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

Re: Docket No. HHS-OS-2026-0332

Dear Ms. Goss:

The 33 undersigned organizations represent public health, older adults, patients, family caregivers, consumers, physicians, and other health care providers who are committed to ensuring access to vaccines for all Americans and raising awareness about the importance of vaccination in individual and public health. We appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*.

While we support the efforts to improve public understanding of vaccine recommendations, strengthen communication, and maintain and increase public trust, we also strongly believe that:

- No additional categories for vaccine recommendations should be adopted and current recommendations based on shared clinical decision-making (SCDM) should be reconsidered, and possibly removed, if found to impede access.
- Continued communication efforts to improve public understanding and trust of vaccines are critical and should be prioritized at every level of the healthcare continuum.
- Access to vaccines at zero-dollar cost sharing should be maintained for all Americans.
- The Advisory Committee on Immunization Practices (ACIP) should remain the venue for vaccine recommendations and any reforms should build upon, rather than circumvent, the existing ACIP.

Additional Vaccine Categories Are Not Needed and SCDM Should Be Reassessed

According to a recent report from the Champions for Vaccine Education, Equity & Progress (CVEEP), SCDM vaccine recommendations often have downstream implications including:

- Complication of decision-making and implementation due to a lack of standard guidance.
- Additional time and resource burdens on clinicians that are not accounted for within the current care frameworks.
- Exacerbation of social determinants of health-related barriers.
- Creation of disparities in understanding and uptake due to the shift of greater responsibility to patients without additional educational resources.
- Increased financial and logistical barriers in vaccine management such as forecasting, ordering, tracking and monitoring, and more.

- Confusion about insurance coverage and reimbursement for vaccines with SCDM recommendations.
- Uncertainty about which vaccines are recommended for which populations.

As noted in the *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, a national survey of physicians underscores these concerns with findings that most physicians report that implementing SCDM requires more time, less than half knew that SCDM vaccines are covered by insurance, and most agreed that the recommendations cause confusion among patients.

While there is support for SCDM use for vaccines where the benefit-risk calculation varies meaningfully from patient to patient, there are still clearly many challenges and outstanding issues that must be resolved to ensure equitable access and optimal vaccination rates.

The undersigned organizations recommend that any changes to the existing vaccine categories be carefully evaluated for downstream effects on vaccine access, coverage, and public health infrastructure. SCDM recommendations should also be reassessed to determine whether they create unintended barriers to access, while recognizing that clear communication about the benefits and risks of vaccination is essential to every vaccination decision, regardless of recommendation category. Additionally, for all vaccine conversations, a CPT code that reimburses Medicare health professionals is critical to supporting the communication and educational efforts needed for all vaccine categories.

ACIP Remains the Appropriate Venue for Vaccine Recommendation Deliberations

For more than 50 years, the ACIP has been a trusted source of evidence-based vaccine recommendations that guide healthcare professionals, patients, families, and payers. The process by which this committee reviews and makes recommendations on the use of vaccines has historically been based on the best data and evidence available. As new science has emerged, the committee has also been diligent in making informed and updated recommendations that are in the best interest of the American people.

ACIP's use of the Grading of Recommendations, Assessments, Development and Evaluation (GRADE) approach and Evidence to Recommendations (EtR) Frameworks ensure that scientific and clinical evidence are reviewed, as well as individual and population-level data around benefit versus harm and other relevant factors. This critical process ensures a consistent, rigorous, and transparent way to review scientific evidence and ensure maximum individual and population benefits while minimizing potential harms from a vaccine.

We recommend that to align with the Administration's commitment to "Restoring Gold Standard Science," that HHS and the CDC uphold the critical processes and standards—including GRADE and EtR—of the ACIP. ACIP should remain the venue for vaccine recommendations and any reforms should build upon the existing ACIP, rather than circumvent it. Additionally, the CDC should initiate the review of ACIP workgroups and recommendations as directed by the 21st Century Cures Act (P.O. 114-355) to look for ways to improve the consistency of GRADE and EtR.

Continued Efforts to Improve Public Understanding and Trust Are Critical
Despite the significant evidence on the benefits of vaccines, 3 out of 4 adults miss at least one of their recommended vaccines, and around 50,000 adults in the U.S. die each year from vaccine-preventable diseases.

The ultimate decision of whether to get a vaccine should be limited to patients, families, and their clinicians. But trust is strengthened when individuals understand what is recommended and why.

Communication practices should be evidence-based, transparent, written in plain language, multilingual, and consistent across this Administration. **We recommend that effective communication about vaccine recommendations should occur at every level of the healthcare continuum.**

Access to Vaccines for All Americans at Zero-Dollar Cost Sharing Should be Maintained
Out-of-pocket costs and copays are found to directly lower vaccination rates, but removing financial barriers significantly increases coverage. Studies show that even small out-of-pocket costs lead people to skip recommended vaccines.

All Americans who want vaccines should be able to access them at zero-dollar cost sharing. We ask that HHS continue to ensure that all vaccines are offered at no cost, and that communication and messaging reiterates the commitment to coverage regardless of the category of vaccine recommendation.

We believe that the current recommendation categories should be maintained, while the SCDM category should be re-evaluated to account for unintended consequences. Additionally, ACIP should remain the appropriate venue for vaccine recommendations and these recommendations should be communicated consistently to the public and underscore zero-cost sharing of vaccinations.

Respectfully submitted,

Alliance for Aging Research
Academy of Medicine of Cleveland & Northern Ohio (AMCNO)
AiArthritis
Allergy & Asthma Network
American Association of Nurse Practitioners
American Association of People with Disabilities
American Geriatrics Society
American Pharmacists Association
American Society on Aging
Cancer Nation
Caregiver Action Network
CaringKind
Chronic Care Policy Alliance
Dia de la Mujer Latina Inc.

Diverse Elders Coalition (DEC)
Families Fighting Flu
Gerontological Society of America
Global Coalition on Aging
H.E.A.L.S. of the South
HealthyWomen
Immune Deficiency Foundation
Infectious Diseases Society of America
Lupus and Allied Diseases Association, Inc.
National Alliance for Caregiving
National Association of Nutrition and Aging Services Programs (NANASP)
National Consumers League
National Down Syndrome Society
National Hispanic Health Foundation
Neuropathy Action Foundation
Partnership to Fight Chronic Disease
The California Chronic Care Coalition
Vasculitis Foundation
Voices of Alzheimer's