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September 19, 2026

Secretary Robert F. Kennedy, Jr.
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted via Regulations.gov

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making — Docket No. HHS–OS–2026–0332; RIN 0991-ZA62

Dear Secretary Kennedy:

March of Dimes appreciates the opportunity to provide comments to the U.S. Department of Health and Human Services (HHS) regarding the Request for Information (RFI) on federal vaccine recommendation categories and the role of shared clinical decision-making (SCDM). March of Dimes is committed to improving the health of all moms and babies and supports evidence-based immunization recommendations, equitable access to vaccines, strong vaccination coverage, and public confidence in immunization.

Routine immunization is one of the most effective public health interventions available. Vaccines prevent illness, disability, and death, while reducing the health and economic burden of vaccine-preventable diseases. March of Dimes supports evidence-based vaccine recommendations and has consistently supported efforts to ensure that eligible children and pregnant women receive recommended immunizations on schedule and without financial barriers.[1]

At a time when vaccine-preventable diseases are resurging and public confidence in health institutions is under strain, clarity matters. HHS should avoid creating additional categories that may further complicate communication and access. Instead, HHS should strengthen the existing evidence-based process, ensure that recommendation changes are supported by compelling evidence, protect access to recommended vaccines, and invest in education and public engagement.

[1] March of Dimes, *Vaccinations and Immunizations in the United States*, Position Statement (2025). The statement supports evidence-based vaccine recommendations, vaccination on schedule, community immunity, equitable access, and immunization without cost sharing. March of Dimes Position Statement

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Creating new or different recommendations categories risks confusion and access challenges

March of Dimes is concerned that creating additional or differently named immunization recommendation categories could make an already complex system more difficult for families and providers to understand.

Most importantly, recommendations categorized as "SCDM" should not be conflated with the concept of a vaccine counseling conversation or informed consent. Vaccination decisions (across all categories) already involve patients, parents, families, and healthcare professionals. A routine recommendation does not eliminate the need for appropriate clinical discussion, informed consent, consideration of contraindications, or parental involvement.

Indeed, federal law requires vaccine information materials describing vaccine benefits and risks to be provided before administration of covered vaccines, and those materials may be supplemented by oral explanations or visual presentations as appropriate.[2] The current HHS RFI itself recognizes that SCDM is distinct from consent, parental permission, and assent, and that meaningful decision-making can apply across vaccine recommendation categories.[3]

SCDM as a recommendation category serves a more specific purpose. It is appropriate when the federal recommendation does not establish a default for an entire age or risk group because the balance of benefits and risks varies materially among individuals, or because the evidence concerning population-level benefits are limited or evolving.[4] It should not be repurposed as a label suggesting that patients and parents only participate meaningfully in vaccination decisions when a vaccine carries an SCDM designation.

Recent polling demonstrates why additional categories could be counterproductive. In an August 2025 nationally representative survey conducted by the Annenberg Public Policy Center, only 22% of respondents selected the interpretation that SCDM means a vaccine "may not be a good idea for everyone but would benefit some."[5] In a subsequent survey, only 33% identified a pharmacist as a healthcare provider with whom they could engage in a shared decision-making conversation about vaccination.[6] These findings demonstrate that the public does not understand SCDM as policymakers intend.

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[2] 42 U.S.C. § 300aa–26. Federal law requires vaccine information materials describing benefits and risks and requires their provision before administration of covered vaccines. (Legal Information Institute)

[3] HHS, *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, 91 Fed. Reg. 54724 (Aug. 24, 2026). The RFI expressly distinguishes SCDM from consent, parental permission, and assent.

[4] CDC, *ACIP Shared Clinical Decision-Making Recommendations*. CDC describes SCDM as individually based and informed by a decision process between the health care provider and patient or parent/guardian, distinguishing it from routine, catch-up, and risk-based recommendations. (CDC)

[5] Annenberg Public Policy Center, *CDC Urges 'Shared Decision-Making' on Some Childhood Vaccines; Many Unclear About What That Means* (Jan. 5, 2026). The survey included 1,699 U.S. adults and found that 22% selected the interpretation that SCDM means vaccination "may not be a good idea for everyone but would benefit some." (Annenberg Public Policy Center)

[6] Id. The December 2025 survey included 1,637 U.S. adults; only 33% identified pharmacists as health care providers who could participate in vaccine SCDM conversations. (Annenberg Public Policy Center)

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Adding more categories before resolving these existing communication challenges could increase, rather than reduce uncertainty.

Vaccine recommendations should continue to be based on an evidence-based and transparent process

The United States already had an established process for determining immunization recommendations through the Advisory Committee on Immunization Practices (ACIP).

Recent changes to the ACIP include replacing its previous voting members, revising membership requirements and the committee's charter, and modifying certain vaccine recommendations. In alignment with other medical and public-health organizations, March of Dimes has concerns about the committee's current level of scientific expertise, evidence-review processes, transparency, vaccine access, and the potential impact of these changes on public confidence.

ACIP recommendations were developed using an explicit evidence-based methodology that incorporates GRADE and the Evidence to Recommendations (EtR) framework. The process considered the certainty and quality of evidence, the balance of benefits and harms, values and preferences, acceptability, feasibility, and resource use.[7] The EtR framework was specifically designed to improve transparency, consistency, and communication surrounding vaccine recommendations.[8] This process should be strengthened and not replaced by additional recommendation labels.

Public deliberation is particularly important when recommendations have consequences beyond clinical encounters. ACIP meetings provide opportunities for expert presentations, discussion, voting, and public participation. A transparent process enables clinicians, parents, patients, states, insurers, manufacturers, researchers, and public health organizations to understand not only the recommendation, but also the evidence and reasoning underlying it.

At a time when confidence in public health institutions is already under pressure, public trust will not be restored simply by changing the names of vaccine recommendation categories. Trust is built through a transparent process, credible evidence, consistent communication, and meaningful engagement with the public.

Recent national polling underscores the challenge. In a 2026 national survey, only 50% of U.S. adults reported trusting health recommendations from CDC, down from 77% in spring 2025.[9] HHS

[7] CDC, *Evidence-Based Recommendations for ACIP*. ACIP uses GRADE and the EtR framework, considering evidence certainty, benefits and harms, values and preferences, acceptability, feasibility, and health economic/resource considerations. (CDC)
[8] CDC, *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, MMWR (2018). The report explains that the EtR framework facilitates transparency, consistency, and communication. (CDC)
[9] Harvard T.H. Chan School of Public Health and de Beaumont Foundation, *One Year In: Public Views of a Changing Public Health Landscape* (June 2026). The nationally representative survey of 2,205 U.S. adults found that 50% reported trusting health recommendations from CDC. (Harvard Chan School)

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should therefore prioritize interventions that directly address public understanding, provider education, access barriers, and confidence in the evidence-based process.

Recommendation categories should reflect evidence; they should not be used to redefine informed consent

March of Dimes recognizes and supports the importance of individual autonomy, informed consent, and meaningful discussions between families and healthcare professionals. These principles already apply to vaccination decisions regardless of whether a vaccine recommendation is classified as routine, risk-based, or SCDM.

A federal recommendation answers a population-health question: based on the available evidence, should vaccination be recommended for a particular population? The clinical encounter then allows the provider, patient, and/or parent or guardian to apply that recommendation to the individual circumstances of the person receiving the vaccine. These are complementary processes, not competing ones.

The distinction is important because routine childhood immunizations generally provide benefits not only to the vaccinated child but also to families and communities. Maintaining high vaccination coverage can reduce transmission and help protect people who cannot be fully vaccinated, including some infants and people with medical contraindications.

Moving a vaccine from a routine recommendation to the SCDM category as currently defined should require a clear, vaccine-specific evidentiary rationale demonstrating why a population-level recommendation is no longer appropriate. The mere existence of individual variation in risk or preferences is not sufficient to establish that a vaccine should be moved into an SCDM category.

HHS should require a clear evidentiary rationale before changing the immunization schedule of separating combination vaccines.

March of Dimes is concerned about changes to the immunization schedule that are not clearly supported by vaccine-specific evidence demonstrating improved safety, effectiveness, or health outcomes. We continue to support a transparent, science-driven process for immunization policy — one that prioritizes the health and safety of all pregnant women, children, and families.

HHS should not alter the timing, frequency, or recommendation category of a vaccine simply because another country uses a different schedule. Differences between countries can reflect differences in disease epidemiology, health systems, access, vaccination coverage, population characteristics, and public health infrastructure.

Similarly, any proposal to separate combination vaccines should be supported by specific evidence demonstrating a meaningful clinical or public-health benefit. Changes to combination vaccines can affect the number of injections, opportunities for missed vaccination, adherence, scheduling,

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and the complexity of clinical care. Such changes should therefore be evaluated based on evidence concerning the products and populations involved.

The appropriate question should be whether the proposed change improves health outcomes, not whether a different schedule appears simpler or more consistent with another country's approach.

Access must remain central to any changes in federal vaccine recommendations

Recommendation categories have important consequences for vaccine access.

Federal law expressly connects ACIP recommendations to private insurance coverage. Section 2713 of the Public Health Service Act generally requires group health plans and issuers offering group or individual coverage to provide recommended immunizations without cost sharing when the applicable ACIP recommendation is in effect.[10] CDC also explains that ACIP recommendations based on shared clinical decision-making can qualify for this coverage when they have been adopted and listed on the CDC immunization schedules.[11]

ACIP recommendations also have important implications for Medicaid and the Vaccines for Children (VFC) program. Medicaid identifies ACIP-recommended vaccines as central to vaccine coverage, and the VFC program automatically covers vaccines recommended by ACIP and adopted by CDC for eligible children.[12] Federal law also directs the pediatric vaccine program to use the list established by ACIP for the purchase, delivery, and administration of pediatric vaccines.[13]

For these reasons, changes to recommendation categories can have consequences far beyond terminology.

March of Dimes urges HHS to ensure that **no change to vaccine recommendation categories, timing, frequency, or terminology results in reduced coverage, new cost-sharing, loss of VFC eligibility, reduced Medicaid access, or other barriers for children, pregnant women, or families**.

The Task Force on Safer Childhood Vaccines should operate within its statutory role and complement, not replace, ACIP.

March of Dimes recognizes that the Task Force on Safer Childhood Vaccines has a statutory basis. Federal law directs the Secretary to establish the Task Force and provides that it is to consist of the

[10] 42 U.S.C. § 300gg–13. The statute generally requires group health plans and health insurance issuers to cover immunizations with an applicable ACIP recommendation without cost sharing. (Legal Information Institute)
[11] CDC, *ACIP Shared Clinical Decision-Making Recommendations*. CDC states that SCDM recommendations adopted by CDC and listed on the immunization schedules generally are covered by applicable private insurance without cost sharing. (CDC)
[12] Centers for Medicare & Medicaid Services, *Quality of Care Vaccines*. Medicaid identifies ACIP-recommended vaccines as central to coverage, and VFC provides vaccines at no cost to eligible children. (Medicaid)
[13] 42 U.S.C. § 1396s. Federal law directs the pediatric vaccine program to use the list established and periodically revised by ACIP for the purchase, delivery, and administration of pediatric vaccines. (Legal Information Institute)

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Directors of NIH and CDC and the FDA Commissioner, with the NIH Director serving as chair. The statute directs the Task Force, in consultation with the Advisory Commission on Childhood Vaccines, to prepare recommendations to the Secretary concerning implementation of the statutory requirements relating to safer childhood vaccines.[14]

That statutory role is distinct from ACIP's role in developing recommendations on the use of vaccines to control disease in the United States.

HHS should therefore clearly delineate the respective responsibilities of the Task Force, ACIP, CDC, FDA, NIH, and other advisory bodies. The Task Force's work should complement established vaccine recommendation processes and should not substitute for the transparent, evidence-based deliberations used by ACIP to evaluate vaccine recommendations.

HHS should focus urgently on evidence-based interventions to increase vaccination coverage

The need for clarity is particularly urgent given the resurgence of vaccine-preventable diseases.

The United States experienced substantial measles activity in 2025, with 2,289 confirmed cases reported for the year and 48 outbreaks.[15] In 2026, measles activity continued, with CDC reporting 3,294 confirmed cases as of September 10, 2026.[16] CDC also reports that kindergarten MMR coverage has fallen below the 95% level associated with community protection, reaching 92.4% during the 2025–26 school year.[17]

These circumstances argue for a focus on interventions that increase vaccination coverage and reduce barriers to vaccination.

Based on the considerations above, March of Dimes respectfully recommends that HHS:

- Maintain the existing three-category federal framework of routine, risk-based, and shared clinical decision-making recommendation categories unless compelling vaccine-specific evidence demonstrates that a change is necessary;
- Do not conflate the SCDM recommendation category with informed consent**.** Make clear that meaningful clinical discussion, informed consent, and parental decision-making apply to vaccination decisions across all recommendation categories;
- Preserve ACIP's transparent, evidence-based recommendation process, including GRADE, the EtR framework, open deliberation, expert input, public participation, and clearly documented evidence;

[14] 42 U.S.C. § 300aa–27. The statute establishes the Task Force on Safer Childhood Vaccines and directs it to prepare recommendations to the Secretary concerning implementation of statutory requirements relating to safer childhood vaccines.
[15] CDC, *Measles Cases and Outbreaks*. CDC reports 2,289 confirmed U.S. measles cases and 48 outbreaks for 2025. (CDC)
[16] CDC, *Measles Cases and Outbreaks*, updated Sept. 11, 2026. As of September 10, 2026, CDC reported 3,294 confirmed measles cases in the United States in 2026. (CDC)

[17] CDC, *Measles Cases and Outbreaks*. CDC reports that MMR coverage among U.S. kindergartners declined to 92.4% during the 2025–26 school year and notes that coverage above 95% generally provides community protection against measles. (CDC)

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- Require a rigorous evidence review before changing the recommendation category, timing, frequency, or administration of any vaccine;
- Do not separate combination vaccines or otherwise modify vaccine administration practices without vaccine-specific evidence demonstrating a meaningful benefit to patients or public health;
- Conduct comprehensive access and coverage analysis before implementing any recommendation change, including analysis of private insurance, Medicaid, CHIP, Medicare where applicable, VFC, state laws, pharmacy administration, provider reimbursement, and electronic health record systems;
- Guarantee that families do not lose affordable access to vaccines because of changes to federal recommendations;
- Strengthen education for parents, patients, physicians, nurses, pharmacists, and other vaccine providers so that the SCDM category is accurately understood and applied;
- Clearly define the statutory role of the Task Force on Safer Childhood Vaccines and assure that its work complements rather than substitutes for ACIP's vaccine recommendation process; and
- Focus federal resources on increasing vaccination coverage and restoring public confidence, particularly in communities experiencing outbreaks or declining immunization rates.

March of Dimes supports informed decision-making, parental involvement, patient autonomy, and meaningful conversations between families and healthcare professionals. These principles are not unique to SCDM category recommendations. They are fundamental components of good medical care and apply whenever a vaccine is considered.

The United States already has an established process for translating scientific evidence into vaccine recommendations. That process can and should continue to evolve as new evidence emerges, and any changes should be grounded in rigorous evidence, transparent public deliberation, and careful consideration of their consequences for access and vaccination coverage.

March of Dimes appreciates the opportunity to submit these comments and looks forward to continuing to work with HHS and its agencies to protect the health of moms, babies, children, and families.

Sincerely,
Stacey Y. Brayboy

Sr. Vice President, Public Policy & Government Affairs
March of Dimes