

September 18, 2026

[Submitted electronically via regulations.gov]

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)

U.S. Department of Health and Human Services (HHS)

200 Independence Ave, SW

Washington, DC 20201

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

Dear Secretary Kennedy,

As the organizations representing pharmacists, pharmaceutical scientists, pharmacy technicians, and student pharmacists who serve on the front lines of vaccine delivery and public health, we are pleased to submit comments to the Department of Health and Human Services (HHS) Request for Information (RFI) regarding potential modifications to federal vaccine recommendations and shared clinical decision-making framework. The following comments reflect our steadfast commitment to providing our patients with safe, effective, and evidence-based vaccines.

1. Ensure scientifically grounded, evidence-based, and transparent federal vaccine recommendations

The longstanding review process utilized by the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), with input from their respective expert advisory committees, is a national standard for evaluating vaccine safety, effectiveness, and public health impact. The use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach and the Evidence-to-Recommendation (EtR) framework by the Advisory Committee on Immunization Practices (ACIP) has served as an important foundation to its evidence-based decision-making process. These processes appropriately balance evidence from randomized clinical trials, epidemiological studies, post-marketing surveillance, and real-world effectiveness data to inform vaccine recommendations.

Maintaining public confidence in the nation's vaccination program requires a recommendation process that is transparent, scientifically rigorous, and informed by those with direct experience in vaccine research, policy, and implementation. As HHS, CDC, and ACIP consider any changes to federal vaccine recommendations, it is essential that decision-making reflects the perspectives of the healthcare professionals and

scientists who evaluate, recommend, and administer vaccines every day. Frontline vaccination providers, vaccine scientists, public health experts, and other stakeholders possess critical expertise regarding vaccine effectiveness, safety monitoring, patient acceptance, and operational implementation.

In particular, pharmacists and pharmacy personnel play a central role in the nation's vaccination infrastructure and should be represented throughout ACIP's work. As the most accessible healthcare professional, pharmacists administer millions of vaccines annually in community pharmacies, health systems, long-term care facilities, and public health settings. Their extensive expertise in vaccinology, vaccine delivery, patient counseling, and access-related challenges provides valuable perspectives that will strengthen ACIP deliberations and support successful implementation of vaccine recommendations. Given this and the pharmacy profession's substantial contribution to national immunization efforts, ACIP should include at least one pharmacist member with demonstrated subject matter knowledge and experience. ***We urge the appointment of at least one pharmacist with demonstrated vaccine expertise to ACIP to ensure that the committee's recommendations are informed by the perspectives of one of the nation's largest and most accessible vaccine delivery workforces.***

2. Promote Clarity and Consistency for Patients and Providers

Clear and consistent vaccine recommendations are essential for patient and provider decision making and efficient implementation across the healthcare system. When recommendation processes become unclear or appear unpredictable, provider confidence is weakened and patient uncertainty increases, ultimately undermining vaccination efforts. Inconsistent recommendation structures create vaccine-related patient access barriers, increase administrative burden and operational challenges, and generate inconsistent implementation.

We strongly urge HHS to preserve the current ACIP recommendation framework, from routine to risk-based and ultimately to the shared clinical decision-making (SCDM) recommendation category. These categories provide clarity for clinicians, patients, schools, employers, insurers, and public health agencies, while reinforcing confidence in the integrity and consistency of vaccine recommendations. Consistent recommendations establish a national baseline that supports effective vaccination programs and straightforward clinical implementation.

The SCDM recommendation category serves an important role within ACIP's recommendation framework by recognizing circumstances in which vaccination decisions are best guided by an individualized assessment of patient-specific factors and preferences. Pharmacists routinely implement SCDM recommendations by evaluating clinical considerations, counseling patients, and supporting informed, patient-centered care. Preserving a clear distinction between routine, risk-based, and SCDM

recommendation categories promotes consistent implementation, patient access, provider education, coverage determinations, and appropriate application across healthcare settings. However, SCDM recommendations should complement, rather than replace, routine or risk-based recommendations when the evidence supports broader vaccination recommendations for a population. ***Future ACIP recommendations should continue to utilize the full recommendation framework, including SCDM, while reserving routine and risk-based recommendations for vaccines supported by broader population-level evidence.***

3. Maintain patient access to evidence-based, affordable, and innovative vaccines

The implications of ACIP recommendations extend far beyond clinical guidance. Routine ACIP vaccine recommendations influence decisions related to insurance coverage, public health programs, and vaccine access policies across the United States. Preserving patient access to vaccines and supporting continued innovation in vaccine discovery must remain central goals of federal vaccine policy.

Under Section 2713 of the Affordable Care Act, ACIP-recommended preventive services are generally covered without patient cost-sharing. Likewise, ACIP recommendations are closely linked to coverage policies for Medicare, Medicaid, and commercial health plans, making consistency and predictability in the recommendation process essential to maintaining broad vaccine access. The SCDM recommendation category serves an important purpose by supporting individualized vaccination decisions while helping patients access vaccines at no cost and ensuring providers obtain appropriate reimbursement when vaccination is based on patient-specific clinical circumstances.

ACIP recommendations inform eligibility and coverage policies for numerous federal and state vaccine programs, including the Vaccines for Children Program. Changes to recommendation levels creates uncertainty regarding vaccine inclusion within these programs, potentially affecting access for children and families who rely on them. ACIP recommendations also influence other critical areas of vaccine policy, including determinations related to the National Vaccine Injury Compensation Program, public health implementation strategies, provider authorization and reimbursement frameworks, quality measurement programs, and state and local vaccination requirements. As a result, modifications to recommendation categories can have far-reaching consequences throughout the healthcare system that extend beyond individual clinical encounters. ***Changes to ACIP recommendation categories and recommendations should be made only after careful consideration of their impact on patient outcomes, vaccine access, insurance coverage, and public health programs.***

In summary, protecting population health requires vaccine policies that are firmly rooted in scientific evidence, communicated through clear and consistent recommendation frameworks, and supported by policies that ensure broad access to vaccines. The pharmacy community

stands ready to collaborate with HHS, CDC, and ACIP to strengthen public trust in vaccines and ensure that the nation's vaccination system supports affordable, predictable, and timely access to evidence-based vaccinations and protects communities from vaccine preventable diseases.

If you have any questions or would like to meet with us, please contact Jillanne Schulte Wall, J.D., ASHP's Senior Director, Health & Regulatory Policy at 301-664-8698 or jschulte@ashp.org. We look forward to continuing the collaboration between HHS, ACIP, and our nation's pharmacists and pharmacy personnel.

Sincerely,

American Association of Colleges of Pharmacy
American Association of Psychiatric Pharmacists (AAPP)
American College of Clinical Pharmacy
American Pharmacists Association
American Society of Health-System Pharmacists
National Community Pharmacists Association
Pediatric Pharmacy Association