GOVERNORS PUBLIC HEALTH ALLIANCE

September 19, 2026

Cynthia Goss
Office of the Secretary
Department of Health and Human Services
200 Independence Avenue
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

Dear Ms. Goss:

On behalf of the Governors Public Health Alliance (PHA), we appreciate the opportunity to submit comments on the Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making. As a nonpartisan coalition of 15 Governors, representing approximately one-third of the American population, PHA is committed to protecting and advancing the health and wellbeing of millions of Americans across our states.[1] PHA's member Governors play a central role in overseeing state public health agencies, Medicaid programs, insurance markets, emergency response systems, and state vaccination policy.

PHA's member Governors have experienced firsthand how federal changes to vaccine policy impact state legal and regulatory frameworks, which have historically relied on federal vaccine recommendations. Changes to vaccine recommendation categories or the processes used to develop them affect how states administer public health programs, communicate with residents, allocate resources, and prepare for and respond to infectious disease threats.

We therefore urge the Department of Health and Human Services (HHS) to:

1. Preserve a stable national vaccine recommendation framework that states can rely on as the foundation for immunization policy, insurance coverage, public health programs, and outbreak preparedness.
2. Maintain established, transparent, and evidence-based advisory processes for evaluating vaccines and developing federal recommendations through the Advisory Committee on Immunization practices.
3. Avoid changes to recommendation categories or schedules that would increase administrative burden, create implementation challenges for states, or generate confusion among providers and the public.
4. Fully assess and publish the operational, fiscal, and public health impacts on states before adopting changes that may affect vaccination policy, coverage, or outbreak response.

[1] PHA membership includes California Governor Gavin Newsom, Colorado Governor Jared Polis, Connecticut Governor Ned Lamont, Delaware Governor Matt Meyer, Guam Governor Lou Leon Guerrero, Hawai'i Governor Josh Green, Illinois Governor JB Pritzker, Maryland Governor Wes Moore, Massachusetts Governor Maura Healey, New Jersey Governor Mikie Sherrill, New York Governor Kathy Hochul, North Carolina Governor Josh Stein, Oregon Governor Tina Kotek, Rhode Island Governor Daniel McKee, and Washington Governor Bob Ferguson.

1. States Depend on Consistent, Evidence-Based Federal Vaccine Recommendations

Response to questions 1, 4, 6, and 14.

Governors rely on a stable federal framework to support consistent vaccination policies across states and jurisdictions and provide clarity to State agencies, health care providers, insurers, schools, and families. For decades, Governors' health agencies built regulatory schemes that expressly incorporated the Advisory Committee on Immunization Practices (ACIP) as the national standard for vaccination policy and implementation, given the Committee's prior organization as a gold-standard for public health evidence and transparency (see greater discussion in Section 2). ACIP's schedules are referenced in areas including school-entry requirements, mandatory insurance coverage, provider scope of practice, health care worker immunization rules, Medicaid coverage mandates, and public health emergency protocols.[2] As of June 2025, forty-nine States, three territories, and the District of Columbia had incorporated ACIP recommendations by reference in nearly 600 statutes and regulations.[3] Recent federal changes to the ACIP, including replacing all members of the ACIP simultaneously and adding several members who have ties to anti-vaccine research or organizations, changing conflict-of-interest policies, sharing presentations that have not been reviewed to ensure alignment with current scientific understanding, prohibiting medical organizations from participating as non-voting members of ACIP working groups,[4] and eliminating the schedule of required public meetings, have disrupted this settled framework. This has forced 30 states to reduce their reliance on ACIP recommendations alone, though few states have delinked all parts of state vaccine regulation from ACIP.[5] Further, states are unable to fully delink from ACIP since they lack the authority to change coverage requirements for large multi-

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[2] See Ass'n of State & Territorial Health Offs., Impact of the Advisory Committee on Immunization Practices Recommendations on State Law (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/ (school and healthcare worker immunization schedules); Kavya Sekar et al., Cong. Rsch. Serv., R48982, The 2026 Childhood Immunization Schedule (June 11, 2026), https://www.congress.gov/crs-product/R48982 (vaccination administration); Jennifer Kates, ACIP, CDC, and Insurance Coverage of Vaccines in the United States, KFF (June 13, 2025), https://www.kff.org/other-health/acip-cdc-and-insurance-coverage-of-vaccines-in-the-united-states/ (Medicaid coverage mandates); Kavya Sekar, Cong. Rsch. Serv., IF12317, The Advisory Committee on Immunization Practices (ACIP) (updated Sept. 15, 2025), https://www.congress.gov/crs-product/IF12317 (public health emergency protocols).

[3] Ass'n of State & Territorial Health Offs., Impact of the Advisory Committee on Immunization Practices Recommendations on State Law (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

[4] Kevin B. O'Reilly, Latest ACIP Move Is Dangerous to the Nation's Health, Am. Med. Ass'n (Aug. 1, 2025), https://www.ama-assn.org/public-health/prevention-wellness/latest-acip-move-dangerous-nation-s-health (reporting that ACIP work groups would no longer include liaison representatives from outside medical organizations); see also https://vaxintegrity.cidrap.umn.edu/federal-vaccine-action-timeline (general timeline of federal vaccine policy actions); KFF, Tracking Key HHS Public Health Policy Actions Under the Trump Administration (last visited Sept. 18, 2026), https://www.kff.org/other-health/tracking-key-hhs-public-health-policy-actions-under-the-trump-administration (same).

[5] KFF, *Reliance on Sources Other Than CDC/ACIP for State Childhood Vaccine Recommendations* (last updated Aug. 11, 2026), https://www.kff.org/other-health/state-indicator/reliance-on-sources-other-than-cdc-acip-for-state-childhood-vaccine-recommendations (noting 30 states and the District of Columbia rely on sources other than ACIP for state childhood vaccine recommendations); Common Health Coalition, *State Vaccine Access Policy Tracker* (last visited Sept. 14, 2026) https://www.commonhealthcoalition.org/resources/state-vaccine-access-policy-tracker?returnTo=%2Fvaccine-response%23vaccine-response-grid (showing that few states have fully delinked from ACIP).

state employer health plans, or to determine coverage standards under the National Vaccine Injury Compensation Program.

Changes to federal recommendation categories or the creation of alternative recommendation pathways will introduce uncertainty into systems that depend on clear and widely understood guidance.[6] Changes will cascade through school-entry requirements, insurance coverage,[7] and licensure protections simultaneously, requiring State agencies to reevaluate policies, update program materials, and modify operational procedures at significant cost.

The Alliance does not contend that the current category structure is beyond improvement. Rather, we are concerned that changes of this magnitude -- affecting state legal requirements, budgets, and the lives of our residents -- must be made by subject matter experts, on a developed evidentiary record, through a defined and transparent process.

At a time when many state public health agencies face resource constraints and increasing demands, maintaining a clear, predictable, and evidence-based national recommendation framework is essential.

2. **Transparent, Evidence-Based Advisory Processes Are Essential to Public Trust and Effective State Governance**
   Response to Questions 14,15, and17.

The confidence of Governors, health system leaders, health providers, and the public in federal recommendations rests on both the science used to evaluate them and the transparency, consistency and credibility of the process that produces them. Prior to the recent federal actions described above, ACIP's open meetings, public evidence review, and stakeholder input had been the gold-standard for transparent and thoughtful public health recommendation processes.[8]

ACIP is chartered under 42 U.S.C. § 217a and operates subject to the Federal Advisory Committee Act. When Congress conditioned coverage, program eligibility, and cost-sharing protections on ACIP recommendations, it incorporated the committee as it functioned: a chartered advisory body with balanced membership with clinical, scientific, and public health expertise in immunization, conflict-of-interest screening, public meetings, published evidence reviews, and recorded votes.

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[6] Nat'l Vaccine Advisory Comm., A Pathway to Leadership for Adult Immunization: Recommendations of the National Vaccine Advisory Committee, 127 Pub. Health Rep. Suppl. 1, at 1 (2012), https://pmc.ncbi.nlm.nih.gov/articles/PMC3235599/.

[7] Amy Killelea, et al., Will Insurance Plan Coverage Policies Help Clarify ACIP Confusion? Probably Not, Health Affs. Forefront (Sept. 10, 2026), https://www.healthaffairs.org/content/forefront/insurance-plan-coverage-policies-help-clarify-acip-confusion-probably-not.

[8] Kavya Sekar, Cong. Rsch. Serv., IF12317, The Advisory Committee on Immunization Practices (ACIP) (updated Sept. 15, 2025), https://www.congress.gov/crs-product/IF12317.

A request for information, followed by action taken through the Task Force on Safer Childhood Vaccines ("Task Force") or by HHS directly, or rubber stamped[9] without full evidence review by ACIP, is not a substitute for that process and cannot carry the legal consequences attached to it.

This RFI itself observes that overriding a deliberative advisory process in favor of a top-down determination could "contribute to public doubt about whether Federal recommendations in fact reflect the process created to produce them."[10] The Alliance accordingly requests that HHS state whether it intends any recommendation-category change to be developed and voted by ACIP under its Evidence to Recommendations framework, and, if the Task Force is to play any role, how the Task Force will satisfy the balance, transparency, and conflict-screening requirements historically applicable to ACIP prior to the recent federal changes discussed in Section 1. Category changes developed outside ACIP's ordinary deliberation will be harder for State officials to explain to residents and providers, especially when communicating with the public during periods of uncertainty, such as during outbreak response.[11] Public confidence is strengthened when people can see that decisions are based on evidence and reached through a transparent and predictable process.[12]

In addition, the RFI suggests that HHS is considering applying "a presumption in favor of individual autonomy and religious freedom"[13] in setting vaccine recommendations. Federal vaccine recommendations should be grounded in scientific evaluation of safety, effectiveness, and public health impact. ACIP's Evidence to Recommendations framework already accounts for patient values, preferences, and acceptability within that assessment. The RFI does not address how the presumption would be defined, weighted, or reconciled with the assessments the ACIP framework already requires. Changes cannot be made without addressing these questions.

Any changes to federal vaccine recommendation categories should be considered alongside the processes used to develop them. Preserving transparent, evidence-based, and publicly accountable advisory structures is essential to maintaining public trust, supporting effective state implementation, and ensuring that Governors have the tools they need to protect the health of their communities.

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[9] The Federal Advisory Committee Act requires that advisory committee advice not be inappropriately influenced by the appointing authority. A vote taken on a predetermined conclusion, without the evidentiary development that framework requires, would not satisfy that requirement.

[10] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. (Aug. 24, 2026) (Docket No. HHS-OS-2026-0332) pt. I.D, https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared.

[11] State Health & Value Strategies, HHS Announces Major Updates to Childhood Immunization Schedule (Jan. 2026), https://shvs.org/resources/hhs-announces-major-updates-to-childhood-immunization-schedule/ (noting the January 5, 2026 decision memorandum was issued unilaterally, without public comment, and without initial review by designated advisory bodies).

[12] Am. Med. Ass'n, AMA Statement on Changes to Childhood Vaccine Schedule (Jan. 5, 2026), https://www.ama-assn.org/press-center/ama-press-releases/ama-statement-changes-childhood-vaccine-schedule (stating that the process lacked adequate "rigor and transparency" and that changes made this way "undermines public trust").

[13] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. (Aug. 24, 2026) (Docket No. HHS-OS-2026-0332) https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared.

3. Changes to Recommendation Categories or Schedules Could Increase Administrative Burden, Create Implementation Challenges, and Generate Public Confusion

Response to Questions 4, 7, 11, 12, 13, 14

Federal vaccine recommendations are most effective when they provide clear, consistent, and actionable guidance for the individuals and organizations responsible for implementing them. States are responsible for translating federal recommendations into public health practice —- updating guidance documents, educational materials, provider communications, and immunization information systems. Changes to recommendation categories or schedules may require states to reassess existing policies, coordinate with insurers and health systems, and communicate new requirements or expectations to multiple stakeholders, consuming staff time and resources that could otherwise be used to improve public health.

HHS's own record underscores these concerns. The Department has assembled a record indicating that practitioners want the intermediate category retained and made to work.[14] SCDM has a legitimate and useful role when the expected benefit of vaccination truly varies in a clinically meaningful way among individuals. However, the record also shows that only 24 percent of pediatric providers could accurately define a permissive recommendation, that a majority did not know such vaccines are covered by private insurance or the Vaccines for Children program, that 90 to 95 percent of physicians report shared clinical decision-making (SCDM) recommendations consume more time than routine recommendations, that electronic health record and immunization forecasting tools display them inaccurately or not at all, and that these issues create barriers to vaccination.[15]

Existing evidence suggests that provider confusion surrounding SCDM recommendations stems primarily from communication, training, and implementation gaps,[16] given the counseling, consent, and informed choice that appropriately accompany every vaccine decision. The remedy to reducing this confusion is the one Question 13 itself contemplates: decision aids, provider

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[14] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. (Aug. 24, 2026) (Docket No. HHS-OS-2026-0332) https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared, citing: A. Kempe et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?, 36 J. Gen. Intern. Med. 2283 (2021), https://link.springer.com/article/10.1007/s11606-020-06456-z.

[15] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. (Aug. 24, 2026) (Docket No. HHS-OS-2026-0332) https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared, citing: A. Kempe et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?, 36 J. Gen. Intern. Med. 2283 (2021), https://link.springer.com/article/10.1007/s11606-020-06456-z; J. Vietri *et al., Pneumococcal Vaccine Uptake Among Medicare Beneficiaries Aged ≥65 Years Following the Shared Clinical Decision-Making Recommendation for 13-Valent Pneumococcal Conjugate Vaccine in 2019,* 41 Vaccine 5211 (2023).

[16] A. Kempe et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?, 36 J. Gen. Intern. Med. 2283 (2021), https://link.springer.com/article/10.1007/s11606-020-06456-z (noting the need for SCDM implementation with decision-making support for patients and physicians).

training, corrected forecasting logic, and clear coverage guidance, paired with clear system-level distinctions between recommendation categories.

The Alliance agrees that once adopted by the CDC Director, an SCDM recommendation triggers the same coverage requirements as a routine recommendation, including coverage without cost sharing under the Affordable Care Act and availability through the Vaccines for Children program. It is important that HHS consistently and continually clarify this protection of coverage to address the existing provider confusion HHS has asserted, and to avoid worsening it.

HHS's proposal to establish additional recommendation categories is also in tension with the problem it identifies: if clinicians and the public do not reliably understand the current categories, the remedy is clearer distinctions, not more of them. Adding new recommendation categories would multiply the number of categories a clinician must distinguish at the point of care, multiply the coverage questions that must be answered, and require every immunization information system, electronic health record, and forecasting tool in the country to be rebuilt to display distinctions. HHS should explain how five or six categories would be better understood than the current one of three.

Finally, requiring vaccines to be administered individually, rather than together at a single visit, as contemplated by Question 7, would create further system-wide confusion and burden, particularly in rural and underserved areas already facing workforce shortages and access challenges.[17]

4. **Governors and States Bear the Human and Fiscal Costs When Vaccination Rates Decline and Outbreaks Occur, and These Costs Warrant Formal Assessment Before Any Change is Adopted**
   Response to questions 11, 14 and 18.

Governors coordinate the response when vaccination rates decline and outbreaks occur in their states. State and local health departments investigate cases, trace contacts, and communicate with the public—costs that recur with each outbreak in an under-vaccinated community. Decisions affecting vaccine recommendations should therefore be evaluated not only for their individual clinical implications, but also for their potential effects on vaccine uptake and community (or herd) immunity, public confidence, and the public's health.

Confusion or delay caused by category changes can translate directly into human[18] The United States is experiencing the highest numbers of measles cases, outbreaks, hospitalizations, and deaths in more than 30 years, driven by populations with low vaccination rates.[19] Unvaccinated individuals, particularly young children and pregnant people, face the highest risk of severe illness

[17] L.K. McCormick et al., Parental Perceptions of Barriers to Childhood Immunization: Results of Focus Groups Conducted in an Urban Population, 12 Health Educ. Res. 355 (1997), https://pubmed.ncbi.nlm.nih.gov/10174218/.
[18] Cal. Dep't of Pub. Health, CDPH Urges Vaccination as Measles Cases Rise Across Multiple Counties (Feb. 9, 2026) (quoting Erica Pan, CDPH Dir. & State Pub. Health Officer), https://www.cdph.ca.gov/Programs/OPA/Pages/NR26-007.aspx.
[19] Cal. Dep't of Pub. Health, CDPH Urges Vaccination as Measles Cases Rise Across Multiple Counties (Feb. 9, 2026) (quoting Erica Pan, CDPH Dir. & State Pub. Health Officer), https://www.cdph.ca.gov/Programs/OPA/Pages/NR26-007.aspx.

and even death. Ninety percent of unvaccinated people who are exposed to measles will contract the disease.[20] Death, and serious health complications including pneumonia and encephalitis, from the disease can occur both close to the time of infection to years later.[21] A 2025 review found the average measles outbreak costs approximately $43,000 per case;[22] a single 2025 outbreak that began in Texas and spread to New Mexico cost nearly $5.4 million to contain across 100 confirmed cases, or roughly $53,000 per case.[23]

Changes that create confusion regarding vaccine recommendations, reduce confidence in the recommendation process, or make implementation more difficult may increase the risk of delayed vaccination and lower coverage over time, leaving states more vulnerable to outbreaks and increasing the demands on public health and health care systems. Where a federal determination can produce consequences of this magnitude for state residents and state budgets, it should be preceded by a documented assessment of those consequences, conducted by the body Congress designated, and on a record the public can examine.

5. **Procedural Requests**
   Response to Questions 6, 15, and 18.

Comment period. HHS has allowed thirty days for comment on questions bearing on more than 600 State statutes and regulations and on at least five distinct federal programs. That period is inadequate for States to assess programmatic and fiscal consequences with the rigor the HHS's questions invite.

Rulemaking. Any change to recommendation categories that affects coverage obligations, program eligibility, or the substantive criteria governing recommendations would establish or amend a substantive legal standard and must proceed through notice-and-comment rulemaking.

Pending litigation. Recommendation changes closely related to those contemplated here — including the adoption of individual-based decision-making terminology and the December 2025 hepatitis B birth-dose recommendation — are presently subject to judicial stay. The Alliance requests that HHS explain how any action taken in reliance on this RFI is consistent with that order.

Consideration of comments. The Alliance requests that these comments be incorporated into the administrative record of any subsequent rulemaking, guidance, schedule revision, Task Force product, or other action addressing federal vaccine recommendation categories, and that the HHS

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[20] Cal. Dep't of Pub. Health, CDPH Urges Vaccination as Measles Cases Rise Across Multiple Counties (Feb. 9, 2026), https://www.cdph.ca.gov/Programs/OPA/Pages/NR26-007.aspx.
[21] Ctrs. for Disease Control & Prevention, Measles Signs and Symptoms (last visited Sept. 15, 2026), https://www.cdc.gov/measles/symptoms/signs-symptoms.html.
[22] Salin Sriudomporn et al., Quantifying the Cost of Measles Outbreak in the U.S. and How Costs Scale with Outbreak Size, medRxiv (Oct. 24, 2025) (preprint) https://www.medrxiv.org/content/10.1101/2025.10.24.25338724v2.full-text.
[23] Jamison Pike et al., Economic Impact of the 2025 New Mexico Measles Outbreak: Highlighting the Cost of Efforts to Prevent Future Outbreaks, Annals of Internal Medicine (Aug. 4, 2026), https://www.acpjournals.org/doi/10.7326/ANNALS-26-00718.

address the significant issues raised here in the statement of basis and purpose or equivalent explanation accompanying any such action. Incorporation of these comments does not substitute for, and the Alliance does not consent to treating this proceeding as satisfying, notice-and-comment requirements as to any subsequent action.

Conclusion

Governors depend on federal vaccine recommendations as the foundation for State immunization programs, insurance coverage policies, public health planning, provider communications, and outbreak preparedness efforts. The effectiveness of these federal recommendations rests not only on the strength of the underlying science, but also on the stability, transparency, and credibility of the processes used to develop them.

Changes that introduce uncertainty, increase administrative complexity, or reduce public confidence may have far-reaching effects on State implementation, public health operations, and the ability of Governors to protect their communities from vaccine-preventable disease. PHA therefore urges HHS to preserve a stable national vaccine recommendation framework, maintain transparent and evidence-based advisory processes, avoid changes that create unnecessary implementation burdens, and fully assess and publish the operational, fiscal, and public health impacts on states before acting, and to proceed by notice-and-comment rulemaking for any change carrying legal effect.

Respectfully submitted,

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