February 23, 2026

Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Assistant Secretary for Technology Policy
U.S. Department of Health and Human Services
330 C Street SW
Washington, D.C. 20201

Re: HHS Health Sector AI RFI

Submitted electronically via regulations.gov

Dear HHS Deputy Secretary and Assistant Secretary Dr. Keane,

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Department of Health and Human Services' Request for Information, *Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care*, regarding the adoption and use of artificial intelligence (AI) in clinical care. We are encouraged by the Department's decision to approach this effort as a cross-agency collaboration with ASTP/ONC.

HIA is a diverse coalition of patient advocates, specialty care providers, and technology companies who support the commonsense use of data and technology to improve health outcomes and lower costs. For nearly two decades, HIA has advanced a risk-based, innovation-forward approach to health technology policy, grounded in patient benefit, interoperability, and market competition.

Artificial intelligence provides significant benefits in clinical care outcomes and efficiency. Encouraging AI use in federal health programs for clinical care would spark widespread patient outcome improvements, provider productivity increases, and reduction in physician burnout and total cost of care. Federal policy should align incentives to support those measurable outcomes without being tied to abstract deployment goals.

Patient and Provider Outcomes as the Anchor for AI Policy

AI-enabled tools are currently deployed across the patient life cycle and are actively reducing friction in care coordination.[1,2,3] Administrative applications (billing automation, fraud detection, and workflow optimization) can reduce documentation burden and free clinicians to focus on patient care. In drug and device development, we are seeing improvements in clinical trial design, patient recruitment, and post-market surveillance that are attributable to AI models.[4,5,6] These use cases illustrate new opportunities for patients and care delivery. But they also underscore an important principle: AI adoption must be grounded in measurable improvement.

    i.   Patient benefit, including improved access, earlier detection, and more personalized care

    ii.   Provider impact, including reduced administrative burden and enhanced clinical decision support

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See, for example:

[1] Evaluating sepsis watch generalizability through multisite external validation of a sepsis machine learning model | npj Digital Medicine

[2] A systematic literature review of predicting patient discharges using statistical methods and machine learning | Health Care Management Science | Springer Nature Link

[3] Expanding care coordination in an integrated health system through causal machine learning | npj Digital Medicine

[4] The potential of artificial intelligence in pharmaceutical innovation: from drug discovery to clinical trials | Pharmaceuticals

[5] Post-market surveillance of medical devices using AI | J Complement Altern Med Res pg 111.

[6] Harnessing the AI/ML in drug and biological products discovery and development: the regulatory perspective | Pharmaceuticals

iii.   Systems efficiency, including reductions in total cost of care

These lenses reflect HIA's previously adopted principles for the use of artificial intelligence in health care and life sciences:

- **Risk-Based Approach:** Regulation of AI in health care should be proportionate to risk.

- **Transparency:** Patients, users, and regulators should have access to meaningful information about how AI technologies are being used, without mandating disclosure of proprietary information.

- **Privacy:** Any use of health information by AI must comply with existing laws and regulations, including HIPAA.

- **Responsibility:** Developers and users of AI programs in health care should adopt and adhere to best practices and oversight processes.

- **Fairness:** AI tools should mitigate bias and be available for all users, not just those who can afford them.

These principles provide the foundation for how HHS should approach reimbursement, interoperability, evaluation, and research policy in the clinical space.

Barriers to AI adoption are no longer primarily technological; adoption of AI tools in federal programs lags because of a lack of formal payment pathways to encourage their use and constraints from data fragmentation. As the federal government seeks to accelerate adoption of AI in clinical care, it must address these structural barriers head on.

Reimbursement and Incentive Alignment as the Primary Adoption Lever

Reimbursement materially influences whether innovation is widely deployed and how it is used. Across our membership, there is broad agreement that incentive alignment is the most powerful federal lever for accelerating responsible AI integration into the broader health care system.

In volume-based environments, specific productivity gains and associated cost of delivering care reductions are not reflected in current reimbursement frameworks. In risk-bearing arrangements, savings may accrue primarily to managing entities, not patients or taxpayers. These dynamics can create uncertainty for innovators and care delivery organizations seeking to deploy accessible AI tools.

HIA does not endorse a single payment architecture but instead believes that:

1. AI-enabled innovation should be viable in traditional Medicare, Medicare Advantage, Medicaid managed care, accountable care arrangements, and commercial markets alike.
2. Improvements in care delivery should be portable across payment models and not confined to reimbursement structures.
3. Federal policy should ensure that reimbursement in cross care and dual coverage environments will recognize measurable improvements in outcomes, access, and efficiency without favoring one care delivery model over feasible technology-enabled care improvements.

These ideas are developed below.

Expand CPT Pathways Where Appropriate

Where AI materially enhances a covered clinical service or enables new forms of care management, HHS should work with relevant stakeholders to ensure that coding and reimbursement pathways reflect enhanced services. This does not require developing new reimbursement codes for software as a standalone product.

Instead, the Department should reward AI-enabled services that require additional clinical oversight, infrastructure, or workflow redesign that is not adequately captured under Current Procedural Terminology code set. Clear and predictable coding pathways reduce uncertainty and encourage responsible deployment tied to measurable service improvement.

Recent developments in Remote Physiologic Monitoring (RPM) illustrate how CMS can design payment structures that align incentives with high-value, digitally enabled care. Introduced in 2019, CPT codes 99453, 99454, 99457, and 99458 have seen utilization increase more than fourfold.[7] Payment policy clearly influenced adoption during a period of Medicare coverage expansion (amidst the COVID-19 pandemic), underscoring nuances in provider demand, and driving reimbursement discussions regarding targeting, documentation standards, and value under fee-for-service payment. RPM uptake provides a practical template for how future AI-enabled services can be incorporated into the CPT framework. HIA supports thoughtful refinement of reimbursement pathways when new technologies materially enhance care delivery, such as many applications of AI. The coalition believes that HHS should expand reimbursement pathways where appropriate to recognize AI-enabled services that demonstrably improve patient outcomes and integrate seamlessly into existing care delivery structures. Targeted updates to CPT provide innovators with predictable reimbursement clarity tied to measurable value and lead to greater uptake.

Coding infrastructure is evolving to better capture AI-enabled services that produce clinically meaningful outputs. HHS should continue engaging with stakeholders to ensure that these pathways support measurable service improvement, promote consistency across payment environments, and provide innovators with predictable reimbursement clarity. Inadequate space for new procedures and lack of specificity are fundamental limitations of CPT. Expanding AI enabled care through new reimbursement codes would be easier, more logical, and better designed under an ICD10 PCS framework. PCS is open source and in the public domain, which avoids administrative costs associated with CPT. ICD-10-PCS is based on a uniform alphanumeric seven-character multi-axial structure with clear definitions of the core terminology used in the code descriptions. Each character of an ICD-10-PCS code represents a specific clearly defined concept and would more easily and logically expand AI-enabled clinical care into the physician office space (beyond hospital inpatient) in Medicare and other programs. HIA welcomes the opportunity to provide input as these frameworks mature.

AI-Inclusive Bundled and Episode-Based Payments

AI applications improve efficiency and reduce administrative obstacles. For example, ambient documentation tools shorten time spent on paperwork. Clinical decision support tools reduce duplicative testing and improve diagnostic precision. Remote monitoring and predictive analytics help prevent avoidable admissions. AI-enabled intake and scheduling systems streamline care delivery. Bundled payments and chronic care models offer flexibility to integrate AI tools that reduce complications, improve adherence, and enhance coordination.

HHS should emphasize that AI-enabled workflow improvements are permissible within existing and future bundled and value-based arrangements (DRGs, APCs, MSSP, and CMMI accountable care models). A clear message should be delivered to care delivery systems that are considering using AI tools: payment models will continue to reward outcome improvement and efficiency. Federal reimbursement structures should not inadvertently favor legacy, site-based delivery assumptions when high-quality care can be delivered through distributed, virtual, and hybrid models supported by AI.

The Center for Medicare and Medicaid Innovation should explicitly allow testing AI-enabled care models across Medicare and Medicaid populations. Demonstrations should focus on areas of highest need and opportunity in chronic disease management, documentation processing, and technology-enabled integrated care models, including those that build upon the ACCESS initiative. Pilots without demonstrated improvements should sunset accordingly and should have no ramp to permanent entitlements.

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[7] Rapid Growth Of Remote Patient Monitoring Is Driven By A Small Number Of Primary Care Providers | Health Affairs

CMMI demonstrations allow providers and innovators to share in savings generated through measurable improvements while maintaining appropriate beneficiary protections.

CMMI Demonstrations and Transitional Add-On or Pass-Through Payments

In certain contexts, temporary add-on or pass-through payments will accelerate responsible adoption. The New Technology Add-on Payment (NTAP) designation enhances reimbursement for services based on:

- Newness
- Cost not recognized in traditional payment pathways
- Easily demonstrable and substantial clinical improvement

CMS has created alternative NTAP approval pathways that could be enhanced to include a new alternative pathway for AI assistive technologies. For AI, we suggest adding new categories of burden reduction, access expansion, or outcome and patient engagement improvement metrics as qualifiers for AI NTAP classification and create flexibility around the FDA marketing requirement.

Catalysts for evidence generation must fasten support to measurable enhancement. CMS should specifically engage stakeholders through the annual NTAP process to encourage AI model applications for alternative NTAP pathways.

Interoperability and Information Blocking Enforcement as Safety Infrastructure

AI tools depend on access to complete and timely patient data to generate clinically meaningful outputs. When electronic health information is incomplete, delayed, or fragmented across systems, model performance degrades and patient risk increases.

Interoperability is the foundational infrastructure for safe and effective AI in clinical care. Incomplete longitudinal records jeopardize patients through elevated clinical decision support error risk, imaging misinterpretation, medication contraindication oversight, and treatment misalignment. Advanced AI agents and decision-support systems require structured data that is reliably captured across care settings in real time. Document exchange alone is insufficient; AI-enabled tools depend on consistent data elements and machine-readable formats that permit algorithms to interpret clinical context accurately. Reliable interoperability also enables site-specific validation, allowing model performance to be evaluated under real-world conditions rather than inferred from training environments. Even well-validated models may degrade in real-world environments when information blocking limits lawful access to the high-quality data required for safe, accurate, and consistent performance.

Despite statutory guardrails established under the 21st Century Cures Act, information blocking remains a persistent structural barrier to data exchange. When data exchange is restricted through technical, contractual, or economic barriers, technology developers and care delivery organizations are forced to operate in fragmented environments. This reduces competition, limits innovation, and constrains patient benefit. The Administration has demonstrated an appetite for linkable longitudinal data across federal health programs, recognizing AI in clinical care depends on cross-setting patient records that allow algorithms to interpret clinical context accurately.

HIA supports these efforts and believes stronger longitudinal data linkage requires enforcement against information blocking and continued progress on interoperability standards. We are concerned many bad actors flaunt information blocking requirements because HHS enforcement has been lackluster. The Trusted Exchange Framework and Common Agreement (TEFCA) represents an important step toward expanding exchange pathways. Participation in TEFCA should increase data availability and reduce friction. However, participation alone should not be treated as a safe harbor for behavior that functionally restricts access, exchange, or use of electronic health information.

HIA urges ASTP/ONC, CMS, and the HHS Office of Inspector General to coordinate actively and use all its enforcement tools against bad actors who seek to limit interoperability that frustrates new AI tools. Without meaningful enforcement, even well-designed AI reimbursement policies will fail to deliver their intended patient benefits.

Risk-Based Evaluation and Governance

HIA reiterates its longstanding position that regulation should not be triggered solely by the presence of an algorithm. A function-based regulatory approach that treats all AI-enabled tools as inherently high-risk will chill beneficial deployment without improving patient safety.

HIA does not support the creation of a new federal AI certification regime or centralized validation body as a condition of adoption or reimbursement. Federal "seals" or technology-specific approval structures risk slowing innovation cycles in software and AI while duplicating existing authorities.

HHS should encourage the use of established governance practices that promote transparency and accountability without mandating disclosure of proprietary information. Model documentation, lifecycle monitoring, performance tracking, and drift detection can operate together to preserve accountability. Oversight should be proportionate to risk, weighing regulation against reliance level, potential of downstream harm, and context of deployment. Additionally, risk could vary for one specific AI tool depending on where and how it is deployed– any regulatory structure and oversight should take this into account.

Preserving U.S. Leadership in Health Care AI

As health agencies consider additional AI governance structures, they should avoid regulatory models that single out specific AI architectures or impose categorical restrictions without regard for use case. Some international proposals have favored static models with one-size-fits-all regulatory frameworks, rather than tailoring existing device, payment, privacy, and program integrity authorities already in place to address misuse. Many AI-enabled tools are derivative of existing processes embedded in healthcare delivery and therefore should be evaluated based on their application rather than the presence of an algorithmic component. HHS should build on current statutory and regulatory authorities across FDA, CMS, ASTP/ONC, and OIG rather than creating duplicative, technology-specific oversight structures. Federal oversight across regulating agencies is already capable of risk-based calculations that may be triggered by the clinical or administrative use case, not solely by the inclusion of an AI component. Precise, incremental improvements to existing authorities will encourage responsible innovation in return, without replicating more rigid approaches emerging in other jurisdictions.

Future regulatory frameworks must incorporate the benefits of post-deployment testing, ongoing monitoring, and drift detection that is calibrated to risk and intended use through site specific training. Clinical environments differ meaningfully in patient populations, workflow design, data completeness, and technical infrastructure. As a result, performance demonstrated in development or training environments may not fully reflect how a model performs in practice. Our membership views real-world testing and monitoring as the gold standard for performance demonstration. Training data cannot replace site-specific testing as an AI performance evaluation tool. At the same time, transparency requirements should focus on communicating intended use and known limitations to regulators, without mandating disclosure of proprietary model architectures. Protecting intellectual property while promoting meaningful performance documentation preserves incentives for private-sector investment. Maintaining America's edge in clinical AI innovation requires sustained engagement with developers and care delivery partners, while pushing back against trends from international regulatory bodies where AI applications are singled out without risk-based rationale.

Federal Research, Development, and Demonstration Pathways

Public-private partnerships, cooperative agreements, and pilot programs provide structured environments to test AI-enabled care models under real-world conditions. Integration of AI into models such as ACCESS and

other technology-enabled care initiatives can provide early signals about clinical effectiveness, operational feasibility, and beneficiary experience.

Conclusion

HIA appreciates the Department's coordinated approach to accelerating AI adoption in clinical care. AI adoption should be measured by improvements in patient outcomes, reduced administrative burden, expanded access, and lower total cost of care. When incentives are aligned, data flows freely, and governance is proportionate to risk, innovation will follow.

We look forward to continued engagement with HHS and stand ready to serve as a resource as the Department advances this important work.

Sincerely,

Joel White
President