American Society of Transplantation
1000 Atrium Way, Suite 400
Mount Laurel, NJ, 08054

September 15, 2026

Department of Health and Human Services (HHS)
Via www.regulations.gov

Subject: Docket No. HHS-OS-2026-0332 for "Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making"

On behalf of the American Society of Transplantation (AST), the largest professional transplant society in North America representing over 5,000 organ transplant health care professionals, I submit the following comments in response to the Department of Health and Human Services (HHS) request for information entitled *Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, docket HHS-OS-2026-0332.

- Question 1: Are the current categories (routine, risk-based, and shared clinical decision-making/individual-based decision-making) adequate, clear, and well understood by clinicians, patients, and parents? What evidence bears on how each category is understood in practice?

The traditional routine and risk-based categories have been, and remain, adequate, clear and well understood by clinicians, patients, and parents. They provide evidence-based and clear-cut recommendations. Meanwhile, the introduction of SCDM into vaccination policy inappropriately frames evidence-based medicine as optional. SCDM is designed for clinical scenarios where two or more treatment options carry roughly equivalent risks and benefits, and the overall decision needs to be individualized. Vaccinating versus remaining susceptible to vaccine-preventable diseases are not equivalent options, especially for immunocompromised individuals such as transplant recipients and patients undergoing transplant evaluations.

- Question 2: Do the current categories convey meaningful differences in the strength of the evidence, the magnitude of individual and population benefit, and the room left for individual circumstances and values? If not, how should those differences be conveyed?

Introducing "shared clinical decision-making"/"individual-based decision-making" incorrectly implies that medical recommendations (i.e. vaccines) are entirely up to the patient discretion. This framing is dangerous; it allows people to disregard scientifically validated recommendations on the grounds of individual choice. Public Health branches should return

to presenting vaccine guidance as straightforward evidence-based recommendations as they traditionally have done. The medical recommendation must remain an unambiguous statement of scientific consensus on safety, efficacy, and benefit.

- 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?

No, the current categories do not imply that there is no individual consent involved. Vaccines, like all medical interventions, require a discussion between the clinician, patient, and patient advocate (which, in this context, is usually a parent), no matter what category. Current efforts to create a category of SCDM is dangerous to transplant recipients, as it creates unnecessary confusion and devalues the importance of vaccines. Declining vaccine rates subsequently place our patients at higher risk for these preventable infections. For example, not vaccinating children against measles puts our transplant recipients at a much higher risk of exposure to this life-threatening infection that does not have treatment.

- 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 emphatically do not recommend adopting new categories such as "recommended with qualification," " recommended, but not during infancy " or "shared clinical decision-making with qualification." Adding further classifications creates unnecessary complexity that will confuse both clinicians and patients, which will ultimately lead to missed or delayed immunizations during already time-constrained clinical visits.

Proposing delayed or age-de-emphasized schedules (such as altering infant recommendations) is not supported by scientific evidence. The immunization schedule is based on data from immunogenicity and efficacy trials. Changing intervals or delaying doses will leave infants vulnerable and will also lower overall population immunity.

Adding additional categories will lead to increased vaccine deferments, eroded herd immunity, and preventable disease outbreaks, which will further place transplant patients at risk for preventable illnesses. Furthermore, more convoluted categorization system will make it significantly harder for clinicians to efficiently protect and vaccinate high-risk populations, such as organ transplant candidates, who depend on timely immunization.

- Question 5. What can be learned from the recommendation structures of peer bodies abroad, such as global or international health bodies of peer regulatory bodies?

Internationally, vaccination schedules are dependent on local epidemiology (i.e. MenB in UK), health care infrastructure, rates of screening for vaccine-preventable diseases

(Hepatitis B as an example), scientific evidence on vaccine safety/immunogenicity, and cost/payor. Because the US does not have universal healthcare, relying on healthcare infrastructure to care for those who contract vaccine-preventable illnesses is costly and deadly.

- 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?

The US government would need to mandate that all vaccines that provide individual or societal benefit, particularly those recommended by expert bodies like the AST, remain covered by insurance regardless of category changes. This will prevent insurers from discontinuing coverage. Without explicit legal protection, the re-categorizing of vaccines could lead to inconsistent insurance coverage and program eligibility.

- Question 7: If categories remain the same, what modifications to timing and frequency of vaccine administration (for example, clearer presentation of flexible age ranges such as the 12-through-15-month window for the first dose of measles-containing vaccine) or guidance on administering vaccines individually versus at a single visit would help parents and clinicians understand that a vaccine is recommended while affording flexibility in timing of administration?

No additional modifications are needed at this time; the guidelines provided by the ACIP are clear and evidence-based, designed to maximize the benefits of vaccines. Attempting to continually amend or expand the rules around vaccine timing and frequency creates unnecessary ambiguity for clinicians, patients, and families. This added complexity leads to missed doses rather than improved access, which is especially difficult for transplant patients who have multiple healthcare appointments that they must keep up with.

Similarly, breaking up combination vaccines into individual, monovalent components severely jeopardizes patient completion rates. Extended schedules mean children remain under-vaccinated for longer periods, placing them at higher risk for contracting these diseases. High-risk patients, like transplant recipients, do not have the luxury of extending their immunization timelines. In clinical practice, we often accelerate rather than delay schedules based on safety and immunogenicity data to establish immunity before immunosuppressive therapy begins. Extending schedules leads to more clinic visits, higher out-of-pocket costs, missed wages (because of multiple visits), and increased disease outbreaks

- Question 8: What does, or what should, shared clinical decision-making (SCDM) mean in the vaccination context? How, if at all, does individual-based decision-making differ?

SCDM was only intended to be used when there was not have enough evidence about the safety or efficacy of a vaccine. It is not intended to be used when high quality and clear data exist for the general population. Nevertheless, SCDM still implies a thoughtful discussion between clinicians and patients/patient advocates. Individual-based decision making, on the

other hand, strongly implies that there is no such discussion and that the decision is being made by an individual in isolation. This is not a reasonable or effective approach when it comes to vaccines.

- 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?

SCDM creates an unintended contrast with routine recommendations and risks undermining trust in scientific evidence by implying decisions are based on subjectivity rather than clinical trial outcomes. Since patient and family autonomy is inherent to all medical decisions, SCDM should be reserved for rare scenarios where evidence is emerging or definitive recommendations cannot be established, rather than labeling all vaccine choices as such.

Recommendations should be streamlined into clear categories, such as universal recommendations for all or conditional recommendations based on specific medical conditions, e.g. transplant recipients.

- Question 10: What are the benefits of an SCDM category, including respect for autonomy, informed consent, religious conviction, and individualized clinical judgment, and what evidence supports them?

Establishing a formal SCDM category will create confusion and increase vaccine hesitancy. The existing framework is sufficient, as clinicians already incorporate personal goals, patient values, and scientific evidence into routine clinical recommendations. Any revised framework should allow risk-based recommendations to incorporate timing, additional-dose schedules, and revaccination when clinically appropriate, not leaving these to SCDM.

- 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?

SCDM for a vaccine is often interpreted as a vaccine is unnecessary or purely optional.

- Question 12: An SCDM recommendation, once adopted by the CDC Director, triggers the same coverage requirements as a routine recommendation. What steps should the Department take to educate the public and the provider community that SCDM-recommended vaccines are covered? What communication formats would most effectively ensure that an SCDM designation is not misread as a lapse in coverage or a signal that a vaccine is unavailable?

This will need to be made abundantly clear to insurance companies, with a penalty for not providing coverage for any SCDM vaccines requested by clinician/patient. Our transplant patients must navigate the complex healthcare system regularly, and to ask them to also advocate for coverage of vaccines recommended by public health bodies will likely diminish the number of patients protected against vaccine-preventable illnesses. Thus, these

vaccines should NOT require prior authorization, and this will need to be communicated to insurance companies as well (with additional penalties for those that do try and implement prior authorizations).

Any communication regarding coverage and access to vaccine should be Included in a clear and up to date communication on the CDC website that clinicians and patients may refer to.

- Question 13: What supports would make SCDM work as intended, such as decision aids, provider training, documentation standards, coverage clarifications, or category-specific communication materials, and who should develop them?

It is our position that SCDM should rarely be used as a vaccine category. In those rare occasions, however, there should be major efforts to clarify the recommendations to the population and train providers to understand and discuss the risks and benefits to their patients.

- Question 14: What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate? Address the availability, quality, and strength of evidence; the appropriate approach where RCT evidence is absent; disease severity and epidemiology; individual versus population benefit; and a presumption in favor of individual autonomy.

The CDC ACIP had an excellent world class process and was among the most admired organizations in the world for its evidence-based approach. We should return to that process.

Additionally, transplant recipients are frequently excluded from RCT. This poses a major issue if only RCT data is being considered when recommending a vaccine, as this population may not be represented in sufficient numbers. Thus, expert guidance, like that provided by the CDC ACIP, can assess available clinical evidence and make a judgement on the application to immunosuppressed patients.

- 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?

Standardized tools like the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach already provide rigorous frameworks for these questions. Creating a novel approach bypasses established scientific consensus and contributes to government waste.

- Question 16: What does the evidence show about the effects of mandates and other compulsory or high-pressure approaches on public trust, vaccine confidence, and long-run vaccination behavior? How should Federal recommendation policy account for those effects?

Public health policy must strictly separate clinical recommendations (i.e. vaccine recommendations provided by the ACIP) from regulatory mandates. Conflating the two creates the false impression that scientific recommendations inherent to patient care restrict personal liberty. To safeguard public trust and long-term vaccine confidence, Federal policy should clearly frame recommendations as objective statements of scientific consensus on safety and efficacy, keeping them distinct from administrative enforcement mechanisms.

- 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?

Earning and maintaining public trust requires public health authorities, federal agencies, and clinical organizations to present a unified, non-partisan message grounded strictly in scientific consensus.

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

Accurately measuring success requires immediately restoring funding to comprehensive communicable disease surveillance systems. Re-initiating nationwide, real-time tracking of both immunization uptake rates and disease incidence is an absolute prerequisite for any meaningful assessment.

In summary, a universal application of SCDM to vaccination of transplant candidates and recipients undermines evidence-based and time-tested medical recommendations. It will place patients at unnecessary risk of serious, preventable infections and adverse health outcomes.

Sincerely,

Nicole Turgeon, MD, FACS
President, American Society of Transplantation