MASSACHUSETTS MEDICAL SOCIETY
Every physician matters, each patient counts.

September 10, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: Docket No. HHS-OS-2026-0332; RIN 0991-ZA62 - Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (91 Fed. Reg. 54724, Aug. 24, 2026)

Dear Secretary Kennedy and Ms. Goss:

On behalf of the more than 20,000 physician, resident, and medical student members of the Massachusetts Medical Society (MMS), the nation's oldest continuously operating state medical society and the publisher of the *New England Journal of Medicine*, we respectfully submit these comments. Our members administer vaccines, counsel patients and families, and incorporate federal vaccine recommendations into clinical practice every day. Our comments reflect that firsthand experience and our organizational policy, which strongly affirms the duty of HHS and its agencies to adhere to and advance scientifically derived, high-quality, evidence-based recommendations and policies, including those related to vaccines.

Vaccination is among the most extensively studied, and successful, public health interventions in modern medicine. Current recommendations rest on decades of research, clinical experience, real-world evidence, and ongoing safety and effectiveness review. The questions raised in this RFI should therefore be considered in the context of this substantial existing evidence base. The central challenge is not only how recommendation categories are defined, but also how any changes to those categories could affect clinical implementation, patient understanding, vaccine access, and public confidence. How vaccine recommendation evidence is best communicated, understood, and implemented in ways that support informed decisions and public confidence is also of central importance.

MMS evaluates any proposed change to the recommendation framework by asking whether it remains grounded in the best available scientific evidence and developed through a rigorous, objective, and trusted process. Proposed changes should be supported by published evidence specific to the changes, with the scientific rationale and relevant limitations presented transparently. MMS has applied that standard to the issues raised in this notice in further detail below.

In summary, we urge the Department to:

- **Safeguard access and coverage before changing categories.** Before adopting any new or revised category, publish an assessment of how the change would affect insurance coverage, Vaccines for Children eligibility, vaccine injury compensation, federal programs, and state law, and ensure that no category change inadvertently restricts access to proven vaccines.
- **Require evidence before any category, schedule, or product change.** Require any proposed change to the timing, formulation, dosing, combination, or administration of a vaccine to follow from published evidence specific to that change, rather than from a category label or policy preference.

- **Make categories clear, distinct, and implementable.** Affirm that federal recommendations are not mandates, that patients and parents retain decision-making authority, and that informed consent or parental permission and clinical conversation apply across all recommendation categories.
- **Preserve process integrity, communicate clearly, and measure results.** Maintain a transparent, independent, and evidence-based deliberative process as the mechanism through which federal vaccine recommendations are developed and revised.

Please find our detailed comments below. The Massachusetts Medical Society appreciates the opportunity to comment and stands ready to work with the Department, the Task Force on Safer Childhood Vaccines, and ACIP on implementation approaches that protect scientific rigor, public trust, and the physician-patient relationship. If you should have any questions, please contact Casey Rojas, JD, MBE, Federal Relations Director, at crojas@mms.org or (781) 434-7082.

Sincerely,

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President
Massachusetts Medical Society

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Detailed Response to the RFI Sections

Consistent with the Department's guidance that commenters need not address every question, the discussion below provides clinical experience, research findings, and implementation rationale corresponding to the RFI's five major sections.

A. Adequacy of the Current Categories

The notice's evidence points primarily to challenges regarding communication, coverage confusion, clinical display, and workflow support. When coverage status is unclear, physicians are often forced to investigate coverage during the clinical encounter or risk exposing patients to unexpected costs. Renaming categories would not repair those issues and could instead exacerbate them as payers, health systems, pharmacies, EHR vendors, and immunization information systems interpret the new terminology. Any proposed change should therefore demonstrate a meaningful improvement over the existing framework and account for the practical implications of implementation.

A single category label also cannot communicate three distinct concepts at once: certainty of evidence, variation in expected benefit, and the clinical default. These dimensions do not always move together. High-certainty evidence, for example, may support individualized assessment when expected benefit varies, while lower-certainty evidence may still support a default when disease is severe and the intervention is low risk. Rather than introducing new terminology, HHS should clearly define the purpose and meaning of each category and evaluate whether proposed changes would improve understanding among physicians, patients, and families. HHS should also reinforce that vaccine recommendations provide clinical guidance rather than individual mandates and that informed consent or parental permission and clinical conversation apply across all categories.

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

Category assignments have downstream legal and operational effects. A change in category may affect far more than the language that physicians use to describe a vaccine recommendation.

Before changing a category or adopting a new one, HHS should publish an assessment of how the proposed changes would interact with preventive-services coverage requirements, VFC resolutions, vaccine injury compensation, federal purchasing and reporting programs, and state-law references. Where changes are adopted, HHS should provide clear transition instructions for health plans, programs, states, pharmacies, EHRs, and immunization information systems.

Questions concerning timing and administration also require vaccine-specific evidence. Relevant considerations include disease incidence and severity by age, immune response, residual risk from delay, performance of screening or other alternatives, and the likelihood that a deferred dose will be missed.

Importantly, the recommended timing of childhood vaccines reflects not only evidence about vaccine safety and effectiveness, but also epidemiologic evidence about when children are most vulnerable to infection and severe disease. For example, the recommended timing of vaccines against *Haemophilus influenzae* type b (Hib) and pneumococcal disease reflects the significant burden of these diseases in young children. Any proposal that would delay vaccination to a later age or require additional visits to complete a recommended series must therefore consider the consequences of leaving children less protected during periods of heightened vulnerability.

Changes to recommended timing should be supported by evidence demonstrating that an alternative schedule would provide appropriate protection during the ages when the risk of severe disease is greatest and would not increase the likelihood of delayed or missed vaccination.

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

If HHS considers a new name for the Shared Clinical Decision-Making (SCDM) category, it should test whether clinicians, patients, and parents understand whether the vaccine is recommended, whether it is covered, and whether individualized assessment is needed.

Shared clinician decision-making (SCDM) addresses that, while evidence supports offering the vaccine, benefit varies materially among eligible people, thereby requiring individualized care. SCDM should not signal that evidence is insufficient to support any recommendation or imply that routine recommendations involve less consent or discussion.

HHS should also consider how changes to SCDM would be implemented across the diverse settings in which vaccines are delivered. State laws vary in who may administer vaccines and use standing orders, delegation, supervision, and other vaccination protocols. Significant changes to SCDM terminology or requirements could therefore create operational challenges if state requirements and existing clinical workflows do not align with a revised federal framework. Given existing primary care workforce constraints, changes that limit who may participate in vaccine decision-making or the use of standing orders could create bottlenecks and impede timely access to vaccination.

MMS and its physician members are prepared to help test guidance, decision aids, terminology, and evaluation measures so that federal recommendations remain scientifically rigorous and workable at the point of care.

D. Considerations in Setting Recommendations

Federal vaccine recommendations should reflect the totality of clinical, safety, effectiveness, and implementation evidence. A 2025 NEJM systematic review illustrates the breadth of the contemporary evidence base. Investigators searched PubMed/MEDLINE, Embase, and Web of Science; screened 17,263 references; and included 511 studies of U.S.-licensed immunizations against COVID-19, RSV, and influenza, encompassing randomized trials, cohort studies, case-control studies, and other observational designs. The review assessed effectiveness, safety, coadministration, and risk of bias, and found similar pooled results when studies with moderate or high risk of bias were excluded.

The review found COVID-19 vaccine effectiveness against hospitalization of 46 percent in cohort studies and 50 percent in case-control studies among adults; effectiveness of 68 percent or more for maternal RSV vaccination, nirsevimab for infants, and RSV vaccination in older adults; and pooled influenza vaccine effectiveness against hospitalization of 48 percent among adults ages 18 to 64 and 67 percent among children. It also identified uncommon safety signals and areas for continued surveillance. The attached NEJM correspondence further reported no association between first-trimester mRNA COVID-19 vaccination and major congenital anomalies in a French cohort of 527,564 infants, and no increased overall risk of preterm birth, stillbirth, or other maternal or neonatal outcomes in a matched study of nearly 25,000 vaccinated and 25,000 unvaccinated pregnant women receiving maternal RSV vaccination.

Taken together, these findings underscore that federal vaccine recommendations should not be narrowed, delayed, or reassigned absent evidence relevant to the specific proposed change and a transparent scientific rationale for that decision.

E. Trust, Communication, and Evaluation

Physicians play an essential role in translating federal vaccine recommendations into individual clinical decisions. To do so effectively, they must be able to understand and explain the evidence supporting a recommendation, the degree of certainty, the reasons for any change, and areas where evidence continues to evolve.

Transparency is therefore not ancillary to the scientific process; it is essential to its integrity and to the effective implementation of federal recommendations. When recommendations change, HHS should clearly identify the evidence prompting the change and explain the scientific reasoning supporting it. Changes made without a clearly documented evidentiary rationale risk creating uncertainty about the scientific basis and consistency of federal recommendations. That uncertainty places physicians in the difficult position of attempting to reconstruct or explain the rationale during individual patient encounters and can undermine confidence in the recommendation process. Such changes to longstanding vaccine recommendation categories could also jeopardize the public's trust in well-researched, high-quality vaccines.

Any framework change should have a pre-specified evaluation plan and baseline measures. HHS should separately assess clinician comprehension; patient and parent comprehension; accuracy of EHR and forecasting displays; claims-level cost sharing; clinician time and documentation burden; vaccination coverage and missed opportunities; and vaccine-preventable disease incidence. If a change does not improve comprehension or implementation, or reduces access or appropriate vaccination, HHS should revise or withdraw it; scheduled re-review is preferable to automatic sunset because expiration may imply an evidentiary change that has not occurred.

The MMS appreciates the Department's consideration of these comments. As HHS evaluates the federal vaccine recommendation framework, we urge the Department to preserve the principles that are essential to sound vaccine policy: rigorous scientific review, transparency, meaningful consideration of the full evidence base, protection of patient access, and recommendations that physicians can confidently translate into clinical care that improves patient outcomes.