Submit Public Comments on HHS Request for Information (RFI) on Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

The White House recently issued an Executive Order (EO) declaring the U.S. Department of Health and Human Services (HHS) should adopt a significantly altered childhood vaccine schedule. In response to the EO, HHS recently issued a request for information (RFI) seeking public comment on whether categories currently used in federal vaccine recommendations are adequate and what considerations should be relied upon in setting vaccine recommendations. AAP is concerned that **the RFI may be used to support unscientific changes to the U.S. federal vaccine infrastructure that will have lasting consequences for children and for pediatrics.**

HHS is accepting public comments through September 20, 2026.

AAP members can read below about the implications of the EO and RFI and how to add their voices to the comment period.

Background

About the Executive Order

On August 10, 2026, the White House issued an Executive Order (EO) entitled "Delivering Gold Standard Childhood Vaccine Recommendations for Americans." The EO:

- Declares that the US should adopt a significantly altered vaccine schedule for the United States, downgrading currently routine recommendations for respiratory syncytial virus (RSV), influenza, COVID-19, hepatitis A, hepatitis B, rotavirus, and meningococcal ACWY to risk-based or shared clinical decision-making. Measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type B (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella are listed as immunizations recommended for all children.
- Declares all childhood immunizations should be administered at separate medical visits, and directs the development and use of single-antigen measles, mumps and rubella vaccines in favor of the MMR vaccine.
- Advises states and territories to update school immunization requirement laws and regulations to align with practices from peer nations that have fewer recommended immunizations than the U.S., per a report claiming high childhood vaccination rates can be maintained without mandates.
- Directs the Secretary of HHS, through the HHS Task Force on Safer Childhood Vaccines, to present plans to the President within 90 days of the order (Nov. 8) to:
    - Offer combination vaccines as single vaccines

- Study alternatives to aluminum adjuvants, the timing and sequence of the childhood immunization schedule and the risk/benefit profiles of vaccines, and
- Improve vaccine safety monitoring, transparency, and research.

The EO has no immediate impact on federal or state vaccine policies, including access:

- Only state and local governments have the authority to change school vaccine requirements.
- Federal vaccine recommendations are developed by the Advisory Committee on Immunization Practices (ACIP) and formally adopted by the Director of the Centers for Disease Control and Prevention (CDC), although the CDC Director may choose not to follow ACIP guidance. ACIP is required by law to determine which vaccines are included in the Vaccines for Children Program, and health insurance plans are required by law to cover the vaccines on the CDC's schedule.
    - *Note: A ruling in a lawsuit filed by the American Academy of Pediatrics and other organizations against Secretary Kennedy has blocked HHS's January 2025 attempt to implement a new federal childhood immunization schedule. The lawsuit challenges Secretary Kennedy's decision to reconstitute ACIP with people who lack the appropriate credentials and experience. The ruling also prevents ACIP from meeting with those members.*

Additional context: Autism is not mentioned in the Executive Order. However, President Trump and Health and Human Services Secretary Robert F. Kennedy, Jr., brought up autism repeatedly during a signing event for the Executive Order. Their comments implied an unfounded link between routine childhood immunizations and autism, noting children receive too many shots and that vaccines should be spaced out.

A copy of the full EO is available to read on the White House website: Delivering Gold Standard Childhood Vaccine Recommendations for Americans – The White House.

About the RFI

On August 24, 2026, HHS issued a request for information (RFI) in support of the EO, seeking public comment on whether the three categories currently used in federal vaccine recommendations (routine or universal, risk-based, and shared clinical decision-making (SCDM), also referred to as "individual-based decision-making") are adequate. The notice explains that public input will help inform consideration by HHS and the Task Force on Safer Childhood Vaccines of whether the current category structure adequately serves the goals of scientific rigor, informed choice, and public trust.

The RFI specifically asks for comments on the following topics:

- **Adequacy of the Current Categories:** Whether the categories are understood in clinical practice, if they convey meaningful differences in the strength of evidence and individual vs. population benefit, and whether SCDM is misleading.

- **Potential Additional or Modified Categories and Timing and Frequency Recommendations:** Whether additional or different categories should be adopted, what can be learned from "peer" countries, how can access be preserved if categories change, and what changes on timing and frequency guidance can be made if categories stay the same.
- **Shared Clinical Decision-Making: Meaning, Risks, and Benefits:** What should SCDM mean, does it create an unintended contrast with routine recommendations, what are the benefits and risks of an SCDM category, does the public need to be educated about access for SCDM recommendations and what supports would help SCDM work as intended.
- **Considerations in Setting Recommendations:** What evidence is necessary to establish vaccine recommendations and how should uncertainty be reflected in the recommendation when evidence is limited?
- **Trust and Communication:** What effects do mandates have on public trust, vaccine confidence and vaccine behavior; what communications practices should accompany vaccine recommendations to earn public trust and how can the success of a recommendation framework be measured.

A copy of the full RFI is available to read in the Federal Register: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making.

Adding Your Voice

This RFI pertains to issues that directly impact the work of pediatricians and the health and wellbeing of children. Please consider drafting a public comment **highlighting the importance of routine childhood immunizations and an evidence-based immunization schedule, and how changes to either of these could impact your patients**. More information on how to do that below.

HHS has noted that comments for consideration must be submitted no later than September 20, 2026.

Key Considerations

Here are some considerations to keep in mind when submitting public comments.

- **Be aware that public comments, even those submitted anonymously, will be made available publicly.** Therefore, the use of personally identifiable information in the text of the comment is not recommended. This includes information about yourself or any patient stories you may consider incorporating into your comment.
- When drafting your comments, identify the specific question or topic you are discussing throughout the comment. This can best be done by placing the relevant question number in brackets before each comment, such as [A.1] or [C.13].
- Comments can be brief or comprehensive, but comments describing your real-world experience are strongest.

- You may submit comments with your name or anonymously. If submitting anonymously, you do not need to provide your name, email address, affiliation, or other identifying information; however, you will not be able to enter an email address to receive submission confirmation. If submitting anonymously, be sure to describe your credentials (e.g. "I am a pediatrician with experience in…").
- Comments may be uploaded as a Word document or PDF, or pasted directly into the docket text box. When uploading a file, remove all personal metadata to preserve anonymity.
- For additional privacy, consider using a VPN or accessing the Internet on a public computer (e.g., at a public library) when visiting Regulations.gov to submit comments online.
- Once uploaded, public comments cannot be edited or deleted.
- If desired, comments can be printed and mailed to the address in the Federal Register notice for the RFI.

Submitting Comments

Here's how to submit comments to the RFI:

1. Go to the Docket for the "Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making" (HHS-OS-2026-0332) on Regulations.gov. It will indicate that the comment period ends on Sept. 20.
2. Select the blue "Comment" icon underneath the rule's title in the top lefthand corner of the webpage.
3. Draft a public comment using the discussion points below.
4. Submit your comments using the form.

Discussion points

- Explain the importance of routine childhood immunization, describing the benefits of prevention in keeping children healthy and thriving, setting them up on a path to lifelong health. If outbreaks of vaccine-preventable diseases, such as measles or whooping cough, have affected your patients or your community, consider describing the impacts to child health, your clinic operations and your community. Be as specific as possible.
- Describe how unscientific changes to the child vaccine schedule would have lasting consequences for children and communities, potentially drawing on impacts you've already seen following vaccine-related announcements from the federal government. For example, if parents are asking more questions and have become more hesitant to vaccinate, consider writing about these interactions. Describe parents' concerns about vaccine access.
- Make clear that the vaccine guidance you rely on for your patients—the child and adolescent immunization schedule from the American Academy of Pediatrics—is evidence-based and tailored to the health of the children in the United States. Describe how you have not changed

your routine recommendations in practice because there is no new evidence to support the changes outlined in the EO.

- Reinforce the importance of clear immunization guidance and provide examples of the issues that arise when federal recommendations are not aligned with the evidence-based advice pediatricians are giving their patients' families. If you have examples of how parents are more hesitant to vaccinate because there's too much conflicting information and confusion, consider describing these interactions. Note examples where vaccine hesitancy has had a spillover effect, causing parents to refuse other routine preventive care, such as the newborn vitamin K shot.
- Describe how the partnership between parents/caregivers and physicians has long been a standard and necessary part of pediatric care. Explain how informed consent works in clinical practice, and how there are unique factors to consider because young children cannot consent for themselves.
- Explain what SCDM indicates (there is more than one medically reasonable option) as compared to a routine recommendation, and consider using examples to explain how you've approached these conversations with parents. Make clear that the type of recommendation does not impact the informed consent process or prevent parents from asking questions. Consider offering examples of how you've answered parents' questions about routine vaccines.
- Provide specific examples of how category changes or other federal immunization schedule changes could affect your work, your organization's operations, or your ability to serve children, families, patients, or communities. For example, you could mention the logistical and financial impacts of downgrading routine recommendations to SCDM, including issues your practice would face with integrating SCDM in electronic health records.
- Write about the importance of school vaccine requirements for keeping children safe in your state, including how they protect immunocompromised children or those who cannot be vaccinated.
- Share any concerns you've been hearing from parents or caregivers of children with autism in response to vaccine news or Administration officials' comments about autistic children. Describe what children with autism and their families need and deserve, including supports and research that helps health care and other systems address genuine needs.