

AMERICA'S PHYSICIAN GROUPS

September 20, 2026

Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
Office of the Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Email: osaspeinfo@hhs.gov

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Submitted via <https://www.regulations.gov>

Dear Deputy Assistant Secretary Goss:

America's Physician Groups (APG) appreciates the opportunity to respond to the request for information cited above. We welcome the Department's openness to stakeholder input and its ongoing commitment to improving health care for all Americans.

As this letter will argue in the analysis set forth below:

1. APG believes that it is essential to distinguish between the important and regular use of shared clinical decision making (SCDM) in routine clinical practice involving the administration of vaccines, and the separate Health and Human Services Department and Centers for Disease Control and Prevention efforts to attach SCDM to specific federal vaccine recommendations. This letter will primarily address SCDM in that latter context.
2. APG believes that HHS's and CDC's previous actions (now stayed due to litigation) to cease classifying certain vaccines as routinely recommended, and to recategorize them as being subject to shared clinical decision making (SCDM), constituted an effort to muddy the science around vaccines and undermine use and take-up of approved and recommended vaccines.
3. APG is specifically opposed to the planned expansion of this explicit SCDM classification in the context of federal vaccine recommendations and believes that the classification of SCDM should be attached to

only a very few vaccines and under very limited circumstances, as is the case now and as will be discussed further below.

4. The use of SCDM, when attached to vaccine recommendations, should be used only in the relatively rare instances in which the science supports it due to considerations of clinical equipoise, in that there is genuine uncertainty within the expert medical community about the preferred intervention or treatment (as discussed further below). Otherwise, the use of SCDM when officially attached to vaccine recommendations will only serve to undermine use of and trust in vaccines and lead to avoidable illness and death.

Below, APG will first provide (I) a brief description of our organization, followed by (II) background on the regular and routine use of shared clinical decision making (SCDM) among APG's member organizations; (III) the distinction that APG and its members believe must be drawn between the use of SCDM in clinical practice and the attachment of the category of SCDM to specific federally-backed vaccine recommendations; and (IV) APG's recommendations to the Department of Health and Human Services to minimize any further attachment of SCDM to federal vaccine recommendations. Together, these perspectives reflect the voice of APG's membership and our commitment to working with the agency to ensure that all Americans have consistently accessible, high-quality, equitable, person-centered health care grounded in evidence and science and a commitment to preserving and protecting the public's health.

I. About America's Physician Groups

APG is a national association whose membership comprises more than 300 physician groups, and whose approximately 260,000 physicians and other clinicians provide care to an estimated 1 in 4 Americans. APG's members care for patients across the full range of accountable, value-based care models, including multiple ones created over the years by the Centers for Medicare & Medicaid Services and its Innovation Center and that are fully backed by the current administration. APG's motto, 'Taking Responsibility for America's Health,' represents our members' commitment to clinically integrated, coordinated, value-based health care in which physician groups are accountable for the costs and quality of patient care.

As APG has repeatedly emphasized in its public statements, vaccines are key to prevention, and prevention is key to the accountable, value-based care that our member organizations deliver. Any policy or other changes to the current vaccine recommendation regime that would undermine the use of appropriate and recommended vaccines is not only potentially dangerous to individuals' and the public's health but also threatens the very efforts in which APG's physician groups and many others engage to provide health care that is fully accountable for costs and quality. The United States, which has led the world in vaccine provision and science and in efforts to produce superior outcomes from health care, should not undermine the effectiveness of its vaccine recommendation regimen.

Although shared clinical decision making is a bedrock principle across all of value-based health care, and one that APG's member groups aspire to practice continuously, especially in the context of providing vaccines, APG wishes to draw a sharp distinction between the use of shared clinical decision making (SCDM) in the day-to-day clinical practice of medicine, versus that use of the category of SCDM in federally backed vaccine recommendations. As noted above, and as will be expanded upon further below, APG has grave reservations about the administration's proposal to expand the category of "shared clinical decision making" (SCDM) or "individual decision making" in the context of changing the current federal vaccines recommendation regimen.

II. Commitment to the Use of SCDM in APG Members' Clinical Practices

APG's member groups, in practicing patient-centered health care, believe in, accept, and practice the principle of shared clinical decision making as a "process that respects the rights of patients to be fully involved in decisions about their care," and through which, by weighing available health care options and "patients' personal values and preferences against available evidence, patients and healthcare professionals can make health-related decisions together as partners."¹ The administration of vaccines to patients implicitly involves shared clinical decision making between clinicians and their patients, or, if the patients are children or have otherwise delegated the decisions to others, those authorized to make decisions in their behalf. As the American Academy of Pediatrics notes, "SCDM is something that most pediatricians already do every day in practice when communicating risks and benefits of immunization, answering questions, and making shared decisions with patients and families."²

APG's clinicians prefer the use of the term "shared" decision making over "individual" decision making, since the "shared" connotes that both clinicians and individuals together are making decisions on a particular treatment plan or intervention. APG's clinicians fully respect patients' agency and autonomy as a foundational principle of biomedical ethics and clinical professionalism.³ Thus, it is assumed that patients or their representatives will make decisions in their own interests after they have been informed about the clinical evidence behind a given therapy or intervention, obtained clinicians' best advice and counsel, shared their preferences and goals of care with their clinicians, and jointly arrived at a point where they feel willing and competent to make decisions about their care.

APG member organizations delivering pediatric care underscore that SCDM has long been an essential component of their effective vaccine counseling and patient care. Parents look to their children's pediatrician not only for expertise but also for guidance that respects their values, concerns, and perspectives. Developing a therapeutic relationship depends on establishing trust, which is built through consistent, evidence-based counseling and reliable clinical care. Pediatricians therefore invest significant time educating new parents about all aspects of child health, including the role of immunizations and the risks and benefits associated with vaccination. The conversations that result are fundamentally grounded in shared decision-making.

Even when a vaccine has a long track record of safety and use, and is routinely recommended, clinicians must listen, educate, answer questions, and help families make informed decisions. SCDM is therefore not an alternative to strong vaccine recommendations; rather, it is an essential component of the trusted relationships that ultimately support vaccine acceptance. When a new vaccine is introduced, such as was the case with COVID-19 vaccines during the pandemic, clinicians must first become sufficiently informed and comfortable with

¹ Hughes TM et al, Association of shared decision-making on patient-reported health outcomes and healthcare utilization, *The American Journal of Surgery*, Volume 216, Issue 1, 2018, Pages 7-12, ISSN 0002-9610, <https://doi.org/10.1016/j.amjsurg.2018.01.011>.

² See "Shared Clinical Decision Making For Immunizations" at <https://www.aap.org/en/patient-care/immunizations/shared-clinical-decision-making-for-immunizations/?srltid=AfmBOoq2JVggqfPU5esZmknDdLtnWVBdO9XazQ7EWK6vCita2b-ZRR19>

³ See, for example, the American Medical Association's Code of Medical Ethics at <https://code-medical-ethics.ama-assn.org/ethics-opinions/decisions-adult-patients-who-lack-capacity>.

the evidence before they can confidently recommend it to patients and families. During this period of early adoption of new vaccines in particular, pediatricians often engage families in SCDM. Some families readily embrace new interventions, while others require more discussion regarding benefits, risks, and uncertainties. Clinicians effectively bring families along as their own confidence grows through familiarity with emerging evidence and real-world experience.

Importantly, once the evidence is established and clinicians are confident about the benefits of a vaccine, the most effective communication strategy is generally a presumptive recommendation. Rather than asking, "*Would you like your child to receive vaccine X today?*", clinicians achieve greater acceptance of vaccines when they state, "*Today your child is due for vaccines X and Y. What questions can I answer for you?*" This approach communicates confidence in the recommendation while still creating space for discussion, questions, and shared decision-making. An essential point is that shared decision-making and presumptive recommendations are not mutually exclusive but rather go hand in hand. Effective pediatric vaccine counseling often begins with a strong, evidence-based recommendation and then uses SCDM techniques to address parental questions, concerns, and values. The trust created through those conversations is frequently what enables families to accept both long established and newly introduced, recommended vaccines.

III. The Specific Attachment of SCDM to Federal Vaccine Recommendations

APG notes that the term SCDM has been explicitly applied to some vaccine recommendations by the Centers for Disease Control and Prevention (CDC) since 2019, when the agency's Advisory Committee on Immunization Practices (ACIP) first incorporated the term into new recommendations for the use of human papillomavirus (HPV) vaccine in adults 27–45 years of age and the use of pneumococcal conjugate vaccine (PCV13) among immunocompetent patients ≥ 65 years of age.⁴ The CDC's website now applies the SCDM recommendation to a total of five vaccines, adding to the existing HPV recommendation for adults ages 27–45 the meningococcal B vaccination for adolescents and young adults aged 16–23 years; the hepatitis B vaccination for adults aged 60 years and older with diabetes mellitus; the pneumococcal conjugate vaccination (PCV20 or PCV21) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥ 65 years); and additional doses of COVID-19 vaccination for people who are moderately or severely immunocompromised.⁵

Some of the rationale for characterizing this group of vaccines as subject to shared clinical decision making appears to be science-based and reasonable, given the concept of "clinical equipoise" – that there is genuine uncertainty within the expert medical community about the preferred intervention or treatment,⁶ and that the tradeoff among costs, risks, and benefits, and individual preferences is also uncertain. As has been noted with respect to HPV vaccination for adults ages 27–45, by these ages, "most people have already been exposed to HPV, and vaccine effectiveness is lower," even though some individuals in this age group still may benefit. For

⁴ See Centers for Disease Control and Prevention. Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices. 2019; <https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm>. Also see Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices. 2019; <https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm>.

⁵ See <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>

⁶ Freedman B, Equipoise and the Ethics of Clinical Research. N Engl J Med 1987; 317:141-145. Doi:10.1056/NEJM19870716310304

this population, as a result, “a blanket recommendation makes little sense, but foreclosing access entirely would harm the subset who could benefit.”⁷ Similarly, because there is decreased immune response and vaccine effectiveness, as well as lower cost-effectiveness, in giving the Hepatitis B vaccine to adults ages 60 and older – and particularly in those with diabetes – individualized assessment of the costs and benefits of vaccination in such cases would appear more reasonable than mass routine vaccination.

At the same time, there are multiple instances in which attaching the classification SCDM explicitly to contextualize recommendations for certain vaccines and individuals becomes far more problematic and even unwise or dangerous. An example is the CDC’s current guidance for COVID vaccination.

Separately and somewhat confusingly from the aforementioned CDC list of five vaccines subject to SCDM, CDC has also now acted to replace its previous universal recommendation for the COVID vaccine for those ages 18–64 and for two-plus doses for those ages 65 and older with the stipulation that the vaccine is now recommended for people ages 6 months and older “based on individual-based decision-making (also known as shared clinical decision making).”⁸ This action has been stayed for now as a result of litigation,⁹ and APG recommends that the SCDM classification attached to the COVID vaccines not be restored. Aside from the unwise statement equating “individual-based decision-making” as being one and the same with “shared clinical decision making,” this proposed use of the classification SCDM is at odds with, for example, the recommendations from the American Academy of Pediatrics that all infants and children ages six months through 23 months of age who do not have contraindications receive the 2026–2027 COVID-19 vaccine, and that all children and adolescents ages two through 18 years of age who are at increased risk of severe COVID-19 receive the vaccine.¹⁰

Although SCDM discussions between clinicians and patients or their representatives will undoubtedly take place around the topic of administering these vaccines, the AAP’s recommendations, in contrast to the CDC’s guidance, are clear and not deliberately made subject to nuance through specific application of the classification of SCDM to the vaccine recommendation itself, or even further clouded through the use of the classification “individual decision making.” The clearly stated reason behind the AAP’s recommendations that these vaccinations should be routine is that rates of hospitalization and death among children who are unvaccinated against COVID-19 remain relatively high and exceed the rates of hospitalization and death due to influenza infection.¹¹

Equally troubling are other recent actions by ACIP and CDC – also now temporarily stayed by a federal district court¹² -- that moved additional vaccine recommendations for children into the SCDM or individual-based decision-making categories. Among these were a recommendation that administration of hepatitis B vaccine to newborn infants – the so-called “birth dose” – no longer be universal, but that it be subject to individual-

⁷ Scott J, “Quiet dismantling: How ‘shared decision-making’ weakens vaccine policy and harms kids.” CIDRAP op-ed at <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>

⁵ See <https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html>

⁹ See https://litigationtracker.law.georgetown.edu/wp-content/uploads/2025/07/American-Academy-of-Pediatrics_2026.03.16_ORDER-ON-MOTION-FOR-PRELIMINARY-INJUNCTION.pdf

¹⁰ American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents, 2026–2027: Policy Statement. Pediatrics. 2026; doi: 10.1542/peds.2026-079045

¹¹ American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents, 2026–2027: Technical Report. Pediatrics. 2026; doi: 10.1542/peds.2026-079046

¹² Again, see https://litigationtracker.law.georgetown.edu/wp-content/uploads/2025/07/American-Academy-of-Pediatrics_2026.03.16_ORDER-ON-MOTION-FOR-PRELIMINARY-INJUNCTION.pdf

decision making by parents of infants born to women who test negative for the virus.¹³ By contrast, major medical groups such as the AAP and the American College of Obstetrician-Gynecologists continue to recommend the universal hepatitis B birth dose despite the ACIP change. Once again, the reasons for these universal recommendations are clear, consistent, and science-based: The vaccine is safe and effective when given to newborns; prenatal screening of mothers for hepatitis B infection is still subject to gaps; infants who are not infected at birth can still contract the virus from caregivers or others who have chronic infections; and as many as 9 in 10 infants infected with hepatitis B can develop lifelong chronic infections that result in liver failure or death.¹⁴ In addition, hepatitis B vaccine is proven to reduce liver cancer, making it “among the most effective population-level cancer prevention strategies worldwide.”¹⁵ Thus, there appears to be no scientific basis whatsoever for shifting this recommendation from universal to SCDM.

Also moved into the category of SCDM by ACIP and CDC (in actions now stayed by the federal district court) were childhood vaccines for rotavirus, influenza, hepatitis A, and meningococcal vaccines, without adequate justification based on science. Prior to the introduction of the rotavirus vaccine for children in 2006, rotavirus according to the CDC was the leading cause of severe diarrhea among infants and young children in the United States; almost all U.S. children were infected with rotavirus before their fifth birthday; and the condition led to more than 400,000 doctor visits, more than 200,000 emergency room visits, 5,000 to 70,000 hospitalizations, and 20 to 60 deaths in children annually.¹⁶ Given that the vaccine is safe and effective, rotavirus vaccination should continue to be recommended on a routine basis. As discussed above, a presumptive recommendation that the vaccine be administered will automatically go hand-in-hand with shared decision making in a discussion with parents.

As for influenza, the seasonal influenza viruses cause millions of illnesses, thousands of hospitalizations, and rare deaths among children in the United States each year, with the highest risks facing children under age five and those who are unvaccinated. About 10 percent of all children in the nation are infected with the flu virus and an estimated 20,000 under age five are hospitalized with the virus annually. Infants and toddlers under age two face the highest risk of severe illness because their airways and lungs are small and sensitive. Complications include pneumonia, encephalopathy, and aggravation of other health conditions such as asthma or heart problems. During 2024-2025, 297 flu-related deaths in children were reported to CDC, but statistical modeling suggests approximately 790 deaths may have occurred.¹⁷ Roughly 90 percent of children who die from the flu each year were not fully vaccinated. About 50 percent of children under age five who die from the flu had no known prior health problems.¹⁸ Influenza vaccine effectiveness in children has been estimated at 80 percent overall, and at 87 percent in children with no known health conditions, in a study examining data from 2016 to 2025.¹⁹ Overall, the CDC estimates that influenza vaccination during the severe 2024-2025 flu season prevented about 10 million flu illnesses, 5 million medical visits, 180,000 hospitalizations and 12,000 deaths.²⁰

¹³ See <https://cdc.gov/media/releases/2025/acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>

¹⁴ See <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth>

¹⁵ Wang J et al, Global impact of hepatitis B vaccination on the risk of hepatocellular carcinoma: a systematic review and meta-analysis. *Journal of Gastrointestinal Oncology*, vol. 17, no. 4 (August 31, 2026).

¹⁶ See <https://www.cdc.gov/rotavirus/hcp/clinical-overview/index.html>

¹⁷ See <https://www.cdc.gov/flu/highrisk/children.html>

¹⁸ See <https://www.nfid.org/infectious-diseases/flu-and-children/>

¹⁹ Leonard JS et al, Influenza Vaccine Effectiveness Against Pediatric Death in the United States: 2016–2025. *Pediatrics* August 2026; 158 (2): e2026076453. 10.1542/peds.2026-076453

²⁰ See Influenza Activity in the United States during the 2024–25 Season and Composition of the 2025–26 Influenza Vaccine at <https://www.cdc.gov/flu/whats-new/2025-2026-influenza-activity.html>

Thus, given the demonstrated safety and effectiveness of the influenza vaccines, especially in children, routine annual influenza vaccination of children should be universally recommended rather than explicitly set aside in a separate category for SCDM. There is no scientific basis to do otherwise.

IV. Conclusion: Why It Is Wrong To Expand The Category of Vaccine Recommendations Subject to SCDM

As noted above, there is no scientific basis for any of the recent federal government recommendations to move current vaccine recommendations from routine to SCDM. It is difficult to conclude that even this request for information is anything more than an attempt to advance these unscientific and misguided processes under the guise of normal notice-and-comment rulemaking, at a time when the recent moves by the administration and ACIP to recategorize so many vaccines remain blocked due to ongoing litigation. As Jake Scott, MD, Clinical Associate Professor at Stanford Medicine, wrote in a recent op-ed,²¹ “The playbook is now clear: invoke shared decision-making not as a scientifically grounded response to genuine uncertainty but as a mechanism for stepping back from vaccines without formally withdrawing them.”

In addition to the points made above about the dangerous consequences of changing current vaccine recommendations, APG believes that the classification of certain vaccine recommendations as being subject to SCDM will undercut multiple efforts to improve the quality and cost-effectiveness of U.S. health care. Quality-improvement frameworks typically include vaccination rates as a measure of quality, as is the case with the [HEDIS Childhood Immunization Status Combination 10](#) metric, a standardized pediatric quality measure used by health care systems and insurance programs to track whether children have received a specific set of 10 recommended vaccine series by their second birthday. Even before the recent set of changes by ACIP and CDC, completion of the measure among US children aged 24-35 months declined from 53.7% in 2021 to 44.6% in 2023, with a statistically significant survey-weighted annual trend. Influenza vaccination and rotavirus series completion has been the strongest component-level drivers of Combo 10 completion.²² Amid signs that influenza and rotavirus vaccination among children could drop further with a change in recommendations from routine to SCDM, it is inevitable that completion of the measure will drop, even as illness and death in children rise.

Finally, the classification of certain vaccines as being subject to SCDM rather than being recommended as routine will only further undermine the already damaged vaccine framework that has long existed in the United States; increase uncertainty about vaccines; deter acceptance and take-up of vaccines; result in far more unnecessary illness and death; unnecessarily drive up health care costs, imposing a greater burden that will be borne generally across the entire U.S. population; and broadly impair public health, including among people who choose to be vaccinated. Although vaccines offer considerable individual protection, that protection is not 100

²¹ Scott J, Ibid. [“Quiet dismantling: How ‘shared decision-making’ weakens vaccine policy and harms kids.” CIDRAP op-ed at <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>]

²² Ruan J. Explainable Machine Learning for Public Health Informatics in HEDIS Childhood Immunization Status Combination 10. Online J Public Health Inform. 2026 Jul 31;18: e90241. doi: 10.2196/90241. PMID: 42536080; PMCID: PMC13426122.

percent effective, and the immunity achieved for a given individual is buttressed across the population by the level of immunity inherent in broad community protection through vaccination or prior infection, otherwise known as “herd” immunity. Yet in many localities across the country, this level of community immunity for certain infections is already waning. More than three-quarters of U.S. states had measles, mumps, and rubella vaccination rates below the target rate of 95 percent for the 2025-2026 school year.²³ Kindergarten classrooms in more than 70 percent of U.S. counties in effect now lack community or herd immunity against measles.²⁴

The trend of declining MMR vaccination has resulted in the United States experiencing its worst measles outbreak in 25 years, with 3,294 confirmed cases across 45 jurisdictions as of mid-September 2026. Of four recent measles-associated deaths reported in Pennsylvania, one was of an 18-year-old – unvaccinated against measles – who died of acute disseminated encephalomyelitis, a rare and severe neurological complication of measles, according to the county coroner’s office that reported it.²⁵ A recent analysis by the Common Health Coalition and researchers at the Yale School of Public Health modeled the effects of continued decreases in childhood MMR vaccine uptake; it determined that, if the U.S. childhood MMR vaccination rate continues to drop by 1 percent each year, by 2030 the nation will experience an average of 17,232 measles cases, 4,085 hospitalizations, and 36 preventable deaths annually, incurring \$1.5 billion in annual costs and a total \$7.77 billion in greater economic burden over a five-year period due to increased health care utilization, expenditures on the public health response, and workplace disruption.²⁶ It will be a tragic failure of U.S. health care and public health if this scenario plays out, and all the more so if it is fueled in part over ambiguity about science-based, routine (universal) vaccine recommendations.

In sum, true clinical shared decision making about vaccines at the population health level thus requires retaining default, routine (universal) recommendations for most vaccine-preventable conditions in the context of ethical, informed consent regarding vaccine risks and benefits. Any official designations attached to vaccine recommendations such as SCDM should be minimized and used only in the relatively rare instances in which clinical equipoise exists, as described above. Most especially, attaching SCDM to any vaccine recommendations must be avoided when doing so eschews science, as is the case with ACIP’s and CDC’s recent (but now stayed due to litigation) actions. These are actions that, if allowed to prevail, will only serve to undermine the use of and trust in proven, effective vaccines and lead to avoidable illness and death, most especially among some of the nation’s most precious assets: its children.

Sincerely,



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²³ See <https://www.kff.org/medicaid/kindergarten-routine-vaccination-rates-continue-to-decline/>

²⁴ See <https://www.washingtonpost.com/health/2026/08/17/trump-rolls-back-vaccine-recommendations-see-where-your-school-stands/>

²⁵ See news release from Mifflin County, Pennsylvania, coroner’s office at <https://www.facebook.com/photo.php?fbid=122147411583146262&set=pb.61584387886063.-2207520000&type=3>

²⁶ See https://files.commonhealthcoalition.org/storage/v1/object/public/resource-files/SpotlightBrief_ChildImms.pdf