfully among individuals based on relevant clinical, epidemiological, or other evidence-based factors.

D. Considerations in Setting Recommendations

PFID affirms the strength of the current recommendation categories and does not recommend changes. We appreciate the public engagement opportunity reflected by the RFI but have serious concerns about decisions being made that could fundamentally alter people's access to vaccines and further undermine trust by making changes outside the GRADE and Evidence to Recommendations (EtR) frameworks. This concern is not a procedural preference but a substantive necessity: without a transparent, accountable process between evidence and decision, HHS risks replacing decades of scientific rigor with a confusing array of recommendations and categories that providers, payers, and the public cannot trust or reliably act upon. Any modification to the current schedule should be required to include a documented GRADE evidence assessment and EtR table, made publicly available, with opportunities for public comment, before adoption.

We are also deeply concerned that since ACIP's restructuring, no equivalent evidence-review process has taken its place. Future changes to vaccine recommendations, whether to categories, timing, or frequency, must not proceed without a rigorous, standardized process for evaluating evidence.

E. Trust and Communication

Evidence suggests that honest, balanced communication about vaccination is essential to building and sustaining public trust. A recent study by researchers at the University of Cambridge compared traditional persuasive messages encouraging vaccination with versions designed to present information in a more balanced and transparent manner. The study found that balanced communication was no less persuasive than traditional persuasive messaging. Moreover, among participants with neutral or negative views toward vaccination, balanced communication was perceived as significantly more trustworthy than traditional persuasive messaging.

PFID therefore reiterates that government communication regarding vaccines must be transparent, balanced, and based on verified scientific evidence. Like all medical products,

vaccines carry potential risks and side effects, and we strongly support clear disclosure of those risks. However, transparency requires more than simply listing potential harms; it also requires placing those risks in their proper context and communicating them alongside the benefits vaccines provide and the risks associated with the diseases vaccines protect against.

The evidence demonstrates why this context is so critical. Across more than 5.65 billion doses of covered vaccines distributed between 2006 and 2024, the Vaccine Injury Compensation Program compensated approximately one claim per million doses. This figure reflects both the rarity of serious vaccine-related injuries and the existence of a system designed to identify and compensate individuals who experience them. At the same time, routine childhood vaccinations have prevented an estimated 508 million illnesses and more than one million deaths, generating an estimated \$540 billion in direct savings and an additional \$2.7 trillion in societal savings. Adult vaccination likewise delivers substantial and immediate public health benefits: during the 2024–2025 influenza season alone, vaccination prevented an estimated 10 million illnesses, 180,000 hospitalizations, and 12,000 deaths in the United States.

Public trust is not built by minimizing either the benefits or the risks associated with vaccination. Rather, it is built through honest communication that presents both clearly and with the well-documented body scientific and clinical evidence relied upon in developing vaccine recommendations.

We urge HHS to consider the consequences of revising the vaccine recommendations, and instead to focus on clear, evidence-based communication regarding vaccines. Confusion creates barriers and complicates coverage and access. Revising the current vaccine recommendation schedule, which is grounded in decades of scientific evidence, public health experience, and historical precedent, could further undermine public trust in vaccination when we need to do the opposite.

During the 2025-2026 school year, vaccination coverage among kindergartners in the United States decreased for all reported vaccines from the year before, while exemptions from one or more vaccines among kindergartners in the United States increased to 4.2% from 3.6% the year before. And for a second consecutive year, America has the alarming misfortune of declaring this the worst year for measles since the early 1990s.

Protecting individual freedoms and preserving public health need not be competing goals; both depend on policies that provide clarity, maintain access to recommended vaccines, and empower individuals to make informed decisions in consultation with a trusted healthcare professional.

PFID stands ready to support reforms that strengthen public confidence through transparent communication, clear recommendations, and a consistent commitment to scientific evidence.

Respectfully submitted,

Candace DeMatteis