STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Docket No. HHS-OS-2026-0332; Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. 54,724 (Aug. 24, 2026)[1]

Dear Ms. Goss:

Introduction and Position

The Washington State Department of Health submits these comments in response to the Department of Health and Human Services' (Department) request for information on the categories used in federal vaccine recommendations. We appreciate the opportunity to comment and we share the Department's interest in a recommendation framework that is honest about evidence and that earns public trust.

The West Coast Health Alliance, which comprises Washington, California, Hawaii, and Oregon, has also submitted a comment. DOH agrees with the concerns expressed in those comments and submits these additional comments to supplement the multistate comments with Washington-specific information and technical considerations.

[1]Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. 54,724 (Aug. 24, 2026) (Docket No. HHS-OS-2026-0332; RIN 0991-ZA62), https://www.federalregister.gov/d/2026-17250

Washington's Stake in the Federal Recommendation Framework

Washington is a universal vaccine purchase state. Through the Childhood Vaccine Program the state buys the full set of vaccines recommended by the Advisory Committee on Immunization Practices and supplies them at no cost to enrolled providers for children in Washington under nineteen, whatever a child's insurance status.[2] The program is financed by braiding federal Vaccines for Children funds, state funds, and a dosage-based assessment paid by health plans and other private payers through the Washington Vaccine Association.[3] State law establishes a dedicated account for the state share, restricted to purchasing vaccine for children who are not eligible for federal programs.[4]

That architecture depends on a definite federal answer to a single question: what is recommended. The recommended set defines what the state is obligated to buy, what the assessment on private payers may fund, and what a provider may draw from state supply without billing a family.

Washington's school and child care entry requirements rest on the same foundation. The State Board of Health has adopted by rule the ACIP Recommended Immunization Schedule for Children and Adolescents as the standard against which a child's immunization status is measured.[5] A companion rule enumerates the vaccine-preventable diseases against which children must be protected, and compliance is administered by school and child care staff using a parent-reported certificate of immunization status.[6]

Comments That Cross Sections

Federal category assignments therefore do not stop at the federal level. Each one propagates into state purchasing obligations, the scope of a private-payer assessment, State Board of Health rulemaking, the forecasting logic in Washington's immunization information system, and the daily work of school nurses. A change that reads in Washington, D.C. as an adjustment to communication arrives in Washington State as a rulemaking and a budget problem.

Section A. Adequacy of the Current Categories

> *Question 1. Are the current categories (routine, risk-based, and shared clinical decision-making/individual-based decision-making) adequate, clear, and well understood by*

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[2] Wash. State Dep't of Health, Childhood Vaccine Program ("The program supplies all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and eliminates or reduces cost barriers to receiving vaccinations."), https://doh.wa.gov/public-health-provider-resources/public-health-system-resources-and-services/immunization/childhood-vaccine-program

[3] Id.; Washington Vaccine Association, Frequently Asked Questions, https://wavaccine.org/faqs/

[4] RCW 43.70.720 (universal vaccine purchase account), https://app.leg.wa.gov/rcw/default.aspx?cite=43.70.720

[5] WAC 246-105-040 (requirements based on national immunization guidelines, applying the ACIP Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger), https://app.leg.wa.gov/WAC/default.aspx?cite=246-105-040

[6] WAC 246-105-030 (vaccine-preventable diseases children must be protected against for full immunization); RCW 28A.210.080; Wash. State Dep't of Health, Explanation of School Immunization Data, https://doh.wa.gov/data-statistical-reports/washington-tracking-network-wtn/school-immunization/explanation-school-immunization-data

> *clinicians, patients, and parents? What evidence bears on how each category is understood in practice?*

The notice's background section is candid about how the current framework performs. In the 2021 national physician survey it cites, roughly 90% (FP) and 95% (GIM) of respondents reported that implementing a shared clinical decision-making recommendation takes more time than a routine one, fewer than half knew that such vaccines are covered by insurance, many reported that electronic health record and forecasting tools displayed the recommendations inaccurately or not at all, and most agreed the category confuses patients.[7]

> *Question 3. Do the current categories unintentionally imply that parental permission, individual consent, or meaningful clinical discussion applies only to shared clinical decision-making recommendations? Should the framework expressly distinguish the strength of a Federal recommendation from the consent, parental-permission, and assent processes involved in administering a vaccine?*

The framework should distinguish the two. Our response to Question 14, in Section D below, explains why the strength of a federal recommendation and the consent and parental-permission processes that govern administration are separate matters that should not be merged in category design.

Section B. Potential Additional or Modified Categories

> *Question 4. Should additional or different categories be adopted, such as "recommended, but not during infancy" (or otherwise age-de-emphasized recommendations); "recommended with qualification"; or "shared clinical decision-making with qualification"? For any proposed category, describe its definition, its default (if any), its evidentiary basis, and its intended downstream consequences.*

We take that evidence seriously, and we read it the opposite way the notice's questions suggest. Adding "recommended with qualification," "shared clinical decision-making with qualification," or an age-de-emphasized category to a set that already fails these tests multiplies a documented failure.[8] Every additional category adds a distinction that must be taught to hundreds of thousands of clinicians, encoded by every electronic health record and immunization information system vendor, explained to parents in a fifteen-minute visit, and administered by school staff who are not clinicians.

Additional categories could also have a negative impact on the electronic reminders used by our health care and public health systems. Clinical decision support and immunization information systems operate on deterministic logic: given a patient's age and history, the system returns what is due. A category defined by the absence of a default cannot be forecast, which is why the

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[7] 91 Fed. Reg. at 54,725 & n.8 (citing A. Kempe et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?, 36 J. Gen. Intern. Med. 2283 (2021)), https://link.springer.com/article/10.1007/s11606-020-06456-z

[8] Id. at 54,727 (Question 4).

systems the notice describes display these recommendations inaccurately or omit them.[9] Qualified and age-de-emphasized categories would compound this. A recommendation that clinical decision support cannot represent is a recommendation that does not reach the point of care, whatever its wording in the schedule.

> *Question 6. If new categories were adopted, what is needed to preserve access to vaccines currently available to Americans and ensure predictable and consistent treatment under coverage requirements, program eligibility rules, the injury-compensation programs, and State law?*

In a universal purchase state the cost of that ambiguity does not fall where it is created. If it is unclear whether a qualified recommendation triggers coverage without cost sharing and Vaccines for Children eligibility, it is equally unclear whether Washington's assessment on private payers may fund the dose and whether the state is obligated to purchase it.

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

> *Question 9. Does the term "shared clinical decision-making" create an unintended contrast with routine recommendations? 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?*

The notice asks in Question 9 whether "shared clinical decision-making" should be replaced by "conditional recommendation" or "recommendation based on individualized assessment."[10] That question identifies a defect. Shared decision-making describes a clinical process that belongs to every vaccine encounter, and reserving the phrase for one category implies, wrongly, that discussion and consent are confined to it. But renaming the category does not repair it.

> *Question 11. What are the risks of an SCDM category, including confusion, reduced access or uptake, and time burdens in practice, and what evidence supports them?*

The available evidence on uptake points the same direction. Following the 2019 move of the pneumococcal conjugate vaccine to shared clinical decision-making, uptake among Medicare beneficiaries declined.[11] A category with no default performs like a weaker recommendation because it is one. Expanding the share of the schedule that carries no default should be expected to reduce uptake across a broader set of vaccines.

Washington cannot absorb that. Kindergarten coverage for measles, mumps, and rubella stood at 91 percent in the 2025-26 school year, below the 95 percent threshold associated with

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[9] Id. at 54,725.

[10] Id. at 54,728 (Question 9).

[11] Id. at 54,725 & n.9 (citing J. Vietri et al., Pneumococcal Vaccine Uptake Among Medicare Beneficiaries Aged 65 Years and Older Following the Shared Clinical Decision-Making Recommendation for 13-Valent Pneumococcal Conjugate Vaccine in 2019, 41 Vaccine 5211 (2023)).

community protection, and it has not moved for four years. Non-medical exemptions reached 4.4 percent, above the national median and higher than the year before.[12] Nationally, 2,903 measles cases were confirmed in 2026 as of August 27, across 37 outbreaks, in a country that declared measles eliminated in 2000.[13]

Washington has paid and continues to pay the costs of reduced uptake. The 2019 measles outbreak in Clark County produced 72 confirmed cases and prompted a gubernatorial emergency proclamation. The societal cost was approximately $3.4 million, of which roughly $2.3 million was public health response, for an outbreak confined largely to one county over four months.[14] And this year, measles cases in Washington are already more than quadruple the 12 cases reported in 2025.

> *Question 12. 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?*

The notice recognizes that a shared clinical decision-making recommendation triggers the same coverage obligations as a routine one, and that patients and providers frequently do not know this.[15] Category proliferation would make that error harder to correct, because each new category raises the same question again and the answer must be relitigated with every payer, every vendor, and every clinic.

Section D. Considerations in Setting Recommendations

> *Question 15. When evidence is limited, uncertain, or evolving, how should that uncertainty be reflected in the recommendation itself, whether through category assignment, qualifying language, sunset or re-review provisions, or explicit statements of evidentiary certainty, rather than resolved silently in favor of either a universal recommendation or no recommendation?*

The notice also asks how evidentiary uncertainty should be reflected in a recommendation.[16] The tools for that already exist. The Evidence to Recommendations framework and the GRADE approach were designed to make the certainty of evidence explicit and to require transparency

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[12] Johns Hopkins Int'l Vaccine Access Ctr., Status of Childhood Immunization in Washington (Aug. 25, 2026) (reporting CDC SchoolVaxView data for the 2025-26 school year), https://publichealth.jhu.edu/ivac/resources/reports/monitoring-childhood-immunization-at-the-state-level/washington

[13] Ctrs. for Disease Control & Prevention, Measles Cases and Outbreaks (data as of Aug. 27, 2026), https://www.cdc.gov/measles/data-research/index.html

[14] Societal Costs of a Measles Outbreak, 147 Pediatrics e2020027037 (2021), https://pubmed.ncbi.nlm.nih.gov/33712549/

[15] 91 Fed. Reg. at 54,728 (Question 12).

[16] Id. at 54,728 (Question 15).

about it.[17] We support publishing certainty ratings alongside every recommendation, stating the evidentiary basis in plain language, and scheduling re-review when evidence is expected to mature. What we oppose is encoding uncertainty through category assignment. Payers, electronic health record vendors, school administrators, and parents read a category as a verdict on whether a vaccine is worth getting. Moving a vaccine to a qualified category communicates a substantive downgrade regardless of the explanatory text that accompanies it, and no amount of that text travels with the designation.

> *Question 14. What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate? Commenters are specifically invited to address … a presumption in favor of individual autonomy, informed consent, and religious freedom; and feasibility and programmatic consequences.*

Finally, Question 14 invites comment on whether a presumption in favor of individual autonomy, informed consent, and religious freedom should inform the assignment of categories.[18] We would separate the two ideas. Autonomy, consent, and parental permission govern the administration of every vaccine in every category, as the notice itself acknowledges.[19] Washington law protects them independently through medical, religious, and personal exemptions to school entry requirements, with the personal exemption unavailable for measles, mumps, and rubella vaccine.[20] Building a consent presumption into the evidentiary assignment of a category adds no protection an individual does not already have, it only adds to the confusion. What it removes is the federal government's plain assessment of the evidence, which no patient or parent can assemble alone and which a recommendation exists to supply.

Section E. Trust and Communication

> *Question 17. What communication practices should accompany vaccine recommendations so that they earn and keep public trust, and what lessons from COVID-19-era communication should inform them?*

The notice is right that trust in federal health institutions has to be rebuilt, and right that candor about evidence is how it gets rebuilt. Candor means publishing what is known and how confidently it is known. Proliferating categories that clinicians cannot explain, systems cannot display, and payers cannot interpret works against it. We urge the Department to keep the framework as it stands, make its evidence visible, and repair what is already broken before adding to it.

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[17] Id. at 54,724-25 & nn.3-4 (citing G. Lee & W. Carr, Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices, 67 MMWR Morb. Mortal. Wkly. Rep. 1271 (2018)), https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a4.htm

[18] Id. at 54,728 (Question 14).

[19] Id. at 54,725-26 ("These principles apply across all vaccine recommendations, including routine ones.").

[20] WAC 246-105-055 (philosophical and personal exemption for measles, mumps, and rubella vaccine prohibited), https://app.leg.wa.gov/WAC/default.aspx?cite=246-105-055

Question 18. How should the Department measure whether a recommendation framework is succeeding, and what data should be collected and published for that purpose?

Measure the framework by outcomes and publish them by state each year: vaccination coverage, exemption rates, provider comprehension, and vaccine-preventable disease incidence.

Recommendations

The Washington State Department of Health respectfully recommends that the Department:

1. Retain the current three-category structure and adopt no additional categories. Do not adopt "recommended, but not during infancy" or other age-de-emphasized designations, "recommended with qualification," or "shared clinical decision-making with qualification." (Question 4.)
2. Treat the existing categories as a set, and repair and strengthen the implementation of this set of categories before altering their structure. Publish category designations in plain language for the public, as well as in a machine-readable form that immunization information system and clinical decision support vendors can consume, so that these recommendations are displayed accurately at the point of care. (Question 13.)
3. Issue joint CMS and CDC guidance confirming, in a single document addressed to payers, providers, and the public, that coverage without cost sharing under section 2713 of the Public Health Service Act and eligibility under the Vaccines for Children program attach to every recommendation category without exception. (Question 12.)
4. Preserve the integrity of the Advisory Committee on Immunization Practices deliberative process and the Evidence to Recommendations framework, including public availability of the evidence review supporting each recommendation and each category assignment. (Question 14.)
5. Express evidentiary uncertainty inside the recommendation rather than through category assignment. Publish the GRADE certainty rating with each recommendation, state the evidentiary basis in plain language, and set explicit re-review dates where evidence is expected to develop. (Question 15.)
6. (Question 6.) Undertake any change to the category structure through notice-and-comment rulemaking, with formal consultation with states and with Tribal Nations, and with an implementation runway of no less than one full school year so that state boards of health, purchasing programs, payers, and school systems can conform.
7. (Question 6.) Coordinate directly with universal purchase states before the effective date of any category change, so that state purchasing obligations and payer assessments are settled before providers and families encounter the change at the point of care.

Conclusion

In Washington's experience, federal vaccine recommendations do most of their work through state/local/Tribal agencies, health care partners, and other institutions rather than by persuading each patient directly. A clear recommendation tells a payer what to cover, a state what to buy, a school what to require, an electronic health record what to display, and a clinician what to advise. Each additional category weakens that signal at every one of those points at once. Complexity will contribute to confusion.

The notice is right that trust in federal health institutions has to be rebuilt, and right that candor about evidence is how it gets rebuilt. Candor means publishing what is known and how confidently it is known. Proliferating categories that clinicians cannot explain, systems cannot display, and payers cannot interpret works against it. We urge the Department to keep the framework as it stands, make its evidence visible, and repair what is already broken before adding to it.

We appreciate the Department's consideration of these comments.

Sincerely,

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Washington State Department of Health