September 20, 2026

The Honorable Robert F. Kennedy, Jr
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: **HHS-OS-2026-0332 – Notice; Request for Information**: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-making
91 Fed. Reg. 54724 (August 24, 2026)

Dear Secretary Kennedy,

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) are pleased to submit comments to the Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-making. The ACS is a nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy, and service. The ACS, operating through its national office and throughout the United States (U.S.), is the largest voluntary health organization in the U.S. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of ACS, supporting evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels, and empowering advocates across the country to make their voices heard and influence evidence-based public policy. ACS and ACS CAN advocate for millions of cancer patients and their families.

We are concerned about the impact that potential changes to the federal vaccine recommendation framework could have on vaccine uptake and access, insurance coverage, state policies, and protection for millions of Americans, including immunocompromised populations such as cancer patients. We strongly urge that, given these far-reaching consequences, changes to vaccine recommendations and recommendation categories continue to be guided by rigorous scientific evidence and established evidence-based review processes. We caution that the creation of a parallel framework for evaluating or revising vaccine recommendations risks undermining transparency and public confidence in the federal vaccine system.

Importance of Vaccinations for the Cancer Community

Vaccinations are an essential part of care for the more than 18 million Americans living with a history of invasive cancer[1]. This community-wide protection is critical for people whose immune systems are compromised by cancer or cancer treatment.[2] Individuals with cancer face a higher risk of serious illness, complications, and deaths from vaccine-preventable diseases. Some cancer patients are unable to[3] receive certain vaccines, while others may not develop a strong immune response following vaccination. As a result, these individuals rely on high community-wide vaccination rates to reduce exposure to infectious diseases and safely participate in everyday activities.[4] Vaccination for the household contacts of people with cancer is particularly important to reducing risk of infectious diseases, as an estimated one in four cancer patients lives with a child or adolescent.[5]

Vaccines also play an important role in cancer prevention. The human papillomavirus (HPV) and the hepatitis B (HepB) vaccines prevent infections that can cause cancer. The HPV vaccine has substantially lowered the risk of HPV-related head and neck cancers among men[6] and cervical precancers and cancers among women.[7] Recent ACS research found that birth cohorts with access to recommended HPV vaccines experienced dramatic declines in cervical cancer and precursor lesion incidence rates compared to cohorts that did not have such access.[8] These reductions are expected to continue as vaccinated cohorts age. Additional ACS research demonstrates that declines in cervical cancer incidence vary across states, with states achieving higher HPV vaccination rates experiencing significantly larger reductions in cervical cancer incidence.[9] The HepB vaccine has dramatically reduced HBV infections among children and adolescents and lowered the risk of chronic infection and HBV-related liver cancer later in life.[10] When the vaccine series begins at birth, it can reduce an individual's risk of developing liver cancer by approximately 84%.[11]

Vaccines are also increasingly being used to treat certain cancers. Unlike vaccines that protect against infectious disease, therapeutic cancer vaccines are designed to stimulate the immune system to recognize and attack cancer cells that are already present in the body. These treatments have improved outcomes for some patients, and several therapeutic cancer vaccines have been

approved by the U.S. Food and Drug Administration, including vaccines for certain prostate and bladder cancers.[12]

A. Adequacy of the Current Categories

We strongly believe that the current routine recommendation categories provide a clear, evidence-based framework for providers, patients, and policymakers. They establish a consistent standard of care that supports equitable access to vaccination, promotes high vaccination coverage, and helps protect public health.

We caution that changes to these categories, particularly the reclassification of vaccines currently recommended for routine use in the absence of new scientific evidence, could undermine these benefits. Recommendation categories should be driven by the strength of the scientific evidence and the expected benefit to the patient. When vaccine categories include nonstandard or complex recommendations, they create confusion for both providers and patients. For example, implementation studies show that broad use of shared clinical decision-making (SCDM) recommendations in clinical practice resulted in lower vaccine uptake and increased disparities in vaccination coverage.[13]

Current routine recommendation categories do not diminish individual choice. Informed consent and discussions between patients, parents, and providers are already fundamental components of care under both routine recommendations and SCDM. Creating additional or more complex recommendation categories is unnecessary to preserve patient autonomy and may instead weaken vaccination efforts and public health protections.

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

We are greatly concerned about the impact of additional or modified categories in weakening and diluting vaccine recommendations. Recommendation categories should primarily communicate the strength of the scientific evidence, the expected benefits of vaccination, and the populations for whom vaccination is recommended. Changes to recommendation categories should be carefully evaluated for their potential impact on vaccine confidence, access, coverage, and health equity. Potential changes should not inadvertently reduce access to vaccines by increasing patient

confusion, creating uncertainty regarding insurance coverage or program eligibility, or increasing barriers for rural, underserved, medically vulnerable, and other hard-to-reach populations.

The U.S. Department of Health and Human Services (HHS) should continue to ensure that vaccine recommendations are based on the best available scientific evidence and informed by the health needs of the U.S. population, the realities of the U.S. healthcare system, and the needs of populations at increased risk of severe disease, such as cancer patients and other individuals who are immunocompromised.

We are deeply concerned that introducing flexibility in vaccine timing beyond what is supported by the evidence may create confusion among patients, parents, and providers; contribute to delays in vaccination; increase implementation challenges for providers, particularly in underserved communities; and place additional burdens on immunocompromised individuals, including cancer patients and their families, by requiring more healthcare visits and more complex care coordination. Vaccine schedules are most effective when they clearly communicate recommended timing for vaccination based on the best available scientific evidence and include clear catch-up guidance for individuals who have missed receiving vaccines on time as specified in the immunization schedule.

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

Shared clinical decision-making has long been an important part of vaccine discussions between patients, parents, guardians, and health care providers. These discussions work best when guided by clear, evidence-based recommendations from trusted public health authorities and when designed and implemented in ways that are practical, equitable, and responsive to the health needs of the U.S. population and the realities of the U.S. healthcare system.

However, there can be significant unintended negative consequences when vaccines previously recommended for routine use are reclassified as SCDM, as such a change may signal that the vaccine is less necessary, not broadly recommended, and of uncertain benefit, leading to confusion among the public. The recent proposed changes to the Childhood and Adolescent Vaccine Immunization schedule have already created confusion among cancer patients and survivors. According to an ACS CAN Survivor Views survey, 59% of respondents said moving

vaccines from routine recommendations to SCDM makes vaccine decisions more confusing. Sixteen percent reported that confusion about recent vaccine recommendations has caused them to skip or delay a vaccine they would otherwise have received. This finding highlights the need for recommendation categories to clearly communicate when vaccination is broadly recommended and when individual clinical circumstances should guide decision-making.[14]

Beyond increasing confusion and undermining confidence in routine vaccination recommendations, we are concerned that changes to the SCDM classifications may create additional challenges in resource-limited settings, including rural communities where structural barriers to healthcare access persist. For example, national analyses of the pediatric healthcare workforce show that many rural counties lack pediatricians and that the number practicing in rural areas has declined even as the overall pediatric workforce has grown.[15] In these settings, time and resources for preventive counseling may be constrained and SCDM classifications may further exacerbate disparities in vaccine uptake.[16] Creating new barriers to vaccination may disproportionately affect populations that already experience a higher cancer burden. Rates of lung, cervical, and colorectal cancer are about 40%, 30%, and 20% higher, respectively, in rural areas when compared to urban areas.[17] At the state level, many states link school-entry requirements to routine recommendations. Shifting routine vaccines to a SCDM designation may have the effect of making certain vaccines appear optional for school attendance. This could reduce vaccination coverage in school settings and weaken community protection against vaccine-preventable diseases.[18] For children undergoing or recovering from cancer treatment, high vaccination rates may be critical to their ability to safely attend school, as their protection often depends on the immunity of those around them.

D. Considerations in Setting Recommendations

Vaccine recommendations and categories carry significant consequences for public health, clinical practice, insurance coverage, and access to vaccines. Decisions regarding vaccine recommendations and category assignments therefore require a rigorous, transparent process capable of evaluating complex scientific evidence, assessing benefits and risks across populations, evaluating the strength and limitations of available evidence, and communicating clear guidance to healthcare providers and the public.

Given the importance of vaccine policy for millions of Americans, recommendations and category assignments should continue to be guided by scientific evidence and expert review through established processes at the U.S. Centers for Disease Control and Prevention (CDC) and other federal public health agencies. These decisions should remain free from any non-scientific criteria. The Advisory Committee on Immunization Practices (ACIP), a federal advisory body established to provide expert recommendations on vaccine use in the U.S., serves as the nation's established mechanism for evaluating vaccine evidence and developing vaccine recommendations.[19] We are therefore deeply concerned that the approach outlined in this Request for Information could create a parallel federal structure for vaccine recommendations and category assignments, potentially undermining consistency, transparency, and public confidence in the vaccine policymaking process.

ACIP recommendations are incorporated into federal vaccine programs and insurance coverage requirements[20,21] and serve as the foundation for CDC immunization policy and clinical guidance.[22] ACIP has developed and refined rigorous evidence-based methodologies over decades, including its Grading to Recommendations, Assessment, Development and Evaluation (GRADE)[23] approach and Evidence to Recommendations (EtR) framework,[24] to assess available scientific and clinical evidence, evaluate benefits and harms, consider implementation factors, and determine appropriate vaccine recommendations for specific populations. ACIP also considers recommendations from other organizations as a measure of consistency in the interpretation of the available scientific evidence. Evidence-based approaches are similarly used by other immunization advisory bodies globally, including the World Health Organization's Strategic Advisory Group of Experts on Immunization.[25]

Consistent with other federal evidence-based recommendation bodies, ACIP has historically relied on transparent review processes that incorporate systematic evidence review, expert deliberation, stakeholder input, and opportunities for public comment.[26]

E. Trust and Communication

Vaccines are one of the great public health achievements, saving millions of lives and preventing countless illnesses,[27] and the U.S. has one of the safest and most rigorously monitored vaccine systems in the world. For children, advances in this science translate into protection against more

than sixteen vaccine-preventable diseases, including prevention of some cancers.[28] Despite this success,[29] vaccination rates have steadily declined since 2020, and during the 2025-2026 school year, coverage for routine kindergarten vaccines fell nationwide. Recent changes to the childhood immunization schedule[30] that alter long-standing recommendations were not based on new evidence regarding vaccine safety or effectiveness .[31] These trends underscore the importance of maintaining public confidence in vaccines and ensuring that vaccine recommendations are communicated clearly, consistently, and through trusted evidence-based processes.

To maintain and strengthen public trust, vaccine recommendations must be accompanied by policies and infrastructure that make vaccination accessible, affordable, and effectively delivered. This includes no-cost coverage for recommended vaccines, a strong Vaccines for Children (VFC) program, sustained federal investment in CDC's vaccination program to support vaccine delivery, public education, disease surveillance, and outbreak response, as well as ongoing surveillance and monitoring systems. Public trust is also reinforced through clear communication about the safety of the current vaccine supply and rigorous processes used to test, review, approve and continuously monitor vaccines.

States and localities are essential partners in translating vaccine recommendations into effective immunization programs. Although federal vaccine recommendations are not mandates, they provide an important evidence-based foundation for a wide range of state and local policies that support vaccine access and uptake. School and childcare vaccination requirements, insurance coverage policies, Medicaid and Children's Health Insurance Program (CHIP) programs, and state and local public health guidance all rely on the consistency and credibility of federal recommendations.[32,33] School vaccination requirements protect not only students but also families, including cancer patients and others with weakened immune systems, by reducing the spread of vaccine-preventable disease throughout communities.[34] ACS CAN polling demonstrates strong support for these protections among cancer patients and survivors with eighty-six percent supporting school-entry vaccine requirements, while only six percent opposing them.[35]

Public trust also depends on confidence in the process used to develop vaccine recommendations. Recommendations should be developed through a transparent, evidence-based process informed by appropriately qualified experts across relevant scientific and clinical disciplines. Changes to

vaccine recommendations or recommendation categories should occur through the established federal framework and be accompanied by clear explanations of the evidence considered, the rationale for the changes, and the implications for patients, providers, coverage, and access.

The success of a vaccine recommendation should be measured not only by its impact on vaccine uptake, but also by public understanding of the recommendation, confidence in vaccine safety and effectiveness, equitable access to the recommended vaccine, reduction in vaccine-preventable disease, and protection of medically vulnerable populations, including cancer patients and survivors.

Conclusion

ACS and ACS CAN appreciate the opportunity to provide comments to HHS on vaccine recommendation categories, SCDM, and the impact changes to these policies could have on the 18 million people with a history of cancer, their families and the millions at risk for cancer.

We are very concerned that this Request for Information contemplates changes to vaccine recommendation categories outside the established federal framework and processes that were created to evaluate complex scientific evidence and inform decisions that affect the health and vaccine access of millions of Americans. Changes to vaccine recommendations, including recommendation categories, that are not supported by new scientific evidence risk further increasing confusion, undermining confidence in vaccine recommendations, and eroding public trust in the federal vaccine system.

For additional information, please contact Laura Makaroff, Senior Vice President, Cancer Prevention, ACS at laura.makaroff@cancer.org, and Cassandra Welch, Senior Policy Analyst, ACS CAN at Cassandra.Welch@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President, American Cancer Society Cancer Action Network

William Dahut, MD
Chief Scientific Officer, American Cancer Society

Shanthi Sivendran, MD
Interim Chief Patient Officer, American Cancer Society

---

[1] Talbird SE, Carrico J., La EM, et al. Impact of routine childhood immunization on vaccine-preventable disease incidence in the U.S.. Pediatrics; 2022;150(3), e2021056013. https://doi.org/10.1542/peds.2021-056013.

[2] American Cancer Society. Infections in People with Cancer. American Cancer Society. Available at: https://www.cancer.org/cancer/managing-cancer/side-effects/infections.html Accessed September 11, 2026.

[3] American Cancer Society. *Cancer Facts & Figures 2026.* American Cancer Society; 2025.

[4] American Cancer Society. Infections in people with cancer. American Cancer Society. Accessed March 18, 2026.

[5] Mota-George G, Martinez A, Dains JE. Quality of Life in Adult Cancer Patients With Underage Children: An Integrative Review. J Adv Pract Oncol. 2023 Jul;14(5):390-402. doi: 10.6004/jadpro.2023.14.5.4. Epub 2023 Jul 1. PMID: 37576361; PMCID: PMC10414533.

[6] Wu CN, Cheng WC, Luo SD, Lan KC, Wang SI, Wei JC. HPV Vaccination and Risk of Head and Neck Cancers: A Large Real-World Cohort Study. Int J Infect Dis. 2026 Aug 16:109067. doi: 10.1016/j.ijid.2026.109067. Epub ahead of print. PMID: 42604649.

[7] Jiang C, Rosenberg PS, Jemal A, Sung H. Cervical cancer incidence rates by birth cohort against the backdrop of human papillomavirus vaccination in the U.S., *JNCI: Journal of the National Cancer Institute*. 2026. https://doi.org/10.1093/jnci/djaf374.

[8] Ibid.

[9] Jiang C, Rosenberg PS, Star J, Bandi P, Bednarczyk RA, Jemal A, Sung H. State-level progress in reducing cervical cancer incidence among US young women between the pre- and post-human papillomavirus vaccination eras. J Natl Cancer Inst. 2026 Aug 1;118(8):1395-1402. doi: 10.1093/jnci/djag051. PMID: 41730310; PMCID: PMC13453532.

[10] Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the U.S., 1980-2019. *Public Health Rep*. 2023. doi: 10.1177/00333549231175548.

[11] Qu C, Chen T, Fan C, Zhan Q, Wang Y, Lu J, Lu LL, Ni Z, Huang F, Yao H, Zhu J, Fan J, Zhu Y, Wu Z, Liu G, Gao W, Zang M, Wang D, Dai M, Hsia CC, Zhang Y, Sun Z. Efficacy of neonatal HBV vaccination on liver cancer and other liver diseases over 30-year follow-up of the Qidong hepatitis B intervention study: a cluster randomized controlled trial. PLoS Med. 2014 Dec 30;11(12):e1001774. doi: 10.1371/journal.pmed.1001774. PMID: 25549238; PMCID: PMC4280122.

[12] American Cancer Society, *Cancer Vaccines and Their Side Effects* (Jul. 7, 2025), https://www.cancer.org/cancer/managing-cancer/treatmenttypes/immunotherapy/cancer-vaccines.html.

[13] Fergie, J., Howard, A., Huang, L., & Srivastava, A. (2021). Implementation Experience With Meningococcal Serogroup B Vaccines in the U.S.: Impact of a Nonroutine Recommendation. Pediatric Infectious Disease Journal, 40(3), 269–275. https://doi.org/10.1097/INF.0000000000003033

[14] American Cancer Society Cancer Action Network. Survivor Views: Cancer patients and survivors nationwide. Survey conducted January 14-15, 2026. N=1,445.

[15] Ramesh T, Yu H. US pediatric primary care physician workforce in rural areas, 2010 to 2020. *JAMA Netw Open.* 2023;6(9):e2333467. doi: 10.1001/jamanetworkopen.2023.33467.

[16] Kenen, J. (2026, January 13). HHS's Stance on Vaccine Shared Decision-Making Risks Patient Health and Overloads Clinicians. Milbank Memorial Fund. Retrieved from https://www.milbank.org/news/why-hhss-stance-on-vaccine-shared-decision-making-risks-patient-health-and-overloads-clinicians/.

[17] Farhad Islami et al., American Cancer Society's report on the status of cancer disparities in the U.S., 2023. 74 CA Cancer J Clin. 136-166 (2024), https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21812.

[18] Williams E, Bell C. A look at recent changes to state vaccine requirements for school children. KFF. September 12, 2025. Accessed September 9, 2026. https://www.kff.org/state-health-policy-data/a-look-at-recent-changes-to-state-vaccine-requirements-for-school-children/.

[19] Centers for Disease Control and Prevention. *Advisory Committee on Immunization Practices (ACIP) Charter*. U.S. Department of Health and Human Services. Available at: https://www.cdc.gov/acip/downloads/acip-charter.pdf. Accessed September 5, 2026.

[20] Johnson, M. Coverage implications of ACIP recommendations [presentation]. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. Published December 4, 2025. Accessed September 5, 2026. https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/02-johnson-coverage-implications.pdf.

[21]Centers for Medicare & Medicaid Services. Mandatory Medicaid and Children's Health Insurance Program coverage of adult vaccinations under the Inflation Reduction Act (State Health Official Letter #23-003). U.S. Department of Health and Human Services. Published June 27, 2023. Accessed September 5, 2026. https://www.medicaid.gov/federal-policy-guidance/2023-06-27/149711.

[22] Centers for Disease Control and Prevention. *Vaccine-Specific ACIP Recommendations.* Available at: https://www.cdc.gov/acip-recs/hcp/vaccine-specific/. Accessed September 5, 2026.

[23] Advisory Committee on Immunization Practices (ACIP). *ACIP Evidence to Recommendation User's Guide.* Atlanta, GA: Centers for Disease Control and Prevention; 2020. Available at: https://stacks.cdc.gov/view/cdc/127248. Accessed September 5, 2026.

[24] Advisory Committee on Immunization Practices (ACIP). *ACIP Evidence to Recommendation (EtR) Framework User's Guide.* Centers for Disease Control and Prevention; October 1, 2020. Available at: https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf. Accessed September 5, 2026.

[25] Development of WHO Immunization Policy and Strategic Guidance: Methods and Processes Applied by the Strategic Advisory Group of Experts on Immunization (SAGE) to Develop Evidence-Based Recommendations (2024).

[26] Centers for Disease Control and Prevention. *Advisory Committee on Immunization Practices (ACIP) Charter*. U.S. Department of Health and Human Services. Available at: https://www.cdc.gov/acip/downloads/acip-charter.pdf. Accessed September 5, 2026.

[27] Centers for Disease Control and Prevention. Ten Great Public Health Achievements — U.S., 20th Century. *Morbidity and Mortality Weekly Report*. 1999;48(12):241-243.

[28] Yale School of Public Health. Childhood vaccinations: Understanding the impact and importance of childhood vaccinations. Yale School of Public Health. Published November 2024. Accessed March 18, 2026. https://ysph.yale.edu/research/information-sheets/childhood-vaccinations/.

[29] Centers for Disease Control and Prevention. *SchoolVaxView Data and Reports.* National Center for Immunization and Respiratory Diseases. Available at: https://www.cdc.gov/schoolvaxview/data/index.html. Accessed September 6, 2026.

[30] American Academy of Pediatrics & [Other Organizations listed]. *Childhood vaccine schedule joint letter*. January 9, 2026. Accessed September 6, 2026. https://downloads.aap.org/DOFA/Childhood%20Vaccine%20Schedule%20Joint%20Letter%20Final.pdf.

[31] American Cancer Society Cancer Action Network. Survivor Views: Cancer patients and survivors nationwide. Survey conducted January 14-15, 2026. N=1,445.

[32] Johnson, M. Coverage implications of ACIP recommendations [presentation]. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. Published December 4, 2025. Access March 18, 2026. https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/02-johnson-coverage-implications.pdf.

[33] Centers for Medicare & Medicaid Services. Mandatory Medicaid and Children's Health Insurance Program coverage of adult vaccinations under the Inflation Reduction Act (State Health Official Letter #23-003). U.S. Department of Health and Human Services. Published June 27, 2023. Access September 6, 2026. https://www.medicaid.gov/federal-policy-guidance/2023-06-27/149711.

[34] Talbird SE, Carrico J., La EM, et al. Impact of routine childhood immunization on vaccine-preventable disease incidence in the U.S.. *Pediatrics;* 2022;150(3), e2021056013. https://doi.org/10.1542/peds.2021-056013.

[35] American Cancer Society Cancer Action Network. Survivor Views: Cancer patients and survivors nationwide. Survey conducted January 14-15, 2026. N=1,445.