AMCP
Optimizing medicine.
Improving lives.

September 20, 2026

Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
Office of the Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Submitted electronically 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 Deputy Assistant Secretary Goss:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) for the opportunity to provide comments in response to the Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (RFI).

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Federal vaccine recommendation categories have direct consequences for patients, providers, pharmacists, payers, public programs, and employers. For managed care pharmacy, the clarity and stability of these categories determine whether plans and pharmacy benefit administrators can support benefit design, formulary and medical policy operations, pharmacy network readiness, clean claims adjudication, patient cost sharing protections, quality measurement, public health outreach, and pharmacist vaccination services within state scope-of-practice frameworks. Recommendation categories also affect statutory and programmatic obligations, including coverage without cost sharing under

section 2713 of the Public Health Service Act and access through the Vaccines for Children program. HHS should preserve a transparent, evidence-based federal vaccine recommendation framework that supports clinically appropriate access, minimizes avoidable administrative barriers, and avoids category assignments that unintentionally create coverage gaps or undermine patient and provider confidence.

A. The Federal Vaccine Recommendation Framework and Its Categories

AMCP supports maintaining recommendation categories that are understandable, operationally workable, and tied to transparent evidence review. The current framework can meet these purposes if HHS clarifies how each category should be assigned, how category changes should be communicated, and how downstream coverage and access consequences will be assessed before a recommendation is finalized. The RFI recognizes these consequences, but it does not fully explain how HHS will weigh them against clinical evidence. That ambiguity is especially important because payer systems, pharmacy systems, public health programs, and state pharmacist authority rules often rely on federal vaccine recommendation categories as operational signals.

AMCP recommends that HHS retain routine and risk-based categories as the principal categories for vaccines that have sufficient evidence of population-level or identifiable-risk-group benefit. HHS should use shared clinical decision-making only when the evidence supports meaningful individualized variation in benefit-risk assessment and when implementation requirements will not predictably reduce access for patients who may benefit from vaccination.[1] This distinction is operationally critical. Routine and risk-based recommendations allow plans and pharmacy benefit administrators to configure coverage, pharmacy network communications, clinical edits, and outreach strategies around identifiable populations. By contrast, a broad or unclear shared clinical decision-making category can create provider and pharmacist uncertainty, inconsistent documentation expectations, claims friction, and patient confusion about whether a vaccine is recommended or covered.

B. Request for Information

HHS asks whether the current categories are adequate, whether additional or different categories should be adopted, and what considerations should inform category assignment. AMCP urges HHS to evaluate recommendation categories through clinical and operational lenses. A recommendation category is not merely terminology. It is an

---

[1] Centers for Disease Control and Prevention, ACIP Shared Clinical Decision-Making Recommendations, https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

implementation instruction that affects benefit coverage without cost sharing, clean pharmacy claims adjudication, provider and pharmacist understanding, immunization information system outreach, and consistent patient communication across care settings. HHS should only consider the adoption of new or revised categories if the new categories improve clarity and avoid barriers to medically appropriate vaccination.

Evidence-based standard for category assignment

HHS should confirm that federal vaccine recommendation categories will remain grounded in a transparent assessment of the totality of evidence, including randomized controlled trials where available, observational studies, immunogenicity data, vaccine effectiveness studies, safety surveillance, burden-of-disease data, implementation feasibility, equity considerations, and real-world evidence. AMCP agrees that randomized controlled trial evidence can be highly informative, but HHS should not treat the absence of a randomized controlled trial for every population, dosing interval, or clinical circumstance as a reason to withhold or downgrade a recommendation when other scientifically valid evidence supports vaccination. Vaccine evidence develops across a lifecycle: pre-licensure trials, FDA review, post-approval monitoring, ACIP review, real-world effectiveness studies, and ongoing pharmacovigilance. Category assignment should reflect that lifecycle rather than applying an evidence hierarchy in a way that could delay access or create preventable disease burden.

HHS should also clarify how it will evaluate certainty, uncertainty, and evidence gaps. When evidence is incomplete, HHS should identify the specific uncertainty, explain how it affects category assignment, and describe whether coverage and access should continue while additional evidence is generated.[2] This matters because vague references to limited evidence can be interpreted differently across coverage policies, provider communications, and pharmacy operations. If HHS moves a vaccine from routine to risk-based or shared clinical decision-making, it should identify the evidence basis for that change, the affected population, the expected access consequences, and the transition period needed for payers and providers to implement the change without disrupting patient access.

Shared clinical decision-making

AMCP recommends that HHS preserve shared clinical decision-making as a narrow, clinically meaningful category for circumstances in which vaccination may benefit some individuals but the balance of benefits and risks depends materially on personal clinical characteristics, exposure risk, or prior vaccination history. HHS should not use shared clinical decision-making as a default category for public debate, incomplete evidence, or

[2] Centers for Disease Control and Prevention, Evidence to Recommendations Frameworks, https://www.cdc.gov/acip/evidence-to-recommendations/index.html.

generalized concerns about autonomy. Used appropriately, shared clinical decision-making supports informed patient choice. Used too broadly, it can signal that a vaccine is optional, less evidence-based, or less important, even when clinically appropriate patients may benefit from vaccination.[3]

For managed care pharmacy, HHS should clarify that shared clinical decision-making does not require burdensome prior authorization, special attestation, or clinician documentation beyond what is clinically reasonable and operationally feasible. HHS should distinguish between the clinical conversation supporting an individualized vaccination decision and payer administrative requirements. HHS should affirm that pharmacists and other immunization providers may participate in shared clinical decision-making where permitted by state scope-of-practice law and applicable federal program rules. This clarification would align federal recommendations with contemporary immunization practice, where pharmacists are often accessible vaccination providers.

HHS should also create implementation guidance that explains what shared clinical decision-making means for benefit design, pharmacy claims adjudication, medical claims adjudication, provider documentation, immunization registries, quality measures, and patient communications.[4] Without this guidance, shared clinical decision-making may be implemented unevenly, with some patients able to receive vaccination at the point of care while others face delays because plans, providers, pharmacies, or state programs interpret the category differently. HHS should make clear that shared clinical decision-making is a recommendation category, not an invitation for coverage denials where the vaccine is clinically appropriate for the patient.

Downstream legal and programmatic consequences of recommendation category assignment

The RFI appropriately recognizes that vaccine recommendation categories have downstream legal and programmatic consequences. HHS should make these consequences a required component of category assignment. Section 2713 of the Public Health Service Act requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage, without cost sharing, "immunizations that have in effect a recommendation from the Advisory

---

[3] American Academy of Pediatrics, Shared Clinical Decision Making for Immunizations, https://www.aap.org/en/patient-care/immunizations/shared-clinical-decision-making-for-immunizations/.

[4] American Academy of Family Physicians, Guide to shared clinical decision-making for adult immunizations, https://www.aafp.org/assets/image/upload/v1781733303/pdf_adult_immunization_shared_decision_making.pdf.

Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved."[5] HHS should preserve recommendation categories in a way that avoids uncertainty about whether a vaccine recommendation is "with respect to the individual involved" for coverage purposes.

HHS should also account for the consequences of category changes for the Vaccines for Children program. Under section 1928 of the Social Security Act, the VFC program is designed to support access to pediatric vaccines for eligible children and relies on ACIP recommendations and VFC resolutions to determine program availability.[6] If HHS creates new categories, substantially revises existing categories, or moves pediatric vaccines into categories that are operationally ambiguous, the Department should explain how it will prevent interruptions in VFC availability, provider ordering, state program implementation, and pharmacy or medical provider administration pathways. For children and other vulnerable populations, category ambiguity quickly becomes an access barrier.

AMCP recommends that HHS adopt a formal access-impact assessment before finalizing category changes.[7] The assessment should identify whether a category assignment affects coverage without cost sharing, public program eligibility, state pharmacist authority, pharmacy claims processing, provider reimbursement, immunization registry reporting, and patient communications. The Department should publish this assessment with the recommendation to support consistent implementation by payers, pharmacists, plans, providers, and states. HHS should also provide adequate implementation timelines for category changes requiring system updates because pharmacy and medical claims systems, benefit files, provider communications, and patient-facing materials require lead time. Abrupt or ambiguous category changes can produce claims rejections, inconsistent coverage, and avoidable patient confusion.

Communication practices necessary to earn and maintain public trust

HHS should communicate recommendation categories in a manner that is accurate, consistent, and implementation-ready. Public trust depends on both the scientific basis for a recommendation and clear information about what the recommendation means for patients, clinicians, pharmacists, payers, and public programs. HHS should avoid language that implies shared clinical decision-making is a weaker or non-recommendation category. Instead, the Department should explain that shared clinical decision-making applies when

---

[5] 42 U.S.C. § 300gg-13(a)(2), https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section300gg-13&num=0&edition=prelim.
[6] 42 U.S.C. § 1396s, https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1396s&num=0&edition=prelim.
[7] Academy of Managed Care Pharmacy, Access Affordability, and Outcomes, https://www.amcp.org/aaoreport-2025.

the decision is individualized and should identify the factors most relevant to that individualized decision. HHS should issue plain-language patient materials and operational materials for payers and providers alongside each recommendation.

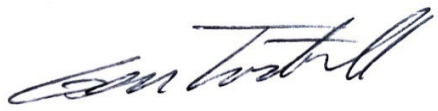
Managed care pharmacy helps translate federal recommendations into practical access. Plans and pharmacy benefit administrators can support outreach, network readiness, quality programs, and benefit communications when the federal recommendation is clear. Conversely, unclear category definitions can create inconsistent patient experiences: one patient may receive a vaccine without delay at a pharmacy, while another faces confusion about whether the same vaccine requires a provider visit, documentation, cost sharing, or prior review. HHS should therefore develop standardized language explaining routine, risk-based, and shared clinical decision-making recommendations and should explicitly state whether a recommendation supports coverage for the indicated individual or population.

Conclusion

HHS should preserve an evidence-based, transparent, operationally clear recommendation framework aligned with patient access. HHS should retain routine and risk-based categories where evidence supports broad or identifiable-risk-group vaccination; reserve shared clinical decision-making for circumstances where individualized assessment is clinically meaningful; assess access consequences before changing categories; and publish implementation guidance that supports consistent coverage, claims adjudication, pharmacist participation, and patient communications. AMCP looks forward to working with HHS to ensure federal vaccine recommendations support public health, patient access, affordability, and appropriate medication use.

AMCP appreciates your consideration of AMCP's comments. If you have any questions regarding AMCP's comments or would like additional information, please contact me at etunstall@amcp.org or (703) 705-9358.

Sincerely,



Geni Tunstall, JD
Associate Vice President, Regulatory Affairs