Georgetown University
McCourt School of Public Policy
CENTER FOR CHILDREN
AND FAMILIES

VIA ELECTRONIC SUBMISSION

September 18, 2026

Office of the Secretary
U.S. Department of Health and Human Services
Attention: Cynthia Goss
200 Independence Ave SW
Washington, DC 20201

Re: Comments on HHS-OS-2026-0332
Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

The Center for Children and Families (CCF), part of the McCourt School of Public Policy at Georgetown University, is an independent, nonpartisan center that conducts research, develops strategies, and offers policy solutions to support access to high-quality, comprehensive, and affordable health coverage for the nation's children and families, particularly those with low- and moderate-incomes. Thank you for the opportunity to make the following comments to the Department of Health and Human Services (HHS) Request for Information (RFI), which are based on our deep expertise in health policy and the Medicaid program.

On August 24, 2026, HHS posted an RFI, "Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making," providing an opportunity for public comment on many aspects of the current Federal system to recommend vaccines.[1] The RFI asks about the current adequacy of recommendation categories, shared clinical decision-making, public trust, and communication by the Federal government on the safety and efficacy of vaccines. This follows Executive Order 14420, "Delivering Gold Standard Childhood Vaccine Recommendations for Americans," (the "E.O."), which was published on August 10, 2026.[2] In the E.O., President Trump calls for the Secretary of HHS to direct the Task Force on Safer Childhood Vaccines, which was reinstated in 2025, to provide recommendations on the following items: 1) options to administer vaccines as individual products, 2) ideal timing and sequencing for core vaccines, 3) development of additional or alternative adjuvants to aluminum, 4) how to ensure continuous evaluation of the risk and benefit profiles of all childhood vaccines, and 5) how to improve vaccine safety monitoring. The E.O. lays the groundwork for several of the questions asked in the RFI, many of the answers to which are already well-established in longstanding Federal vaccine recommendation policies, governed by other laws and entities. Furthermore, the Task Force on Safer Childhood Vaccines

[1] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 *F.R.* 54724 (2026, August 24). Available at https://www.federalregister.gov/documents/2026/08/24/2026-17250/request-for-information-categories-used-in-federal-vaccine-recommendations-and-the-role-of-shared

[2] Delivering Gold Standard Childhood Vaccine Recommendations for Americans (Executive Order 14420), 91 *F.R.* 53173 (2026, August 10). Available at https://www.federalregister.gov/documents/2026/08/14/2026-16730/delivering-gold-standard-childhood-vaccine-recommendations-for-americans

never had and does not currently have the same established infrastructure or legal standing to effectively and transparently review data or change vaccine recommendations.

Established System for Federal Vaccine Recommendations & Safety Monitoring

As it currently stands, vaccines go through a rigorous process of development, testing, and approval before they are recommended. After the initial development and clinical trial phases, manufacturers submit a Biological License Application to the Food and Drug Administration (FDA) for approval. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews safety and efficacy data for new products and provides a recommendation to approve or not approve.[3] This committee is one such external group that HHS officials rely on for assistance in making vaccine policy decisions. It is composed of 15 voting members, many of whom are leading experts in immunology and related fields.[4] Once the vaccine exits the VRBPAC and is approved by the FDA, the data is transmitted to the Centers for Disease Control and Prevention (CDC) for discussion in their Advisory Committee on Immunization Practices (ACIP). This similarly-composed committee meets to review the recommendation from VRBPAC as well as the vaccine's safety and efficacy data. ACIP ultimately votes to recommend (or chooses not to recommend) the product to different population groups based on risk profile, which is then reviewed by the CDC Director and is either adopted or not. The Secretary of HHS has the opportunity to veto the recommendation. This longstanding and rigorous process results in the CDC publishing a vaccine schedule for children, adolescents and adults.[5] The final product is a robust tool that informs individuals, parents and providers about recommended products and includes detailed notes that are helpful in clinical decision making.

Even after the full FDA approval and CDC recommendation of a vaccine product for a particular population, ACIP continues to monitor the safety and efficacy of that product, allowing committee members to modify their recommendations as new data become available. When ACIP considers new data, the committee members utilize the Evidence to Recommendation (EtR) framework to ultimately recommend, or not recommend, a change in the immunization schedule. As the CDC states, "[key] factors considered in development of recommendations include balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses."[6] This EtR framework has long been the standard for how changes to the immunization schedules are made, allowing for flexibility while assessing all available evidence on the benefits and harms of a particular product.

ACIP also works closely with the CDC's Immunization Safety Office, which monitors vaccine safety systems for new signals and presents data both domestically and internationally. The Vaccine Adverse Event Reporting System (VAERS) accepts and analyzes post-vaccination reports of health

---

[3] U.S. Food and Drug Administration. *Vaccines and Related Biological Products Advisory Committee*. Available at https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee

[4] U.S. Food and Drug Administration. *Charter of the Vaccines and Related Biological Products Advisory Committee*. Available at https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee

[5] Centers for Disease Control and Prevention. *Child and adolescent immunization schedule by age*. Available at https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

[6] Centers for Disease Control and Prevention. *Evidence-based recommendations for ACIP*. Available at https://www.cdc.gov/acip/evidence-based-recommendations/index.html

outcomes.[7] Similarly, the Vaccine Safety Datalink (VSD) monitors adverse events in near-real time at member sites and conducts studies to determine possible safety signals.[8] Both programs transmit timely information to ACIP for action. This, for example, worked effectively during the COVID-19 public health emergency, when VAERS detected a possible increased risk of individuals developing Guillain-Barré Syndrome after being vaccinated with the Janssen product. The new data led to several emergency meetings to review the information, culminating in ACIP members voting to revise their COVID-19 vaccination recommendation for preferential use of mRNA vaccines over the Janssen product in late December 2021.[9] This is just one example of the vaccine safety monitoring system working in real time within an established system. If the system is changed, there could be issues relaying time-sensitive vaccine safety data, potentially causing greater harm to more people.

The Critical Role of ACIP in Providing Access to Childhood Vaccinations

ACIP is also responsible for applying their recommendations to the Vaccines for Children (VFC) program, which supplies no-cost vaccines to eligible children, who account for nearly half of the child population in the U.S. VFC serves uninsured children, children with Medicaid coverage, and some children with coverage through the Children's Health Insurance Program (CHIP). VFC is federally funded and is a critical component of improving health care access for children. ACIP, VFC, and Medicaid are inextricably linked in statute and in practice. Section 1902(a)(62) of the Social Security Act (SSA) requires states to "provide for a program for the distribution of pediatric vaccines" in compliance with the rules laid out in section 1928. SSA section 1928 in turn describes the "program for distribution" which is more commonly known as VFC, mentioned above. Under SSA section 1928(c)(2)(B), VFC providers are required to comply with the schedule established by ACIP, and under section 1928(e), the Secretary of HHS must use the ACIP list for purposes of purchasing, delivering and paying for the administration of pediatric vaccines. Separately, under SSA section 1905(r), Medicaid's comprehensive pediatric benefit, Early and Periodic Screening, Diagnostic and Treatment (EPSDT), is defined as specifically including vaccines identified in 1928(c)(2)(B).

Congress expressly requires ACIP to establish and make changes to the CDC vaccination schedule. When the committee determines a previously-approved product should no longer be recommended, the members take two separate votes: one vote to remove the product from the CDC schedule, and another, identical vote to change the VFC schedule. Per ACIP's own charter, "recommendations shall be based on a transparent, evidence-based deliberative process and may be updated or withdrawn as new information becomes available."[10] When this process is deviated from, as was the case last year, the resulting vaccine schedule changes have real harmful impact for U.S. children. In 2025, the newly-reconstituted ACIP membership voted to remove their recommendation of the quadrivalent MMRV (Measles, Mumps, Rubella, Varicella) vaccine for children less than four years

---

[7] Centers for Disease Control and Prevention. *Vaccine Adverse Event Reporting System (VAERS)*. Available at https://www.cdc.gov/vaccine-safety-systems/vaers/index.html

[8] Centers for Disease Control and Prevention. *Vaccine Safety Datalink (VSD)*. Available at https://www.cdc.gov/vaccine-safety-systems/vsd/index.html

[9] Oliver, S. E., et al. (2022, January 21). Use of the Janssen (Johnson & Johnson) COVID-19 vaccine: Updated interim recommendations from the Advisory Committee on Immunization Practices—United States, December 2021. *Morbidity and Mortality Weekly Report, 71*(3), 90–95. Available at https://doi.org/10.15585/mmwr.mm7103a4

[10] Centers for Disease Control and Prevention. (2026, May 27). *ACIP charter*. Available at https://www.cdc.gov/acip/about/acip-charter.html

old, based on little safety data.[11] The committee further voted to exclude its coverage from VFC, impacting tens of millions of children (though the action was later blocked by a federal court).[12] A recent study found that the children accessing the MMRV vaccine were more likely to be in primarily low-income families, many of which are eligible for Medicaid and therefore eligible for free vaccines through VFC.[13] Combination vaccines such as MMRV allow for fewer visits as well as fewer total injections. As the study authors note, "in safety-net settings, where visit time, vaccine inventory, and follow-up may be constrained, limited access to MMRV could disproportionately affect VFC-eligible children by reducing vaccine options and increasing barriers to timely series completion."

To ensure this system is working appropriately, the Centers for Medicare & Medicaid Services (CMS) have included multiple vaccination-related measures in their Medicaid and CHIP quality reporting requirements. Made mandatory in Fiscal Year 2024, the core sets allow states, the public, and CMS to monitor performance on standardized indicators of the quality of care provided to Medicaid and CHIP beneficiaries. However, in December 2025, CMS announced that two of these critical measures will be removed from the mandatory reporting and instead listed as "optional."[14] The first measure dropped for mandatory reporting, childhood immunization status (CIS-CH), measures the percentage of two-year olds who had the recommended doses of DtaP (Diphtheria, Tetanus, Pertussis), polio, MMR (Measles, Mumps, Rubella), HiB (Haemophilus influenzae type B) hepatitis B, chicken pox, pneumococcal conjugate (PCV), hepatitis A, rotavirus, and influenza (flu) vaccines by their second birthday.[15] The second measure that was dropped, Immunizations for Adolescents (IMA-CH), measures the percentage of thirteen-year old adolescents who had the recommended doses of meningococcal, Tdap (Tetanus, Diphtheria, Pertussis) and HPV vaccines by their 13th birthday.[16] CMS' letter to State Health Officials did not provide a rationale for removing these metrics and also did not propose replacement measures to continue capturing vaccine rates for these populations. Allowing states to discontinue reporting of these metrics will obfuscate how many children are protected from disease and make identifying access issues even more challenging. Additionally, proposed changes to other CDC-controlled surveys and data sets, such as the National

---

[11] Schnirring, L. (2025, September 18). *New CDC advisers scale back recommendations on MMRV vaccine in young kids*. CIDRAP. Available at https://www.cidrap.umn.edu/childhood-vaccines/new-cdc-advisers-scale-back-recommendations-mmrv-vaccine-young-kids

[12] A Federal judge has since ruled that this action was not lawful and has blocked the CDC from implementing the change. Read the Court's opinion and preliminary injunction here: https://litigationtracker.law.georgetown.edu/wp-content/uploads/2025/07/American-Academy-of-Pediatrics_2026.03.16_ORDER-ON-MOTION-FOR-PRELIMINARY-INJUNCTION.pdf

[13] Fagalde, M. S., et al. (2026, July 10). Measles-containing vaccine use for children aged 12 to 47 months, 2015 to 2025. *JAMA Network Open, 9*(7), Article e2622734. Available at https://doi.org/10.1001/jamanetworkopen.2026.22734

[14] Centers for Medicare & Medicaid Services. (2025, December 30). *2027 updates to the Child and Adult Core Health Care Quality Measurement Sets and mandatory reporting guidance* (SHO Letter No. 25-005). Available at https://www.medicaid.gov/federal-policy-guidance/downloads/sho25005.pdf

[15] National Committee for Quality Assurance. *Childhood immunization status (CIS)*. Available at https://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality-report/childhood-immunization-status-cis/

[16] National Committee for Quality Assurance. *Immunizations for adolescents (IMA)*. Available at https://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality-report/immunizations-for-adolescents-ima/

Health Interview Survey (NHIS), further restricts available data for use in tracking critical public health measures.[17]

Specific Responses to the RFI Questions

A. Adequacy of the Current Categories

The current childhood immunization schedule clearly shows which vaccines are recommended, by age, and denotes vaccines based on risk status and those left up to shared-clinical decision making. While all vaccines require some amount of clinical decision making at the individual level to account for allergies, contraindications and other factors, the current categories clearly denote which vaccines all children should receive based on the evidence and which need further discussion with a trusted health care provider. A KFF poll shows that the general public overwhelmingly trusts their health care provider the most on health and vaccine issues.[18] Any change to the current categories could cause provider and public confusion, leading to greater mistrust and wider spread of misinformation.

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

As stated above, any additional categorization could cause major confusion or further mistrust. The childhood vaccination schedule is already optimized to allow for age-based recommendations and gives acceptable ranges for vaccine administration based on efficacy and safety data. Additionally, the CDC publishes a "catch-up" vaccine schedule for children who did not receive the recommended vaccines during the optimal age range. This allows for parental flexibility and maximum choice while giving providers needed tools to facilitate these conversations. If HHS, the CDC, or ACIP decide to change the categories, there should be clear evidence for the change, that is openly discussed and published publicly prior to adoption in order to ensure maximum transparency. Furthermore, insurance coverage pathways, including through the VFC, should be preserved to allow for the maximum level of access and affordability for parents who choose to vaccinate. Inclusion on the recommended vaccination schedule is not a mandate to vaccinate; however, excluding vaccines from the recommended schedule would undoubtedly jeopardize access to those vaccines for at least half of the children in the U.S. given the statutory links between ACIP, VFC, and Medicaid.

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

CDC and ACIP define shared-clinical decision making (SCDM) as "individually based and informed by a decision process between the health care provider and the patient or parent/guardian."[19] This definition works clearly in the vaccination space and does not need to be further defined. Individual-based decision making does not work in a vaccination context as there is a necessary provider element —a healthcare provider must be the one to administer the vaccine — and the vaccination

---

[17] Proposed Data Collection Submitted for Public Comment and Recommendations, 91 *F.R.* 53868. (2026, August 20). Available at https://www.federalregister.gov/documents/2026/08/20/2026-17040/proposed-data-collection-submitted-for-public-comment-and-recommendations

[18] KFF. (2026, July 23). *KFF health information and trust polling dashboard.* Available at https://www.kff.org/public-opinion/kff-polling-on-health-information-and-trust/?entry=trusted-sources-of-health-information-who-the-public-trusts-for-health-information

[19] Centers for Disease Control and Prevention. (2025, January 7). *ACIP shared clinical decision-making recommendations.* Available at https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

process already inherently involves consideration of individual needs. Provider input is needed to make these clinical decisions. In fact, the overwhelming majority of parents (85%) trust their child's pediatrician as their most trusted source of vaccine information. Trust in the CDC and FDA is much lower, with just over 50% of parents trusting them to provide reliable information about vaccines.[20] Individuals and parents are already working with their trusted healthcare providers to determine the best course of action to protect against vaccine-preventable diseases.

D. Considerations in Setting Recommendations

The Federal government currently has a longstanding, robust, multi-layered approach to evaluating vaccines for safety and efficacy before recommendation. Utilizing the Evidence to Recommendation (EtR) and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) frameworks ensure vaccines are maximally scrutinized prior to recommendation for any population group. As stated on the CDC website, "this standardized process for developing ACIP recommendations enhances transparency, consistency, and communication."[21] ACIP and established vaccine evaluation pathways already have room built in for review of evolving evidence, including adverse events reported through VAERS and VSD. As these systems already have procedures for relaying information to ACIP, and ACIP has policies in place to change vaccine recommendations based on new safety data, any deviation to how recommendations are set could lead to missed safety signals, increased risk, and lowered public trust in the vaccine recommendation process.

E. Trust and Communication

Federal recommendations are an incredibly important part of the architecture of vaccine policy in the U.S. While states retain the sole power to set and enforce vaccine mandates, Federal recommendations have major implications for vaccine access and cost. All ACIP-recommended vaccines are covered at no cost for eligible children through VFC, which covers nearly half of all U.S. children, making it a critically important public health program. These recommendations open the door to access, but do not force any individual to get vaccinated. All states require some level of vaccination for children to enter school or daycare, and all states allow for medical exemptions to these requirements.[22] The majority of states also allow for religious exemptions.[23] ACIP's recommendation is not a mandate but is the key that unlocks funding and delivery mechanisms that not only allow but also require the vaccine product to be available nationwide.

Transparency is the key to greater public trust. Opaque communications and ever-changing processes erode public confidence and cause misinformation to percolate through communities. Vaccine myths and misleading information, particularly around the MMR vaccine, have contributed

---

[20] KFF. (2026, July 23). *KFF health information and trust polling dashboard.* Available at https://www.kff.org/public-opinion/kff-polling-on-health-information-and-trust/?entry=trusted-sources-of-health-information-who-parents-trust-for-childhood-vaccine-information

[21] Centers for Disease Control and Prevention. *Grading of Recommendations, Assessment, Development and Evaluation (GRADE).* Available at https://www.cdc.gov/acip/grade/index.html

[22] Michaud, J., Bell, C., & Kates, J. (2026, August 21). *State and local policies on school vaccine requirements: Overview and current status.* KFF. Available at https://www.kff.org/other-health/state-and-local-policies-on-school-vaccine-requirements-overview-and-current-status/

[23] National Conference of State Legislatures. (2026, September 1). *State non-medical exemptions from school immunization requirements.* Available at https://www.ncsl.org/health/state-non-medical-exemptions-from-school-immunization-requirements

to declining vaccination rates and outbreaks in vulnerable communities. Recent changes to long-standing CDC processes on vaccine recommendations, childhood immunization schedule updates, and disease reporting have confused the public and made it more difficult for providers to keep their patients healthy. Reinstating mandatory reporting for the vaccine-related Medicaid and CHIP quality measures will allow state and Federal officials to see a fuller picture on vaccination status, including where vaccination levels are too low to fully protect a community from disease.

* * *

Thank you again for the opportunity to make the above comments to the RFI. Please contact us at Hannah.Green@georgetown.edu if you have any questions or if we can be of further assistance.

Respectfully submitted,

Hannah Green
State Health Policy Analyst
Center for Children and Families
McCourt School of Public Policy
Georgetown University

Kelly Whitener
Associate Professor of the Practice
Center for Children and Families
McCourt School of Public Policy
Georgetown University