SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS

Response to the Department of Health and Human Services

Request for Information:

Use of Artificial Intelligence in Clinical Care

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Response from SCAI Advocacy Committee AI Task Force

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Executive Summary

SCAI represents over 5,000 interventional cardiologists whose members already use AI in clinical practice—including AI-assisted coronary physiology, procedural imaging, and echocardiographic analysis. We support AI adoption in clinical care and offer the following perspectives:

1. **AI works best as a physician's tool.** The most successful clinical AI applications generate information that a licensed professional interprets and acts on. That model should guide adoption.
2. **Reimbursement should reflect the work AI creates.** AI generates new data requiring physician interpretation. Payment policy should recognize this as the professional act it is.
3. **Liability clarity benefits everyone.** Developers gain regulatory certainty, clinicians gain reasonable and appropriate protections, and patients retain a clear framework for accountability.
4. **Specialty societies can help.** Professional societies are positioned to develop practical appropriate use guidance within their clinical domains, as they already do for procedures and therapies.
5. **Transparency and monitoring build trust.** Labeling AI involvement in care and establishing adverse event reporting are practical steps that protect patients and accelerate confidence in these tools.
6. **SCAI is available to work with HHS directly** on developing practical guidance for AI in cardiovascular care and clinical care more broadly.

Preamble

The Society for Cardiovascular Angiography and Interventions (SCAI) appreciates the opportunity to respond to this Request for Information. SCAI represents over 5,000 interventional cardiologists and cardiovascular professionals who work daily at the intersection of advanced technology and high-acuity patient care.

Interventional cardiology has adopted new technologies responsibly for decades: from balloon angioplasty to transcatheter valve therapies. Our members are not speculating about AI in clinical care; they are already using it. AI-assisted quantitative coronary analysis, CT-derived fractional flow reserve, automated echocardiographic assessment, and three-dimensional reconstruction for structural heart planning are part of current practice. This experience informs our perspective.

SCAI supports the responsible adoption of AI in clinical care. The responses that follow offer practical perspectives on how to accelerate that adoption while addressing the barriers that currently slow it.

Question 1

What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

Several interconnected barriers impede both development and responsible deployment of AI in clinical care.

Data fragmentation. Patient data remain siloed across EMR systems, claims databases, imaging archives, and research repositories. Variability in format, quality, and volume between institutions limits generalizability. Smaller practices and rural health systems are often excluded from AI development entirely because their data infrastructure cannot support it.

Regulatory and liability ambiguity. The current landscape does not clearly delineate responsibility when AI influences a clinical decision that results in patient harm. The professional accountability framework in medicine is well established: the licensed clinician is responsible. But when an AI tool contributes to a decision, and the clinician had no role in designing, validating, or choosing that tool, the assignment of responsibility becomes unclear. Technology developers operate under liability protections that were not designed for clinical consequences. This ambiguity discourages adoption by the very professionals who would need to use these tools.

Algorithmic opacity. Most clinical AI operates as an associative model whose internal logic is not transparent to clinicians. Licensed professionals are trained to reason from evidence, document their rationale, and defend their decisions. Acting on opaque algorithmic recommendations is fundamentally at odds with how professional clinical judgment is exercised and evaluated.

Workflow integration. AI systems are often designed without adequate understanding of clinical workflows. Tools that generate excessive alerts, require parallel documentation, or interrupt established care pathways create friction rather than efficiency. In high-acuity settings like the catheterization laboratory, poorly integrated AI could compromise rather than enhance patient safety.

Absence of recognized validation standards. Outside the FDA medical device pathway, there is no broadly adopted standard for evaluating AI tools used in clinical care. Every licensed professional must demonstrate competency through examination, supervised training, and ongoing certification. The tools they rely on to make clinical decisions should be held to a comparable expectation of demonstrated performance—yet no such framework currently exists for clinical AI.

Privacy and data use concerns. The potential for third-party monetization, re-identification through metadata aggregation, and secondary use of protected health information without clear consent boundaries erodes the trust necessary for responsible data sharing.

Question 2

What regulatory, payment policy, or programmatic design changes should HHS prioritize?

HHS should pursue reforms that support AI adoption while recognizing the professional work involved in using these tools effectively.

Reimbursement modernization. When a physician interprets AI-generated data—whether from an imaging algorithm, a risk stratification model, or a decision-support tool—that is a professional act requiring clinical training, judgment, and accountability. It is the same professional act that has always required appropriate compensation. Payment policy under existing Medicare and Medicaid authorities (42 C.F.R. Parts 405, 414, 415, and 430) should recognize that AI creates new interpretive work for physicians rather than eliminating existing work. Reductions based on assumptions that AI replaces professional effort would threaten the sustainability of outpatient practices, particularly in rural and underserved areas.

Managed care safeguards. Within Medicare Advantage and Medicaid managed care frameworks (42 C.F.R. Parts 422 and 438), HHS should ensure AI does not worsen prior authorization delays, enable blanket denials, or add clerical burden to licensed professionals. Nondiscrimination protections under 45 C.F.R. Part 92 should apply to AI-influenced coverage determinations.

Liability clarity. The professional liability framework in medicine is clear: the treating clinician is accountable. When AI is inserted into that decision chain, accountability becomes ambiguous. Reforms should preserve the professional's authority while ensuring that developers share appropriate responsibility when their tools contribute to harm. Clarity here benefits all parties—developers gain regulatory certainty, clinicians gain defined protections, and patients retain a clear framework for recourse.

Competitive safeguards. Guardrails consistent with the Antitrust, Stark Law, and Anti-Kickback Statute should be modernized to address scenarios where a single entity controls clinical decision-making tools, care delivery, and commercial platforms simultaneously. Maintaining a competitive marketplace protects both innovation and patient choice.

Implementation support. Streamlined federal grant pathways under 2 C.F.R. Part 200 would help early-adopting practices manage implementation costs without prohibitive administrative burden.

Question 3

For non-medical devices, what novel legal and implementation issues exist and what role should HHS play?

AI tools outside formal medical device classification present a specific governance challenge: they influence the practice of medicine without being subject to the professional and regulatory frameworks that govern clinical care. Billing tools shape documentation. Revenue cycle algorithms modify coding behavior. Triage systems redirect patients. Each of these functions affects clinical outcomes, yet none triggers the accountability structures that apply when a licensed professional makes the same decisions.

This creates an asymmetry. Licensed professionals operate under personal liability, fiduciary obligation, and regulatory oversight on both state and federal levels. Technology developers operating in the same clinical space carry none of these obligations. The practical result is that when AI-influenced processes lead to adverse outcomes, the professional bears full accountability for decisions shaped by tools they did not build, cannot fully interrogate, and had limited input in selecting.

The heterogeneity of AI systems compounds this. Training sets, validation methods, and architectures vary widely, producing a broad range of quality with no minimum standard. HIPAA's de-identification standards were not designed for AI systems capable of large-scale pattern reconstruction, and re-identification risk through metadata aggregation remains a real concern.

Recommended Actions

HHS should consider establishing minimum transparency and validation expectations for AI systems used in healthcare, even outside the device pathway. The key elements are practical: clear labeling of where AI is involved in care processes, defined liability allocation that reflects the actual role each party plays, and developer responsibility for representative training data. Professional societies such as SCAI can assist by developing appropriate use guidance within their clinical domains—not as mandatory credentialing, but as practical frameworks that regulators, health systems, and developers can reference when determining what responsible deployment looks like.

Question 4

What are the most promising AI evaluation methods and should HHS further support these processes?

Pre-deployment validation. Retrospective validation using clinical data remains essential, with performance assessed through stratified analyses across demographic subgroups. Datasets are frequently underrepresented along dimensions of age, race, disease severity, and socioeconomic status. Validation that ignores these gaps produces misleading estimates—and it is the licensed professional, not the developer, who faces consequences when a tool underperforms in a specific patient population.

Simulated deployment. Running AI in parallel with clinical care without influencing management (shadow mode) allows comparison of predictions against actual outcomes. This should precede clinical activation as standard practice.

Post-deployment monitoring. After activation, models should be monitored for performance drift, with clinician error reporting, scheduled revalidation, and bias surveillance. AI-specific adverse event reporting would parallel the post-market infrastructure that exists for devices and drugs.

Role of specialty societies. What constitutes acceptable performance varies by clinical context—the error rate tolerable in a population screening tool is different from what is acceptable in a real-time procedural decision aid. Specialty societies understand these distinctions because their members are the professionals who bear the consequences of getting it wrong. Cooperative agreements between HHS and professional societies to develop evaluation guidance would ensure both scientific rigor and clinical relevance.

Recommended HHS support. Grant funding for multi-site validation infrastructure and shared surveillance systems would have the greatest practical impact. Prize competitions using de-identified datasets can incentivize innovation in areas where proprietary barriers limit progress.

Question 5

How can HHS best support private sector activities to promote innovative and effective AI use in clinical care?

AI used in clinical care should strengthen the patient–provider relationship, which remains the foundation of trust, accountability, and decision-making in medicine.

Clinical care in the United States is delivered by licensed professionals operating under established legal and ethical frameworks. These include professional licensure, fiduciary duty, standards of care, and common law accountability. These structures exist to protect patients and to ensure that medical decisions are individualized, contextual, and responsibly supervised.

AI systems that influence diagnosis, treatment, or longitudinal management without being embedded within this professional framework risk bypassing these safeguards. For this reason, AI in clinical care should be deployed as an augmentative tool within clinician-led care models rather than as an independent decision-making layer.

HHS can best promote innovative and effective AI use by reinforcing clinician accountability and supporting private-sector efforts that align with real-world clinical practice.

Clinician-centered accountability. AI should support clinicians in understanding patient data and making informed decisions. Evaluation and accreditation efforts should emphasize clear clinician oversight, defined responsibility for action, and transparency into how AI outputs are used in care. Clinical responsibility must remain with licensed professionals, consistent with existing legal and ethical standards.

Specialty-specific evaluation and use. Clinical judgment is inherently specialty-specific. Risk tolerance, workflows, and consequences of error vary significantly across clinical domains. AI evaluation should reflect the context in which the technology is used. Professional societies are well positioned to define appropriate use and minimum standards within their specialties, and HHS can support alignment with these efforts rather than imposing uniform models that cannot account for clinical context.

Outcome- and relationship-focused validation. The effectiveness of AI should be measured by its impact on patient understanding, clinician decision-making, workflow efficiency, and clinical outcomes. Private-sector testing should prioritize real-world performance and safety over static algorithmic benchmarks.

Alignment of incentives with professional practice. Payment and programmatic structures should not incentivize AI systems that disintermediate clinicians or weaken the patient–provider relationship. Alignment should favor AI that demonstrably enhances clinician-supervised care.

In summary, HHS should support private-sector AI innovation by reinforcing clinician accountability, respecting specialty-specific expertise, and ensuring that AI augments the professional foundations of clinical care rather than bypassing them.

Question 6

Where have AI tools met or exceeded expectations and where have they fallen short?

AI in clinical care has shown genuine promise in specific applications, but the field remains early and the evidence mixed.

Areas of Demonstrated Value

A Lancet Digital Health review of 86 randomized controlled trials found roughly 81% reported favorable results, with successes in adenoma detection during colonoscopy, reduced acute care utilization during radiation therapy, and improved postoperative pain management. In cardiovascular medicine, AI-assisted echocardiographic interpretation has matched or outperformed physicians in ejection fraction estimation. NLP-based documentation tools are improving efficiency and addressing clinician burnout.

Where Results Are Equivocal

A 2024 JAMA Internal Medicine study of an AI deterioration model across nearly 9,000 inpatients found a 10.4% reduction in composite escalation outcomes but no statistically significant reduction in mortality. Changing escalation patterns is not the same as improving survival. Much of AI's current demonstrated utility falls within operational domains—documentation, coding, scheduling—which represent useful improvements but not transformative advances in patient care.

Highest-Potential Applications

The most promising applications provide actionable intelligence within professional clinical workflows: AI-assisted coronary physiology assessment, real-time procedural guidance, predictive analytics for cardiac decompensation, and automated quality tracking. These tools share a common structure—AI generates clinically relevant information, and the licensed professional decides what to do with it. That structure is where AI delivers the most value: augmenting professional judgment at moments of high consequence.

CT-derived fractional flow reserve (FFR-CT) offers a concrete example. This AI application has reduced the need for invasive diagnostic angiography in patients with stable chest pain—sparing patients an unnecessary procedure while preserving diagnostic accuracy. Its adoption succeeded because it was clinically validated, integrated into existing referral workflows, and interpreted by the treating physician. That pattern—validated, integrated, physician-interpreted—is replicable across clinical domains and should inform how HHS thinks about scaling AI adoption more broadly.

An important caveat: many studies are single-center, evaluate narrow populations, and have not been replicated at scale.

Question 7

Which roles have the most influence on AI adoption, and what are the primary administrative hurdles?

AI adoption decisions involve multiple stakeholders: CMOs who define clinical appropriateness, CIOs who control integration, quality officers who oversee monitoring, and finance leadership who evaluate ROI. The challenge is that these roles often operate in parallel rather than in coordination, and the stakeholders who bear professional accountability for patient outcomes—the clinicians—are not always central to adoption decisions.

Administrative hurdles include procurement processes designed for static equipment rather than dynamic software, compliance frameworks that do not account for continuous-learning systems, and institutional review processes lacking AI-specific expertise. The most consequential barrier may be structural: when AI adoption is led by technology or administrative functions without integrated clinical governance, the resulting tools may meet operational specifications but fail to align with the professional standards and workflows that govern patient care.

Question 8

Where would enhanced interoperability widen market opportunities, fuel research, and accelerate AI development?

Most healthcare data exist in silos. For AI to achieve its potential, interoperability must create a unified landscape where high-quality data drives development, validation, and responsible deployment.

High-Value Data Types

Interoperability yields the greatest impact with heterogeneous, multi-modal datasets: standardized EMR data for risk prediction; unstructured clinical text for NLP training; imaging and waveform data—particularly DICOM data, ECGs, and hemodynamic tracings—for diagnostic and predictive AI in cardiology and critical care; genomic data for precision medicine; and real-world evidence from claims data and remote patient monitoring for longitudinal outcome tracking.

Essential Standards

Fast Healthcare Interoperability Resources (FHIR) is essential for real-time clinical data exchange. The OMOP Common Data Model enables cross-institutional research. SNOMED CT and LOINC provide the semantic consistency needed for generalizability. Specialized standards—GA4GH for genomics, CDISC for clinical trials—bridge research and routine care.

Benchmarking and Validation

Public datasets like MIMIC and eICU serve as benchmarks. Federated learning enables privacy-preserving training across institutions. When health systems adopt the USCDI, vendors can demonstrate external validity more readily. However, interoperability accelerates scale, and scale without appropriate governance accelerates risk. Clinical professionals must guide both the technical standards and the appropriateness of how shared data are used in algorithm development.

Question 9

What challenges do patients and caregivers wish to see addressed, and what concerns do they have?

Patients and caregivers support AI if it improves access, coordination, and quality without increasing costs or creating new barriers. Their priorities include earlier detection, more personalized treatment, better care coordination, and improved communication with their providers.

Their concerns center on the same professional relationship that structures the rest of their care. Patients trust their physician—a trust built on the knowledge that this person is trained, licensed, accountable, and personally invested in their outcome. AI that strengthens this relationship is welcome. AI that interposes an opaque algorithmic layer between patients and their clinicians—through chatbot triage systems, automated denials, or decision tools that function without professional oversight—is not.

Privacy is a paramount concern. Patients expect their health information will not be used beyond their direct care without meaningful consent. Regulatory safeguards should prevent arrangements where technology companies independently control clinical decision-making, data infrastructure, and commercial platforms in ways that create conflicts of interest.

AI should reduce the administrative burdens that already frustrate patients and clinicians—streamlining prior authorization and claims processes, not worsening them—while preserving human oversight, patient autonomy, and equitable access.

Question 10

Are there specific areas of AI research that HHS should prioritize?

10a. Published Findings on AI Impact in Clinical Care

A growing body of peer-reviewed evidence evaluates AI in clinical care. The Lancet Digital Health review of 86 RCTs found broadly positive results in gastroenterology, oncology, and symptom management. In cardiovascular care, AI-assisted echocardiography has matched physician performance in ejection fraction estimation, and AI risk predictions provided directly to patients improved specialist referral adherence.

Many studies are single-center and have not been replicated across settings. Generalizability remains a limitation. A clear regulatory framework, combined with specialty society guidance, may help narrow the gap between technological capability and responsible clinical adoption.

10b. Literature on Costs, Benefits, and Transfers

Published analyses generally project positive cost-effectiveness from improved diagnostics and reduced unnecessary procedures. However, the majority are model-based rather than derived from real-world implementations, and results vary by analytical perspective. Deploying AI based on modeled projections alone, without real-world validation, raises concerns about liability and research ethics. HHS should prioritize funding for pragmatic implementation studies that evaluate AI as it is used in actual clinical practice, within the professional workflows where these tools will ultimately succeed or fail.

Summary

AI has meaningful potential to improve clinical care, and SCAI supports its responsible adoption. Our recommendations reflect a single organizing principle: clinical care in the United States is built on a professional framework of licensure, liability, fiduciary duty, and personal accountability. AI policy should work within that framework, not around it.

1. **AI should be treated as a clinical tool used by licensed professionals,** subject to the same expectations of validation, transparency, and oversight that apply to other instruments used in patient care.
2. **Reimbursement should recognize the professional work AI creates.** Physician interpretation of AI-generated data is a professional act requiring clinical training, judgment, and accountability. Payment policy should value this work accordingly.
3. **Liability should reflect who actually makes clinical decisions.** When AI contributes to a clinical outcome, accountability must be allocated based on the role each party played—giving developers appropriate responsibility and clinicians appropriate protection.
4. **Specialty societies should develop appropriate use guidance.** Professional societies understand the clinical contexts in which AI will be used because their members are the professionals who will use it. HHS should formally support these efforts, as it does with clinical practice guidelines.
5. **Transparency and post-market monitoring are practical necessities.** Labeling AI involvement in clinical care, reporting AI-related adverse events, and conducting ongoing performance surveillance are implementable steps that protect patients and build the trust necessary for broader adoption.
6. **Patients expect AI to strengthen their relationship with their physician, not replace it.** The professional relationship—built on trust, training, and personal accountability—is what patients depend on. AI that supports this relationship will be embraced. AI that undermines it will be resisted, appropriately.

The professional framework that governs clinical care is not an obstacle to AI adoption. It is the reason patients trust what happens in the exam room and the catheterization laboratory. SCAI's members are already using AI in clinical practice, and we want to see that adoption expand. We are available to work with HHS on practical guidance—drawing on the direct experience of physicians who use these tools on patients every day.