Department of Health and Human Services
Office of the Secretary
200 Independence Avenue SW
Washington, DC 20201
ATTN: Docket No. HHS-OS-2026-0332

September 15, 2026

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

Dear Secretary Kennedy,

On behalf of the California Public Employees' Retirement System (CalPERS) and Covered California, we write in response to the Health and Human Services (HHS) Request for Information (RFI): Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making.

Our comments focus on four main points:

- Federal vaccine recommendations should continue to be grounded in the best available scientific and clinical evidence, communicated through trusted providers, and supported by clear guidance on coverage and implementation.
- Childhood immunization rates should remain a key measure of success.
- HHS should retain the current vaccine recommendation framework, including shared clinical decision-making (SCDM), rather than create new recommendation categories or terminology that could increase confusion for patients, providers, payers, and health systems.
- SCDM should be clarified, not renamed. Informed consent, patient choice, and clinical discussion are relevant across all vaccine recommendations. SCDM is distinct because it calls for individualized assessment and does not establish a universal default to vaccinate.

With more than 1.5 million members, CalPERS is the largest purchaser of public employee health benefits in California and the second largest public purchaser in the nation after the federal government. In 2025, CalPERS spent over $13.9 billion to purchase health benefits for active and retired members and their families on behalf of the State of California (including the California State University system) and nearly 1,200 public agencies and schools.

Covered California, as the nation's largest state-based health insurance marketplace, has provided coverage to over 6.3 million Californians – about one in six residents – since its launch in 2014.

A 2024 Centers for Disease Control and Prevention (CDC) study found that from 1994 to 2023, routine childhood immunizations "prevented approximately 508 million cases of illness, 32 million hospitalizations and over 1.1 million deaths, resulting in direct savings of $540 billion."[1] Given the importance of routine childhood immunizations, California's public purchasers, CalPERS, Covered California, and the Department of Health Care Services (DHCS) have aligned on a set of clinical quality measures including the National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set Childhood Immunization Status measure for children up to age two, holding health plans accountable for preventive care.

We agree with the RFI's goals of improving transparency in the clinical guidelines process, keeping the patient at the center of clinical decision-making, and maintaining coverage of evidence-based services patients choose for themselves and their families. At the same time, federal vaccine policy should remain grounded in the best available scientific evidence and the expertise of the healthcare professionals and scientists who have worked in this field for decades. Our comments below are guided by those principles.

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

What does, or what should, "shared clinical decision-making" mean in the vaccination context? How, if at all, does "individual-based decision-making" differ?

SCDM has long been recognized as a fundamental component of patient-centered clinical care in which patients and clinicians make healthcare decisions together. Those decisions consider the best available evidence, the clinician's professional judgment, and the patient's values, preferences, and circumstances.[2]

In the vaccination context, SCDM should continue to mean an individualized approach to vaccination. The decision should consider the patient's circumstances, the available scientific evidence, clinical judgment, and the values and preferences of the patient or parent/guardian.

We do not believe that "individual-based decision-making" is meaningfully different from SCDM. Both terms describe a recommendation category that requires individualized

[1] Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023. *MMWR Weekly* / August 8, 2024 / 73(31);682–685.
[2] About Shared Decision Making | Agency for Healthcare Research and Quality.

clinical assessment rather than a universal expectation to vaccinate. Using both terms creates unnecessary confusion.[3]

Does the term "shared clinical decision-making" create an unintended contrast with routine recommendations?

Yes, the term could create an unintended contrast, if the term is incorrectly interpreted to mean that clinical discussion, informed consent, parental permission, or patient choice are unique to SCDM recommendations. However, these principles are not unique to SCDM. They apply to all vaccine recommendations, including routine recommendations.[4,5]

The key difference is not whether patients, parents, and clinicians are involved in the decision. Rather, it is whether the federal recommendation establishes a default expectation to vaccinate. Under the framework described in the RFI, routine, catch-up, and risk-based recommendations have a default to vaccinate, while SCDM recommendations do not.

HHS should clarify what SCDM means so that it is not misunderstood as the only category that involves discussion or consent. However, this does not require new terminology. Guidance should instead clarify that all vaccine decisions involve informed clinical discussion, while SCDM remains distinct in calling for individualized assessment rather than a universal default.

"Since shared decision-making describes a clinical process applicable to all vaccine decisions, should the Department reserve that phrase for use across all categories and instead adopt 'conditional recommendation' or 'recommendation based on individualized assessment' for recommendations whose expected benefit varies materially among individuals?"

No. We do not recommend replacing SCDM with a new term. Although shared decision-making is a broader concept, SCDM has an established meaning in vaccine policy recommendation category and replacing the term now would likely create unnecessary confusion.

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[3] *Ibid.*
[4] https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
[5] http://aap.org/ImmunizationSchedule

Instead, HHS should work with relevant stakeholders to establish and consistently use clear definitions for the existing categories, indicating that informed consent and clinical discussions apply to all vaccine recommendations.[6,7]

What are the benefits of an SCDM category, including respect for autonomy, informed consent, religious conviction, and individualized clinical judgment, and what evidence supports them?

The primary benefit of the SCDM category is that it provides flexibility to account for individual circumstances, providing a middle ground between universal recommendation to vaccinate and no recommendation at all.

This is useful when the expected benefit of vaccination varies across individuals, evidence is limited, or clinical judgment is especially important. SCDM also supports individualized care by creating an opportunity for patients or parents/guardians and clinicians to discuss the potential benefits and risks of vaccination based on these varying factors.

Respect for autonomy, informed consent, and parental involvement should apply to all vaccine recommendations. The main distinction with SCDM is that it lacks a universal default to vaccinate.

"An SCDM recommendation, once adopted by the CDC Director, 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. Given evidence that patients and even providers may not understand this, what steps should the Department take to educate the public and the provider community that SCDM-recommended vaccines are covered? What communication formats would most effectively ensure that an SCDM designation is not misread as a lapse in coverage or a signal that a vaccine is unavailable?"

HHS should clearly and consistently communicate that an SCDM recommendation remains a federal recommendation and should not be interpreted to mean that a vaccine is not covered, unavailable, or disfavored. HHS should also coordinate with payers, state Medicaid agencies, Vaccines for Children administrators, and provider organizations on the crafting and delivery of the messaging so that coverage information is communicated consistently across healthcare settings.

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[6] Shared Decision-Making: Guidelines From the National Institute for Health and Care Excellence American Family Physician. 2022;106(2):205-207.
[7] Implementation Tools and Resources for Shared Decision Making | Agency for Healthcare Research and Quality.

What supports would make SCDM work as intended, such as decision aids, provider training, documentation standards, coverage clarifications, or category-specific communication materials, and who should develop them?

We recommend that HHS look to research and guidelines that already exist in this area. The Agency for Healthcare Research and Quality provides a number of tools and resources to implement SCDM for various health conditions, and a review of the SCDM guidelines published by the National Institute for Health and Care Excellence in the United Kingdom.[8,9] Any new materials should be developed collaboratively by clinical professional societies, payers, and health systems. A coordinated approach would help ensure that SCDM is understood consistently across clinical care, coverage, and operational settings.

Additional Considerations

Global Perspectives on Vaccine Recommendations

We believe it is helpful to be aware of other countries' recommendations and approaches to understanding the scientific and clinical evidence, but direct adoption of other countries' methods should be done cautiously. Advisory bodies in the United States that provide child and adolescent vaccine recommendations must consider several factors in their deliberations, many of which are unique to this country:

- When children are most vulnerable to diseases;
- When vaccines work best with children's immune systems;
- The safety and efficacy of vaccinations being recommended;
- The risk and prevalence of diseases in the United States;
- Access to healthcare providers and immunizations; and
- The cost effectiveness of implementing national recommendations for a particular vaccination.[10]

While pediatric biology, disease course, and vaccine product may be similar, how those factors interact in a country with a completely different healthcare system, insurance coverage, and public health infrastructure than the United States will impact the comparability of recommendations. In general, guidelines should be based on the best available evidence as outlined in the Level of Evidence hierarchy, and be preferentially based on systematic reviews and meta-analyses where available.[11] For example, in a recent review of the evidence on Tdap in pregnancy, the Vaccine Integrity Project

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[8] Implementation Tools and Resources for Shared Decision Making | Agency for Healthcare Research and Quality.
[9] Shared Decision-Making: Guidelines From the National Institute for Health and Care Excellence American Family Physician. 2022;106(2):205-207.
[10] West Coast Health Alliance Recommends American Academy of Pediatrics Vaccine Schedule.
[11] Levels of Evidence - Systematic Reviews - Research Guides at UC Davis.

screened 14,174 published papers, and reviewed in detail the findings in 91 studies, which included randomized controlled trials and large claims database analyses.[12]

Trust and Communication

On the issue of public trust in vaccine information, recent surveys have concluded that the most trusted source of vaccine information remains a person's healthcare provider. A 2025 Kaiser Family Foundation poll reported 32-39% of respondents trusted their provider "a great deal" while a similar level of trust for federal agencies was only 15-16%.[13] In an Annenberg Public Policy poll conducted from 2021-2026, 87% of respondents stated they were confident their primary healthcare provider provided trustworthy information, while only 59-61% of respondents stated the same for federal agencies.[14] Notably, this percentage was stable for providers over time but declined for federal agencies (from rates of 72-74% in 2024).

Given this, any approach to federal recommendations and communication would be most effective in partnership with trusted provider organizations such as the American Academy of Pediatrics, American Academy of Family Physicians, and the American College of Obstetrics and Gynecology. Providers are best equipped to earn and keep public trust and can assist in crafting messages that will achieve this goal.

Measuring Success

As previously mentioned, the three public purchasers in California (CalPERS, Covered California, and DHCS) made a very deliberate effort several years ago to align on quality and equity work to drive improvement in care.[15] Setting the same goals for all purchasers helps providers see one coherent set of signals rather than a patchwork of different requirements. Childhood immunizations are some of the most cost-effective interventions that we have in medicine. All purchaser partners, in alignment with the California Department of Public Health, remain committed to providing evidence-based preventive care recommendations, and advocate for childhood immunization rates to be a critical measure of success.

We thank you for your consideration and welcome the opportunity to work with you on our shared goal to improve vaccination recommendations. Please do not hesitate to contact Julia Logan, CalPERS Chief Clinical Director, at (916) 795-1735; Danny Brown, CalPERS Chief of the Legislative Affairs Division, at (916) 795-2565; Monica Soni, Covered California's Chief Medical Officer, at (916) 954-3225; or Kelly Green, Covered

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[12] Evidence Reviews | Vaccine Integrity Project.
[13] KFF Tracking Poll on Health Information and Trust: Vaccine Safety and Trust | KFF.
[14] Public Confidence in One's Own Healthcare Provider Remains High | The Annenberg Public Policy Center of the University of Pennsylvania.
[15] https://www.calpers.ca.gov/documents/202601-full-one-voice-big-impact-strategic-alignment-ca-powerpoint/download?inline.

California's Director of External Affairs and Community Engagement, at (916) 228-8309, if we can be of any assistance.

Sincerely,

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