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The Honorable Robert F. Kennedy Jr.
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

Dear Secretary Kennedy,

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,500 family physicians and medical students across the country, we appreciate the opportunity to comment on the [Request for Information](#) (RFI) regarding the Federal Vaccination framework, published by the U.S. Department of Health and Human Services (HHS) in the August 24th issue of the *Federal Register*.

The AAFP [believes](#) that, regardless of economic and insurance status, children and adults should have access to all recommended immunizations. Immunization remains one of the most effective and cost-efficient public health interventions, and family physicians play a central role in delivering vaccines, counseling patients and families, and addressing questions about vaccine benefits and risks across the lifespan.ⁱ Through longstanding relationships with their patients, family physicians are uniquely positioned to provide individualized recommendations that reflect each patient's clinical circumstances, preferences, and values. We also firmly believe that federal vaccine policy should be grounded in the principles of evidence-based medicine, defined as the integration of the best available scientific evidence, clinical expertise, and patient values. We [believe](#) that evidence-based recommendations are essential to delivering high-quality patient care and maintaining the credibility, consistency, and effectiveness of health policy.

Although this RFI focuses on vaccine recommendation categories and terminology, the implications extend beyond nomenclature. Federal vaccine recommendations are incorporated into clinical workflows, electronic health records, quality improvement initiatives, payer coverage policies, federal vaccination programs, public health communications, and patient education materials. Consequently, changes to

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recommendation frameworks may have significant downstream effects on clinical decision-making, operational implementation, patient understanding, and vaccine uptake.

Further, the AAFP appreciates HHS's recognition that public confidence in federal vaccine recommendations is an important consideration when discussing any changes to the recommendations. Confidence in public health recommendations depends on the quality of the underlying evidence, and the transparency and credibility of the processes used to develop them. Given the significant clinical, operational, and public health implications of the issues presented in this RFI, we are deeply concerned that the expedited timeframe for stakeholder input significantly limits opportunities for the robust engagement necessary to support confidence in both the process and the resulting policy decisions. We expressed this concern in [our preliminary response](#) to HHS on August 24, as well as [a letter submitted on behalf of 70](#) other physician, public health, and patient organizations on August 27. As of September 8, over two weeks later, HHS has not responded to the requests, nor has it posted approximately 14,000 other comments received in response to the notice.

We are also concerned by language in the RFI preamble stating that the Secretary, "working through the Task Force on Safer Childhood Vaccines," will develop plans addressing the "timing and sequencing of the Federal immunization schedule." This approach lacks transparency and bypasses established processes for developing federal recommendations, which is the responsibility of the Advisory Committee on Immunization Practices (ACIP), not the Task Force. Congress established the Task Force to advise on vaccine safety, development, and reporting activities in consultation with the Advisory Commission on Childhood Vaccines—not to modify immunization schedules. Particularly at a time when trust in federal public health institutions continues to decline, efforts to strengthen confidence in vaccine recommendations should be accompanied by transparent, deliberative, and inclusive decision-making processes that meaningfully engage the physicians, patients, public health experts, and other stakeholders responsible for implementing and relying upon those recommendations.^{ii,iii} If HHS intends to use the Task Force to make changes to federal vaccine recommendation categories, the AAFP is deeply concerned that doing so will undermine, rather than strengthen, public trust.

Accordingly, the AAFP supports a federal vaccine recommendation framework that is evidence-based, transparent, clinically actionable, operationally feasible, and sufficiently stable and predictable to permit orderly implementation across clinical, operational, and administrative settings. **We offer the following overarching recommendations to HHS over the span of this RFI:**

- **Meaningfully engage practicing clinicians in the development, communication, and implementation of vaccine recommendations to ensure they are scientifically sound, operationally feasible, and trusted in clinical practice;**

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- Preserve evidence-based vaccine policymaking by returning to the use of transparent, established, and reproducible evidence evaluation methods including GRADE criteria and Evidence-to-Recommendation (EtR) frameworks;
- Clarify, rather than redefine, the shared clinical decision-making (SCDM) recommendation category to improve public understanding on meaning, coverage, and access; and
- Protect continuity of vaccine access, coverage, and program eligibility by ensuring that changes in recommendation terminology do not create unintended barriers to vaccination.

A. Adequacy of the Current Categories (Questions 1 – 3)

The current framework of routine, risk-based, and shared clinical decision-making (SCDM) recommendations is generally capable of communicating meaningful distinctions regarding the scope and application of federal vaccine recommendations. The AAFP takes no issue with the existence of recommendation categories that distinguish between broadly applicable recommendations and those that call for greater reliance on individualized clinical assessment. However, while the framework itself remains generally adequate, available evidence suggests that the operational implications of the SCDM category have not been communicated with sufficient clarity to support consistent understanding and implementation across clinical, public health, payer, and health information technology settings.

The implementation history of both Category B and SCDM recommendations demonstrate the challenges associated with communicating that distinction. When ACIP used Category A and B recommendations, only 24% of surveyed pediatricians and family physicians correctly identified the meaning of Category B recommendations. More than half were uncertain about whether Category B vaccines were covered by private insurance or the Vaccines for Children (VFC) program, and 59% reported difficulty explaining the category to patients.^{iv} And the subsequent adoption of SCDM terminology in 2019 presented similar challenges. In a national survey of family physicians and general internists in 2021, more than half of the family physicians surveyed reported that SCDM recommendations increased confusion. Respondents also reported inconsistent representation of SCDM recommendations across electronic health record systems and vaccine forecasting tools.^v These findings suggest that, while the current categories are capable of conveying meaningful distinctions, additional clarity is needed regarding what the SCDM category does and does not signify. In particular, the current SCDM terminology risks conflating two distinct concepts: the scope of a federal vaccine recommendation and the clinical process through which vaccination decisions are made.

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Shared decision-making is a clinical approach used throughout evidence-based medicine whenever clinical judgment, patient-specific circumstances, and patient values are relevant to a health care decision. It is not unique to vaccines, nor is it unique to vaccines designated as SCDM. Family physicians routinely discuss benefits and risks, consider contraindications and precautions, assess individual risk factors, answer questions, obtain informed consent, and incorporate patient and parental preferences regardless of recommendation category. Informed consent, discussion of benefits and risks, clinical judgment, parental permission, assent where appropriate, and consideration of patient values and preferences are not unique to SCDM recommendations. They are fundamental components of vaccination decision-making across recommendation categories and are governed by clinical standards, professional obligations, and applicable state and federal law. A stronger recommendation does not diminish patient autonomy, nor does an SCDM recommendation create autonomy where it did not previously exist. For that reason, use of the term "shared clinical decision-making" as a recommendation category may inadvertently suggest that individualized discussion is uniquely associated with vaccines carrying an SCDM designation, while routine recommendations may be perceived as requiring little individualized deliberation. Neither interpretation accurately reflects clinical practice.

This misunderstanding also extends to patients and parents. National survey data from 2025 from the Annenberg Public Policy Center found substantial confusion regarding the meaning of "shared clinical decision-making," including misunderstanding about the role of health care professionals in the decision-making process.^{vi} Such confusion creates a risk that the public will interpret an SCDM designation as signaling uncertainty regarding a vaccine's safety, effectiveness, or coverage rather than recognizing that the designation reflects variation in anticipated benefit across individuals. These findings are consistent with the SCDM implementation challenges reported by clinicians and suggest that current terminology is not consistently communicating the intended distinction to those expected to rely upon it.

Thus, the AAFP does not view the adequacy of the current framework as the central issue. Rather, the more immediate need is for HHS to provide clearer guidance regarding the purpose, meaning, and implementation of the SCDM category, including the legal and operational implications attached to that designation. We expand on this topic in our responses to RFI Section C. Shared Clinical Decision-Making, below.

A federal recommendation category should communicate the government's evidence-based public health judgment regarding vaccination for a defined population. That judgment should be derived through a transparent evaluation of the available evidence using established methodologies such as GRADE and the Evidence-to-Recommendation (EtR) framework.

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Recommendation categories should not be expected to communicate every aspect of the physician-patient decision-making process.

Accordingly, we encourage HHS to expressly clarify that informed consent, parental permission, developmentally appropriate assent, and meaningful clinician-patient communication remain relevant across all vaccine recommendations. We further recommend HHS to clarify that an SCDM recommendation reflects circumstances in which the expected benefits of vaccination may vary among otherwise eligible individuals and individualized clinical assessment is therefore appropriate. It should not be interpreted as a statement about a vaccine's importance, evidentiary support, coverage status, or the need for physician-patient discussion.

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

4. Should additional or different categories be adopted?

The AAFP does not support adding additional categories to the federal vaccine recommendation framework. Evidence does not demonstrate that additional categories would resolve the principal challenges identified with the current framework. Rather, as mentioned above, existing research indicates that confusion persists regarding category meaning, coverage implications, and implementation requirements.^{vii}

We are particularly concerned that the implementation costs of a revised recommendation taxonomy would fall disproportionately on frontline family physicians and primary care practices. Family physicians and their care teams are responsible for translating federal vaccine recommendations into standing orders, electronic health record workflows, vaccine forecasting protocols, patient counseling, documentation requirements, and vaccine administration at the point of care. A change that may appear modest at the policy level can require substantial operational changes across thousands of physician practices and health systems. HHS should carefully consider these practice-level consequences before modifying a framework that is deeply embedded throughout the nation's immunization infrastructure.

Thus, we strongly believe that changes to recommendation categories should occur only when there is compelling evidence that the existing framework is unable to communicate or operationalize a recommendation effectively. And where additional nuance is necessary, we encourage HHS to provide that context through evidence-based recommendation rationales, updated literature, implementation guidance, patient education resources, and clinical decision-support resources. These approaches allow for greater precision while

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preserving a stable framework that clinicians, health systems, public health agencies, pharmacies, payers, and technology vendors can implement consistently.

Further, we encourage HHS to consider the cumulative effects of successive changes to federal vaccine guidance. Recommendation stability is especially important in primary care, where vaccination is integrated into longitudinal preventive care and where patients may encounter the same recommendation repeatedly across different stages of life. As such, we continue to strongly encourage HHS to meaningfully include practicing family physicians in the development, review, and implementation of any proposed changes to federal vaccine recommendation categories. Family physicians are responsible for translating federal guidance into patient counseling, standing orders, electronic health record workflows, vaccine forecasting, documentation, and administration at the point of care. Their frontline experience is therefore essential to ensuring that any revised framework is not only scientifically sound, but also understandable, trusted, and operationally feasible in the settings where vaccination decisions actually occur.

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

Peer nations can provide valuable insight into evidence-review methodologies and implementation strategies. However, federal vaccine recommendation policy should ultimately be reflective of the clinical evidence, epidemiology, health-system considerations, and population health needs specific to the United States. Rather, we believe that recommendation categories derive their value from the rigor of the underlying evidence review process. Similarity to another country's framework may not, by itself, be a sufficient basis for adopting or modifying a recommendation category.

In fact, recent evidence counsels against assuming that recommendations should be harmonized across countries because the underlying vaccines or clinical studies are similar. A 2026 analysis of European immunization policy concluded that the same body of clinical evidence can legitimately produce different national recommendations because country-specific conditions affect how evidence is translated into policy. The authors found that international collaboration and supranational guidance can support national decision-making but cannot replace context-sensitive, national review.^{viii}

Communication strategies are also largely dependent on context across peer nations. The CDC itself explains that beliefs about health, language, health literacy, and communication practices reflect culture and that public health organizations can improve communication by recognizing and bridging cultural and linguistic differences.^{ix} Research on community engagement reinforces this point. A 2025 review found that communities significantly differ

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in literacy, access to information, and trust in public health programs. The authors concluded that one-size-fits-all materials are insufficient and that effective vaccine communications should place affected communities at the center of message design and implementation.^x

The appropriate lesson from peer bodies is therefore methodological rather than taxonomic. We cautiously support the adoption of transferable practices such as systematic evidence review, transparent rationale, independent, peer-reviewed expert deliberation, and scheduled reassessment. However, recommendation categories and communication strategies should then be designed and tested for the epidemiologic, institutional, legal, linguistic, and cultural conditions of the United States.

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?

If HHS adopts new recommendation categories, preserving continuity of access should be a primary implementation objective. Recommendation categories are incorporated into coverage policies, public health programs, clinical workflows, health information systems, and legal frameworks at both the federal and state levels. As a result, predictable access becomes increasingly important as the recommendation framework becomes more complex.

The AAFP has consistently [supported](#) policies that protect evidence-based recommendations and ensure coverage of recommended vaccines without cost sharing. We have also continued to emphasize that immunization guidance should be evidence-driven, implementable, and worthy of trust and that the value of vaccine schedules lies in their ability to support a strong recommendation delivered with confidence, reduce missed opportunities and inequities, and provide guidance that is scientifically rigorous and operationally usable at the point of care.^{xi} **Patients who are currently eligible for and can access recommended vaccines should not face uncertainty regarding coverage, eligibility, or availability solely because the recommendation framework has been reorganized.**

Accordingly, if new categories are adopted, HHS should clearly define their intended treatment under relevant federal programs and authorities, including Affordable Care Act (ACA) preventive-services coverage requirements, the VFC program, federal vaccine injury-compensation programs, CDC schedules, and related implementation guidance. Where continuity is intended, that continuity should be made explicit. Patients, clinicians, payers, manufacturers, and public health programs should not be required to infer the consequences of a new category from terminology alone.

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Federalism considerations also warrant careful attention. Many states reference ACIP recommendations in statutes, regulations, school-entry requirements, public health programs, pharmacy authorities, and insurance frameworks. While states retain authority to determine how federal recommendations are incorporated into state law, changes to federal recommendation categories may create uncertainty for jurisdictions that have built legal and operational structures around existing recommendation terminology. Advance guidance and clear definitions would help support consistent implementation and reduce the likelihood of unintended consequences.

Further, we encourage HHS to recognize that preserving predictable access is closely related to preserving confidence in the recommendation framework itself. As observed by Dr. Margot Savoy, Chief Medical Officer of the AAFP, "complexity erodes confidence and leads to delays, deferrals, or inconsistent recommendations across clinicians and settings."^{xii} Thus, if new categories are adopted, they should be implemented in a manner that maintains continuity of access, minimizes ambiguity, and allows stakeholders to readily distinguish between a change in recommendation terminology and a change in the underlying policy.

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?

Current immunization schedules already reflect a balance between evidence-based recommendations and implementation flexibility. Recommended age windows, minimum intervals, catch-up schedules, risk-based recommendations, and accommodations for specific clinical circumstances all permit individualized application without departing from the underlying evidence base. For example, the AAFP childhood and adolescent immunization schedule recommends the first dose of measles-, mumps-, and rubella-containing vaccine between 12 and 15 months of age and includes catch-up schedules for children and adolescents who do not receive vaccines at the recommended age.^{xiii} Further, clinicians routinely exercise professional judgment within these evidence-based parameters to account for individual patient circumstances, access considerations, vaccination history, and patient preferences. The existing framework therefore already contains substantial flexibility. Rather, the principal opportunity for improvement is for HHS to clarify where that flexibility exists and the evidence that supports it.

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Accordingly, if HHS seeks to further clarify vaccine administration guidance, we encourage the Department to focus on making existing evidence-based flexibility more transparent. Vaccine recommendations could more clearly distinguish among the recommended age or timing for vaccination, evidence-based timing ranges, minimum intervals required for valid administration, and catch-up pathways when recommended timing is missed. Such distinctions would help patients understand, and clinicians communicate, that a vaccine is recommended while also recognizing that administration often occurs within a clinically appropriate range rather than on a single date.

Guidance regarding co-administration should be approached similarly. Federal recommendations should continue to establish clear, evidence-based parameters regarding recommended ages, minimum intervals, and circumstances in which spacing or sequencing requirements apply. Within those parameters, clinicians should retain appropriate discretion to exercise professional judgment in partnership with patients and parents. Existing recommendations supporting administration of multiple indicated vaccines during the same visit are grounded in extensive evidence and longstanding public health practice. CDC [guidance](#) has long recognized that administering all vaccines for which a patient is eligible during a single visit increases the likelihood that patients will be fully vaccinated at the appropriate age and reduces missed opportunities for vaccination.

Delaying otherwise appropriate vaccination can create additional opportunities for recommended series to remain incomplete, leaving patients and communities vulnerable to preventable disease. Measles outbreaks in recent years have shown how quickly under-vaccination can place children and communities at risk. The United States reported over 2,900 confirmed measles cases in 2026 thus far, surpassing the 2,289 cases in 2025, and the highest annual total since measles was declared eliminated in 2000.^{xiv} CDC surveillance further found that 93% of reported cases occurred among individuals who were unvaccinated or whose vaccination status was unknown.^{xv} These cases highlight the public health consequences of vaccination gaps and the importance of providing protection as promptly as possible. When multiple vaccines are indicated and can appropriately be administered during the same encounter, co-administration remains an important strategy for improving timely vaccination and reducing missed opportunities.

Concurrently, the AAFP does not support a one-size-fits-all approach to vaccine administration. Vaccine-specific minimum ages, interval requirements, contraindications, precautions, and other evidence-based clinical considerations should continue to guide decision-making. Where vaccines should not be administered together, federal guidance should clearly identify the applicable timing or sequencing requirements. Within these evidence-based boundaries, decisions about administering multiple indicated vaccines

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should remain grounded in the physician-patient relationship, informed by clinical judgment and discussion with patients, parents, and caregivers.

The AAFP further encourages HHS to apply a rigorous and consistent evidentiary standard to any proposed modifications involving vaccine timing, spacing, frequency, or co-administration. Such changes should be evaluated not only for immunogenicity and safety but also for their effects on vaccine effectiveness, timely completion of recommended series, missed opportunities, access, implementation feasibility, and real-world public health outcomes. Where evidence is limited or evolving, that uncertainty should be communicated transparently rather than converted into a categorical recommendation.

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

8. What does, or what should, “shared clinical decision-making” mean in the vaccination context? How, if at all, does “individual-based decision-making” differ?

As mentioned previously in Section A, the AAFP [understands](#) shared clinical decision-making in the vaccination context to mean an individualized, evidence-based process in which a clinician and patient, or, as appropriate, a parent or guardian, consider the patient’s clinical circumstances, the benefits and risks of vaccination and non-vaccination, applicable uncertainties, and the patient’s informed values and preferences.

Shared decision-making is a longitudinal process, particularly when employed in primary care, that includes multicomponent interventions, which are more effective than single encounters. The process includes meaningful clinical guidance from clinicians and is not merely satisfied by identifying vaccination as an option without explaining its implications. The CDC similarly describes an SCDM recommendation as one for which there is no predetermined default, and the decision may be informed by the best available evidence, individual characteristics and preferences, clinical discretion, and characteristics of the vaccine.^{xvi} Family physicians routinely apply these skills across preventive, diagnostic, and treatment decisions, including vaccination.

The defining feature of an SCDM recommendation category should therefore be narrower than the broader clinical practice of shared decision-making. The category is appropriate when a vaccine may benefit some otherwise eligible individuals, but expected benefit varies sufficiently that neither a routine recommendation for the full population nor an identifiable risk-based recommendation adequately captures who is most likely to benefit. CDC’s HPV recommendation for adults ages 27–45 illustrates this rationale: expected benefit is limited for many adults because of prior exposure and lower future exposure risk, while particular individuals may still benefit based on their history and anticipated circumstances.^{xvii}

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Further, we do not find an evidence-based basis for treating “individual-based decision-making” as a different clinical or regulatory category. HHS itself describes that phrase as another name used for SCDM, and the operative characteristics (no population-wide default, individualized assessment, and clinician-patient deliberation) are the same. Using both terms without explaining that equivalence risks creating a distinction where none exists. Thus, we encourage HHS to select one primary term and expressly state that the other is synonymous, using the same definition across schedules, clinical guidance, payer materials, and patient communications.

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?

Because “shared decision-making” also describes good clinical practice generally, using the phrase as the name of a single vaccine recommendation category can unintentionally and incorrectly suggest that individualized discussion, informed consent, or patient choice applies only to vaccines in that category. In reality, family physicians consider medical history, contraindications, exposure, patient questions, preferences, and the benefits and risks of vaccination even when a vaccine is routinely recommended. A routine recommendation only establishes the evidence-based default for the relevant population. It does not eliminate the application of the administering clinician’s professional judgment, the natural “shared decision-making” fostered between physician and patient, or the patient’s ability to accept or decline vaccination.

Thus, the AAFP does not recommend renaming the SCDM vaccination category at this time. ACIP replaced “Category B” terminology with SCDM in 2019 to improve clarity, yet subsequent research continued to find substantial confusion. In a national survey conducted in 2021, 64% of family physicians believed SCDM created confusion, while only 41% knew that SCDM-recommended vaccines would generally be covered by insurance.^{xviii} Public polling in 2025 likewise found that 42% incorrectly believed that consulting a health care professional was optional under SCDM.^{xix} This interpretation is deeply concerning as it undermines the purpose of SCDM and risks weakening the trusted physician-patient relationship that patients rely on to understand their health and make informed preventive care decisions. It also places a disproportionate burden on patients to infer the meaning of technical recommendation categories, which can further contribute to confusion, missed opportunities, and preventable gaps in disease protection. Renaming the category again,

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without remedying the underlying communication and implementation failures, may simply substitute one unclear term for another.

The AAFP therefore recommends retaining the SCDM category while pairing it consistently with a concise, plain-language explanation that answers three practical questions:

- **What does SCDM mean?**
 - The vaccine may be appropriate for some eligible patients, and the decision should be made through a discussion between the patient and clinician based on the patient's health, risk, circumstances, and preferences.
- **Is an SCDM-designated vaccine still recommended and available?**
 - Yes. An SCDM designation means the recommendation is individualized; it does not remove the vaccine from federal recommendations or signal that it should be unavailable.
- **How does an SCDM designation differ from a routine recommendation?**
 - A routine recommendation identifies the evidence-based default for a population. SCDM applies when the evidence supports vaccination for some eligible patients but does not support a single default recommendation for everyone in that group.

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?

SCDM can be valuable when individual circumstances materially affect the expected benefit of vaccination and a single population-wide recommendation would not adequately reflect that variation. In that circumstance, SCDM allows population-level evidence to be applied with appropriate clinical specificity, accounting for factors such as exposure risk, prior immunity, health status, likelihood of benefit, patient goals, and informed preferences. When properly bounded, the category can preserve access to a beneficial intervention while signaling that the decision should turn on individualized assessment rather than a universal default or the absence of any federal recommendation.

SCDM also appropriately recognizes that patient values are especially relevant when more than one clinically reasonable course is supported by the evidence. Those values should inform the individual decision and should not substitute for the scientific assessment of disease risk, vaccine effectiveness, or vaccine safety. **Nor should SCDM be framed as the source of autonomy or informed consent, which remain essential across all vaccine recommendations.** The distinct contribution of the SCDM designation should be scoped precisely to instances where expected clinical benefit varies meaningfully among eligible individuals, such that patient preferences and clinical judgment may appropriately carry greater decisional weight.

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Available evidence also supports both individualized deliberation and a carefully limited SCDM category. In a 2021 national survey, 81% of surveyed family physicians supported SCDM recommendations for at least certain vaccines.^{xx} Further, a meta-analysis of 10 randomized trials found that vaccination-focused shared decision-making interventions increased vaccine uptake compared with controls and, in some studies, reduced decisional conflict and increased confidence.^{xxi} And a broader Cochrane systematic review of 209 decision-aid studies found that decision aids improve knowledge, risk comprehension, active participation, and alignment between informed values and choices.^{xxii}

Together, these findings support SCDM as a patient-centered process, while emphasizing that its effectiveness depends on clear federal guidance, usable clinical tools, and the trusted physician-patient relationship through which, the AAFP strongly [believes](#), benefits, risks, uncertainties, preferences, and concerns can be discussed candidly.

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 principal challenges associated with SCDM arise when recommendation language and implementation guidance do not communicate a clear and consistent understanding of how the framework should function in practice for patients.

First, SCDM can be misread as a weaker or less affirmative recommendation. Patients may interpret the designation to mean that a vaccine is not recommended, is less important, or is subject to unresolved concerns about safety or effectiveness. Public survey data from 2025 mentioned above, indicate that respondents frequently misunderstood both the meaning of SCDM and the role of health care professionals in the process.^{xxiii} This type of misunderstanding can carry outsized consequences on long-term patient perception, payer behavior, and whether vaccination is discussed during a visit.

Second, SCDM can impose practice-level burdens when federal guidance is unclear, incomplete, or difficult to operationalize. Two years after SCDM implementation, 90% of family physicians reported that SCDM requires more time than routine recommendations, and 79% said vaccine-specific talking points would be helpful. Clinicians also reported inconsistent treatment in electronic forecasting systems, with only 38% reporting that systems displayed an SCDM vaccine as recommended and 23% reporting no recommendation. Since 2021, major medical associations including the AAFP have since issued robust [guidance](#) and resources to support more consistent implementation, however, clinicians should not be left to translate ambiguity in federal recommendations at the point of care.

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Third, ambiguity can create access inconsistencies even when federal coverage protections remain available. SCDM vaccines may be subject to coverage protections once adopted by CDC and included on the applicable immunization schedule, but unclear communication can still affect payer interpretation, pharmacy workflows, ordering, stocking, and whether clinicians raise the vaccine during an encounter. As the AAFP previously noted in our [comments](#) to ACIP regarding their December 2025 convening, some payers treated SCDM recommendations as nonroutine and declined coverage, even despite CDC [FAQs](#) clarifying that payers must cover SCDM recommendations.^{xxiv} These risks make clarity and precision in the categories developed for the federal vaccine recommendation framework, essential.

Further, SCDM should not become a default destination for vaccines removed from routine recommendation absent vaccine- and population-specific evidence that individualized assessment is appropriate. Rather, recommendation categories should reflect a transparent evaluation of disease burden, expected individual and population benefit, benefits and harms, certainty of evidence, feasibility, equal access, and patient values. This distinction is particularly important as HHS evaluates recent changes to the childhood immunization schedule.

12. & 13. Communicating coverage of SCDM-recommended vaccines

We encourage HHS to communicate the coverage of SCDM-recommended vaccines with precision and in operationally usable terms. When an SCDM recommendation has been adopted by the CDC Director and included on the applicable immunization schedule, CDC has [stated](#) that the recommendation is generally subject to the Affordable Care Act's preventive-services coverage requirement for non-grandfathered group health plans and health insurance issuers, without cost sharing, when furnished by an in-network provider and subject to applicable timing and implementation rules. We urge HHS to present these protections clearly, while also identifying any relevant plan, network, eligibility, timing, or program-specific limitations, so that public-facing simplicity does not come at the expense of legal accuracy.

We also recommend HHS clearly distinguish among coverage, availability, and program eligibility. These concepts are often treated interchangeably in public communications but operate differently in practice. For the VFC Program, communications should separately explain vaccine availability under ACIP VFC resolutions and child eligibility under program rules. VFC eligibility generally extends to children age 18 or younger who are Medicaid-eligible or enrolled, uninsured, underinsured when vaccinated at a Federally Qualified Health Center or Rural Health Clinic, or American Indian or Alaska Native, subject to applicable program requirements. Clearer separation of these concepts would help parents, families,

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clinicians, pharmacies, state programs, and payers understand whether a vaccine is recommended, available for ordering, covered by a particular payer, and accessible through a specific program.

We also encourage HHS to explore the adoption of a standardized coverage statement displayed immediately adjacent to every SCDM designation, rather than relying on a separate FAQ that clinicians, patients, payers, and system vendors must locate and interpret on their own. That statement should answer practical questions most likely to affect access, including at minimum:

- Whether the vaccine remains federally recommended;
- Whether the vaccine remains available to eligible patients;
- Which coverage pathway applies under the ACA, Medicaid, CHIP, Medicare, or VFC; and
- Whether any plan, network, timing, age, indication, or program limitations apply.

The statement should also explain that an SCDM designation reflects the need for individualized assessment and is not a statement that the vaccine lacks federal support or should be treated as outside ordinary coverage pathways.

HHS should further update CDC FAQs, schedule notes, payer-facing guidance, and related implementation materials to address payer interpretation directly. As we mentioned in our answer to Question 11, payers have been reported to treat SCDM recommendations as nonroutine and decline coverage, citing the need for literal or specific language tying SCDM recommendations to the statutory and regulatory preventive-services coverage requirements. Robust federal guidance can resolve this type of implementation ambiguity. We further encourage HHS to issue aligned payer-facing language confirming how SCDM recommendations are treated once adopted and placed on the applicable schedule, including the legal basis for coverage and any permissible limitations. Guidance should be drafted for operational use by health plans, third-party administrators, state Medicaid agencies, pharmacy benefit managers, pharmacies, clinicians, and electronic health record vendors, not only for general public education.

To most effectively ensure that an SCDM designation is not misread as a lapse in coverage or a signal that a vaccine is unavailable, the same plain-language explanation developed above should appear consistently across CDC materials, consumer-facing education resources, insurer and state Medicaid bulletins, pharmacy materials, patient portals, payer implementation guidance, and clinically facing electronic prompts. **Coverage should not depend on whether a patient, physician, pharmacist, payer, or software vendor can correctly infer the legal effect of a technical recommendation category.** Federal guidance should make that effect explicit, consistent, and easy to implement.

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D. Considerations in Setting Recommendations

14. What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate?

As mentioned in our 2025 [comments](#) to ACIP, the AAFP [advocates](#) for the development and use of patient-centered, evidence-based clinical practice guidelines that adhere to principles based on the National Academy of Medicine Standards for Trustworthy Guidelines. We believe clinical practice guidelines should be informed by an independent, systematic review of the evidence and provide an adequate assessment of both benefits and harms. In 2010, ACIP adopted the use of a GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach to evaluate the quality and certainty of evidence considering factors such as study design, risk of bias, and precision. In 2019, ACIP implemented an Evidence to Recommendation (EtR) assessment that also considers risks of the public health threat, costs and benefits of intervention, feasibility of implementation, and other factors relevant to deliberation. The EtR framework has served the public well by balancing scientific rigor with clinical applicability.

Thus, we recommend that HHS return to this transparent, systematic, and reproducible two-stage process that distinguishes the certainty of the evidence from the strength, scope, and direction of the resulting recommendation.^{xxv} GRADE should assess certainty for each critical benefit and harm outcome, while the EtR framework should determine whether the totality of the evidence supports a routine recommendation, a risk-based recommendation, an SCDM recommendation, a recommendation against vaccination, or no recommendation.

In assigning recommendation categories, HHS should apply these considerations according to the decision each is best suited to inform. The availability, quality, and certainty of evidence, together with the balance of benefits and harms, should predominate in determining whether vaccination should be recommended at all. Disease severity and epidemiology (including incidence, transmissibility, hospitalization, disability, mortality, outbreak potential, and the consequences of delayed protection) should inform the urgency and expected absolute benefit of a recommendation within the target population.^{xxvi}

Individual and population benefits should be evaluated separately and then reconciled, so that direct protection for patients is considered alongside broader public health benefits such as reduced transmission, protection of those who cannot be vaccinated, and preservation of health system capacity.

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Category assignment should then consider the distribution of expected benefit: a routine recommendation is appropriate when vaccination should be the evidence-based default for the defined population; a risk-based recommendation is appropriate when benefit is concentrated among persons with identifiable medical, occupational, behavioral, exposure, or other risk factors; SCDM is appropriate when vaccination may benefit some eligible individuals but expected benefit or the benefit-harm balance varies materially in ways that cannot be captured adequately through an objective risk category; and no recommendation, or a recommendation against vaccination, may be appropriate when the balance is unfavorable or the evidence cannot support an actionable conclusion.^{xxvii} Patient values, autonomy, informed consent, and sincerely held beliefs should receive greater weight when clinically reasonable alternatives are closely balanced or when benefits and harms vary substantially among individuals, but they should not alter empirical judgments about disease risk, vaccine safety, or vaccine effectiveness. Feasibility, resources, equal access, and programmatic consequences should guide whether and how a scientifically supported recommendation can be implemented fairly and effectively, including through implementation supports, subgroup-specific guidance, coverage clarification, or operational modifications, but they should not substitute for the underlying scientific assessment.

Further, randomized controlled trials (RCT) generally provide the strongest starting point for determining causal effectiveness, but an RCT designation does not cure methodological limitations, and the absence of RCT evidence does not establish that evidence is inadequate. Where RCT evidence is absent, infeasible, or unethical to obtain, HHS should evaluate the best available nonrandomized and real-world evidence using study-design-appropriate methods. CDC's GRADE [handbook](#) expressly permits nonrandomized studies to complement RCTs when trials do not represent the relevant population, to supply longer-term or patient-important outcomes, or to replace RCT evidence when the nonrandomized evidence is more direct and has greater certainty. Certainty in nonrandomized evidence may also be increased when there is a large association, a dose-response gradient, or plausible residual confounding that would diminish rather than create the observed effect. And post-licensure surveillance is especially important for identifying rare adverse events that preauthorization trials may be unable to detect.

Finally, HHS should distinguish the federal vaccination recommendation framework from mandates and exemptions. Federal recommendations should respect patient autonomy, informed consent, meaningful physician-patient discussion, and consideration of sincerely held beliefs, but these principles do not require scientific bodies to withhold a clear recommendation when evidence supports one. A recommendation communicates the government's evidence-based clinical and public-health judgment; it does not compel vaccination. Questions concerning religious exemptions from school, employment, or other legal requirements arise under separate federal and state authorities and should not alter the

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grading of scientific evidence or the assignment of a recommendation category. Consistent with that distinction, the AAFP [supports](#) informed, patient-centered decision-making and supports medical exemptions for bona fide contraindications but does not support nonmedical exemption policies from required vaccination.

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?

Uncertainty should be disclosed directly and not communicated indirectly through category assignment alone. Evidentiary certainty reflects confidence in estimated benefits and harms, while category assignment expresses the policy judgment about who should be vaccinated and whether a default recommendation is warranted. A routine recommendation may be appropriate despite less-than-high certainty when disease consequences are serious and the best available evidence shows a favorable benefit-harm balance. Conversely, SCDM may be appropriate even with strong evidence when expected benefit varies materially among eligible individuals.

Each recommendation should include a concise, public evidence-and-uncertainty statement grounded in the GRADE framework. That statement should identify the certainty rating for each critical benefit and harm outcome; the main reasons certainty was reduced, such as imprecision, indirectness, inconsistency, risk of bias, limited follow-up, or missing subgroup data; the expected magnitude of benefit and harm; whether uncertainty concerns effectiveness, safety, duration of protection, disease burden, implementation, or the distribution of benefit; and why the selected recommendation category is justified despite those limitations. CDC's GRADE framework already provides the structure for this approach by rating certainty and identifying the domains that materially affect confidence in the evidence.

HHS should also calibrate recommendation language to the level and type of certainty. Standardized terms should distinguish uncertainty about whether an effect exists, the size of the effect, and how evidence applies to particular subgroups or settings. Further, when evidence, epidemiology, or implementation conditions are likely to change materially, HHS should identify the recommendation as interim, time-limited, or subject to mandatory re-review. The recommendation should specify the expected review date or triggering events, such as new effectiveness data, a confirmed safety signal, a material change in disease burden, completion of a relevant trial, or evidence of unintended access consequences.

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Further, the AAFP does not recommend HHS pursue automatic sunset provisions for all vaccine recommendations. Automatic expiration can create avoidable uncertainty for patients, clinicians, payers, pharmacies, manufacturers, and immunization programs when the evidence has not materially changed. Sunset provisions should be reserved for recommendations tied to temporary conditions or specified forthcoming evidence. Rather, any expiration or category change should include a formal review, notice-and-comment opportunities for affected stakeholders to provide valuable user input, transition guidance for clinical practice, coverage, vaccine product availability, and completion of ongoing series.

E. Trust and Communication

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, consistent with the principle that Federal recommendations are not mandates?

The AAFP urges HHS to maintain a clear and consistent distinction between vaccine recommendations and vaccine mandates. A federal recommendation communicates an evidence-based clinical and public health judgment about who is likely to benefit from vaccination. It does not compel vaccination, displace informed consent, or eliminate a patient's ability to accept or decline a vaccine. By contrast, a mandate or other compulsory policy conditions access to employment, education, travel, services, or another important benefit on vaccination or imposes a consequence for noncompliance. These are analytically and legally distinct policy instruments and should not be conflated in federal recommendation terminology or public communications.

That said, vaccination requirements may be justified in limited circumstances, particularly when they are necessary to sustain the population-level immunity that protects children and communities from serious vaccine-preventable diseases. School-entry vaccination requirements have long served this purpose by maintaining high vaccination coverage in settings where infectious diseases can spread rapidly and where outbreaks can disrupt education and threaten vulnerable populations. Recent modeling research found that if routine childhood vaccination declines by 50%, it would likely result in millions of additional cases of measles and other vaccine-preventable diseases and associated complications, including 51,200 cases of post-measles neurological sequelae, 10.3 million hospitalizations, and 159,200 deaths over a 25 year period.^{xxviii} These findings underscore that school vaccination requirements can play an important role in preventing the reemergence of diseases previously eliminated in the United States and protecting both individual and community health.

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Accordingly, while federal vaccine recommendations should remain distinct from mandates, concerns about public trust should not be used to justify abandoning evidence-based school vaccination requirements that prevent the resurgence of serious infectious diseases. Consistent with [AAFP policy](#), such requirements should include medical exemptions but not nonmedical exemptions, which can undermine community-level immunity and increase risks for vulnerable individuals.

Thus, we encourage HHS to not weaken or recategorize an evidence-supported recommendation merely to distinguish it from a mandate; a routine recommendation establishes an evidence-based default, not a compulsory requirement. Further, recommendation language should affirm that patients retain the ability to ask questions and make informed choices.

We also encourage HHS to study mandates using designs that distinguish the effect of the requirement from contemporaneous improvements in access, outreach, insurance coverage, or documentation. The objective of federal vaccine policy should be to support informed, voluntary acceptance of evidence-based recommendations through trusted clinical relationships and accessible vaccination services. Requirements may produce short-term gains in particular circumstances, but they do not substitute for addressing safety questions, access barriers, misinformation, or mistrust. Durable vaccine confidence is more likely when individuals understand why a vaccine is recommended, have meaningful access to it, and can discuss benefits, risks, uncertainties, and questions with a trusted physician.

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 COVID-19 pandemic demonstrated that public trust depends on whether guidance is scientifically sound to the public, whether people understand how decisions were made, why guidance changed, what uncertainty remains, and what action is expected of them. Communications that appear politically influenced, internally inconsistent, or disconnected from practical access concerns can weaken public confidence even when the underlying science is sound. Thus, we encourage HHS to release clear, plain-language, and evidence-based, patient-facing communication regarding any future updates to vaccine recommendations. This communication should clearly state, at minimum, what is recommended and for whom; the expected benefits and known risks; the risks of remaining unvaccinated; the certainty and limitations of the evidence; whether the recommendation is routine, risk-based, or individualized; and what the recommendation means for access and coverage.

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When evidence is evolving, HHS should clearly communicate what is known, what remains uncertain, what evidence would change the recommendation, and when the issue will be reviewed again. Clarity about uncertainty is a vital prerequisite for institutional credibility, particularly during times of heightened public distrust. Conversely, recommendations should change when credible evidence or changing epidemiology warrants change. But when guidance changes, HHS should explain what changed, what did not change, why the change occurred, and whether the change reflects new evidence, a change in disease conditions, or a different policy judgment. Materials should be dated, version-controlled, and clearly labeled when superseded. CDC, FDA, HHS, state and local health departments, professional societies, payers, pharmacies, and clinical decision-support vendors should receive aligned implementation language so that patients do not encounter conflicting messages across the health care system.

Federal vaccine recommendations earn trust when they are transparent in rationale, science-backed, clear in effect, consistent in implementation, and most importantly, delivered through messengers patients already trust: their doctors. However, clinicians cannot effectively communicate recommendations they do not understand, were not consulted on, or do not trust. HHS's communication strategy should therefore be designed with clinicians at its center, from development to deployment. Family physicians understand that trust is built over time through ongoing relationships, not through a single federal announcement. They counsel patients during preventive care visits, answer questions as evidence evolves, and provide recommendations informed by a patient's medical history, family circumstances, and individual concerns. As a result, they are uniquely positioned to translate evidence-based federal guidance into informed patient decisions. However, earning and maintaining clinicians' trust requires transparency about the evidence, clarity about the rationale for recommendations, and meaningful engagement throughout the process. HHS can support physicians by providing clear recommendation language, concise evidence summaries, patient-facing educational materials, straightforward coverage information, and effective clinical decision-support tools.

Additionally, community engagement should begin before recommendations are finalized and continue through implementation. Trusted messengers will differ across communities and may include family physicians, nurses, pharmacists, local health departments, faith leaders, community health workers, educators, and other local leaders. Community partners should help identify information needs, test materials for comprehension, surface implementation barriers, and communicate in culturally and linguistically appropriate ways.

Also, HHS should adopt a disciplined, evidence-based approach to misinformation that distinguishes uncertainty from entrenched opposition. Notably, while parents who report

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skipping or delaying recommended vaccines are more likely than parents who keep their children up to date to believe or lean toward believing vaccine myths, nearly half of those parents fall in the “mixed middle” demographic who delay or skip vaccines hold confused or inconsistent beliefs rather than fixed opposition, creating an important opportunity for accurate information and trusted counseling.^{xxix} Federal communications should therefore lead with clear, evidence-based affirmative facts, explain the basis for recommendations, and correct consequential misinformation rapidly through the channels used by the affected audience. Family physicians are especially important in this work because they can identify the specific concern driving hesitation, respond without judgment, and maintain the relationship even when a patient is not ready to vaccinate during a single encounter. A misinformation strategy that strengthens trusted clinical conversations will be more durable than one that relies primarily on centralized messaging after confusion has already spread.

Finally, communication quality cannot be separated from service delivery. Trust is undermined when a recommendation is clear, but a patient cannot locate the vaccine, obtain coverage, schedule an appointment, or receive vaccination from a usual source of care. HHS should therefore treat communication, access, and implementation as integrated components of every recommendation. A recommendation is most likely to earn and keep trust when patients understand the rationale, clinicians can explain and implement it, and the health care system makes the recommended vaccine accessible.

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

The AAFP recommends that HHS publicly and longitudinally evaluate the federal vaccine recommendation framework by assessing health outcomes, implementation, access, understanding, and trust. Coverage rates alone do not show whether patients understood a recommendation, whether clinicians could implement it, whether payers honored coverage obligations, whether vaccines were available where patients seek care, or whether aggregate uptake masked widening disparities.

HHS should measure both population health outcomes and implementation performance. Core measures should include, at least, vaccine initiation, series completion, timeliness, age-appropriate coverage, delayed or declined doses, and persistence of voluntary uptake over time, linked where feasible to vaccine-preventable disease incidence, outbreaks, hospitalizations, complications, and mortality.

HHS should also measure whether recommendations are operationally usable in real-world clinical settings. These measurements can include, at minimum: whether eligible patients receive a clinician recommendation; whether recommended vaccines are offered and

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administered; whether missed opportunities occur during preventive, chronic-care, or acute visits; whether clinicians have usable decision aids and talking points; and whether electronic health records, Immunization Information Systems, pharmacy systems, and forecasting tools correctly identify eligibility, display the recommendation category, and support appropriate prompts.

We encourage HHS to track public trust longitudinally. HHS should use validated measures of trust in personal clinicians, CDC, FDA, ACIP, state and local health departments, and the recommendation-development process. Surveys should distinguish confidence in vaccine safety, confidence in the scientific process, perceived independence of decision-makers, understanding of changes in guidance, and willingness to rely on future recommendations.

To measure access directly, we urge HHS to collect and publish public data on vaccine availability, ordering and stocking, appointment access, travel distance, out-of-pocket costs, insurance denials, network or prior-authorization barriers, pharmacy and clinician payment, VFC availability, and referral completion. Measures should be stratified, where reliable, by age, geography, rurality, insurance status, income, disability, language, race and ethnicity, and other factors relevant to access and disease risk. Evaluation should ask whether uptake differs across populations, and whether recommendation changes alter clinician offers, coverage, availability, or completion of vaccination series.

Importantly, **HHS should preserve and strengthen the data infrastructure needed to evaluate the federal vaccination recommendation framework over time.** We recognize that quality measurement imposes real reporting burdens on states, plans, clinicians, and health systems, and that measure sets must be periodically reassessed to remain feasible and meaningful. At the same time, CMS's 2027 Core Set [guidance](#) removes the Childhood Immunization Status, Immunizations for Adolescents, and Prenatal Immunization Status measures from the 2026 Medicaid and CHIP Core Sets, including measures that had been mandatory for state reporting. Although CMS indicates that states may voluntarily report these measures as utilization measures while alternative immunization measures are explored, the shift from mandatory to voluntary reporting may make it more difficult to maintain reliable, comparable, and longitudinal data on vaccination coverage, equity, missed opportunities, access, and long-run vaccination behavior. As HHS considers how to measure the success of the federal recommendation framework, it should ensure that efforts to reduce reporting burden do not come at the expense of the longitudinal immunization data needed to assess uptake, equity, access, and health outcomes. Any reporting reforms should be accompanied by a clear strategy to preserve the data necessary for meaningful evaluation.

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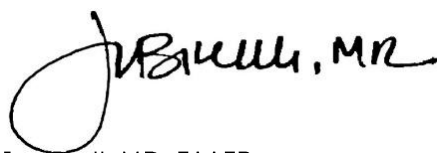
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Thank you for the opportunity to provide comments on this important matter. For additional questions, please contact Sahana Chakravartti, Regulatory and Policy Strategist, at schakravartti@aaafp.org.

Sincerely,

A handwritten signature in black ink that reads "J Brull, MD". The signature is fluid and cursive, with the first name "Jen" and last name "Brull" clearly legible, followed by "MD".

Jen Brull, MD, FAAFP
American Academy of Family Physicians, Board Chair

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