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Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy, National Coordinator for Health Information Technology
Department of Health & Human Services
200 Independence Ave, SW
Washington, DC 20201

RE: RIN 0955-AA13

Dear Dr. Keane:

The Consumer Technology Association (CTA®) appreciates the opportunity to provide input on what the Department of Health & Human Services (HHS) can do to accelerate the adoption and use of AI as part of clinical care.

As North America's largest technology trade association, CTA is the tech sector. CTA is the trade association representing more than 1200 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. CTA's Health Division advances consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

CTA commends HHS on their leadership in advancing the use of technology, including artificial intelligence (AI) in healthcare. Through executive action and agency direction focused on promoting innovation, reducing unnecessary regulatory barriers and improving efficiency, the Administration has created an environment that supports the responsible use of AI to improve treatments, accelerate the development of new cures and lower unnecessary health care spending. CTA looks forward to continuing to work with you to realize this shared vision.

General Comments

CTA member companies are pioneering advances across the spectrum – from AI-powered continuous glucose monitors to remote patient monitoring, to the first FDA-cleared obstructive sleep apnea risk detection feature for consumer wearables. CTA is an American National Standards Institute (ANSI) accredited standards developer. To date, we have published more than 35 digital health standards including five specifically dedicated to health AI. These standards reflect a risk-based approach and are designed to be adaptable to a wide range of technologies while supporting innovation. Through the leadership of the Health AI Planning Council, we are focused on developing standards that meet the industry's needs.

Additionally, in 2025, CTA released research focused on gauging healthcare providers' (HCPs) attitudes toward and current adoption of AI. CTA's *AI's Impact and Opportunity Among Healthcare Practitioners* found:

- *AI adoption in healthcare is in its early stages and lacks formal structure*. HCPs report that AI adoption in their organizations is still early-stage, with little training, guidance or formal strategy in place. Many HCPs are independently exploring AI tools, relying on self-teaching or peer support rather than organizational direction.

- *HCPs' trust in AI is cautious and task-specific*. While providers generally trust AI, this trust is conditional and depends on the task. HCPs are more confident using AI for documentation, diagnostics (with human oversight) and predictive analysis than they are for emotionally nuanced care, ethical decisions or high-stakes judgments. They trust AI more for their own use than for patients, citing concerns about misinformation, anxiety and weakened doctor-patient relationships. Ultimately, they see AI as a tool to support — not replace — their expertise.

- *HCPs recognize AI's benefits but also significant barriers*. HCPs who currently use AI report benefits like improved efficiency and decision-making support, but they remain concerned about privacy and security (e.g., compliance with the Health Insurance Portability and Accountability Act [HIPAA], misuse of sensitive data), accuracy and reliability (e.g., incorrect information, bias), financial constraints (e.g., cost, return on investment [ROI]) and resistance to change. Without clear solutions to these issues, many are hesitant to adopt AI more broadly.

- *Alleviating providers' administrative burden is a key opportunity for AI in healthcare*. Despite efforts to streamline care, tech like electronic medical records (EMRs) and portals have added administrative burden, pulling HCPs away from patient care and contributing to burnout amid staffing shortages. Many see AI as a key solution to automate routine tasks, reduce admin time and enable more meaningful patient interactions.

- *There is a shared fear of an "AI crutch" rather than job replacement*. HCPs aren't worried about being replaced by AI but are concerned about overreliance. They fear it could erode critical thinking, foster blind trust in AI and weaken clinical skills without proper training and oversight.

- *HCPs are overwhelmingly optimistic about the future of AI in healthcare*. Despite current challenges, HCPs remain optimistic about AI's potential to boost efficiency and patient care. With proper support, they see opportunities in automation, diagnostics, post-surgical monitoring and at-home care tools.

A well-calibrated and risk-based regulatory scheme will allow developers and users of health AI to explore these modern tools with confidence, rather than increase operational burdens or create distrust of this promising new technology.

Specific Questions

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

Regulatory Fragmentation and Variability

Between state laws, federal regulations and international frameworks, innovators are facing increasing demands to comply with varied requirements. Without a federal framework, this will only become increasingly complex for developers and deployers of AI to navigate. President Trump recognized this with

his executive order, “Ensuring a National Policy Framework for Artificial Intelligence,” rightfully recognizing that a patchwork threatens AI innovation and national competitiveness. Some specific examples include:

- Patchwork of state laws: In 2025, 1208 AI-related bills were introduced across all 50 states – 145 of those were enacted into law. Already in 2026, 1422 bills across 45 states have been introduced.

- Ambiguity related to device classifications (e.g., software as a medical device (SaMD) v. wellness tools), and

- Uncertainty about the parameters of agency jurisdiction (e.g., FDA's oversight of clinical decision support (CDS) v. ASTP/ONC's oversight of predictive decision support interventions (PDSI).

Lack of Adequate Reimbursement

As White House Office of Science and Technology Policy Director Michael Kratsios said “AI technology is already enhancing the digital revolution in sectors such as health care and agriculture, and further enabling new industries such as robotics, drones, and self-driving vehicles.” Unfortunately, AI adoption in health care has been hampered by lack of predictable reimbursement policies. Since 2018, the Centers for Medicare & Medicaid Services (CMS) has requested feedback on updating Medicare payment methodology for Software as a Service (SaaS)/Software as a Medical Device (SaMD). In 2025, CTA commended CMS for recognizing that the current PE methodology does not accurately account for innovative health software technologies like artificial intelligence (AI). After eight years of feedback and consideration, we urge HHS to swiftly move to propose new updated payment methodology to better reflect that AI should not be considered “indirect costs” (administrative labor, office expenses, computer software) and if it is an FDA-approved medical device, it should be reimbursed as such. To date, FDA has approved more than 1300 AI-enabled medical devices.[1] It is past time to establish new policies that will ensure Medicare beneficiaries have access to innovative technology tools that are medically reasonable, necessary and demonstrably improve care.

Ultimately, CMS must move away from time-based reimbursement codes that incentivize inefficient clinician workflows. Payment incentives should prioritize AI tools that enhance care delivery, improve efficiency, or reduce total cost of care. CTA supports recent steps HHS has taken to support value-based payment systems as we believe this will be crucial to AI and other software-based tools reaching their full potential and utilization in the Medicare program.

Interoperability Challenges

CTA appreciates HHS’ recent focus on improving interoperability and enforcing information blocking regulations. Interoperability is essential to health AI as it allows algorithms to securely access and integrate data across disparate systems, ensuring models are accurate, unbiased, scalable and able to deliver clinically meaningful insights at the point of care. While advances in AI can overcome some past challenges in interoperability (e.g., lack of standardized data sets, inconsistent data quality), HHS must continue to support data interoperability efforts, especially enforcement of regulations against business practices that inhibit interoperability.

Clinician Perceptions

One significant barrier to the adoption of AI in health care is a persistent provider misconception that human clinicians consistently achieve the best outcomes on their own. While clinical expertise is essential, evidence

[1] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

increasingly shows that AI systems can outperform humans in specific tasks, such as early detection of conditions and pattern recognition in high-pressure environments like emergency departments, where fatigue and time constraints affect decision-making. When AI is viewed as a threat to clinical judgment rather than a complementary tool, opportunities to improve diagnostic accuracy, patient safety, and efficiency are often missed. In the United States, an estimated 795,000 patients become permanently disabled or die annually across care settings because dangerous diseases are misdiagnosed.[2] By prioritizing AI tools that improve front-end diagnostic quality particularly in high-acuity environments like emergency departments, HHS can help mitigate preventable harm. Evidence from industry leaders demonstrates that clinical AI can improve disease detection by as much as 81.5% and accelerate time-to-treatment by up to 90%, transforming AI from a mere efficiency tool into a vital infrastructure layer for patient safety.

2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.

Federal Harmonization and Regulatory Certainty

HHS should establish clear jurisdictional lines for health AI within the agency as well as with other federal agencies to reduce fragmentation and confusion. For example, to resolve jurisdictional ambiguity between FDA and ASTP/ONC, the agency should make clear its oversight responsibilities for CDS and the ASTP/ONC's oversight of predictive decision support interventions (PDSIs) integrated into electronic health records. This will help prevent duplicative and potentially contradictory requirements for health technologies. Further, recognizing that not all health AI applications will fall fully under HHS' jurisdiction, HHS should also coordinate with other federal agencies such as NIST and the FTC.

Modernizing and Clarifying Reimbursement

As CMS itself has recognized, it is inappropriate to categorize AI as "computer software" and therefore indirect PE. However, moving AI to direct PE will also not be adequate for AI reimbursement. Currently, RVUs consider the professional work of a provider or clinical staff to calculate direct PE. We are quickly reaching a place where clinical work will be replaced by AI. HHS should convene stakeholders to modernize and update the RVU considerations. In addition to clinical work, AI is also transforming provider administrative tasks. HHS should clarify how AI outputs can be documented and counted toward existing service requirements (e.g., time, data review, clinical decision support).

3. For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?

There are current gaps with existing governance and accountability structures, including:

- *Unclear Roles & Responsibilities:* Roles and responsibilities for errors are often unclear across the developer and deployer. This is complicated more by issues discussed above, including conflicting state laws and requirements.

[2] Newman-Toker DE, Nassery N, Schaffer AC, Yu-Moe CW, Clemens GD, Wang Z, Zhu Y, Saber Tehrani AS, Fanai M, Hassoon A, Siegal D. Burden of serious harms from diagnostic error in the USA. BMJ Qual Saf. 2024 Jan 19;33(2):109-120. doi: 10.1136/bmjqs-2021-014130. PMID: 37460118; PMCID: PMC10792094.

- *Post-Market Monitoring:* Similarly, there are not widely accepted protocols for how AI should be monitored after it is deployed.

- *Gaps in Privacy Protections:* The current privacy framework – rooted in the Health Insurance Portability and Accountability Act (HIPAA) – is outdated and incomplete. Many consumer-facing digital health manufacturers and deployers are not considered covered entities under HIPAA and often are not subject to business associate agreements with a HIPAA covered entity.

To address these gaps, HHS should focus on developing a risk-based framework that leverages existing regulatory authority, promotes transparency, industry best practices and standards, and is focused on AI applications.

4. For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (e.g., contracts, grants, cooperative agreements, and/or prize competitions)?

As an American National Standards Institute (ANSI) accredited standards development organization, CTA is helping advance the use of AI in healthcare by driving industry consensus. To date, CTA's Artificial Intelligence Committee has already developed several health AI standards, including:

- Performance Verification and Validation for Predictive Health AI Solutions (ANSI/CTA-2135)

- Definitions/Characteristics of Artificial Intelligence in Health Care (ANSI/CTA-2089.1)

- The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)

- The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)

We would welcome HHS' involvement in CTA's standards development process, as well as how CTA standards can help support HHS' health AI frameworks.

5. How can HHS best support private sector activities (*e.g.,* accreditation, certification, industry-driven testing, and credentialing) to promote innovative and effective AI use in clinical care?

As mentioned, HHS should establish a baseline regulatory framework focused on AI applications that promotes responsible development, transparency, post-market monitoring, and risk management. HHS has a clear role to play to set baseline "rules of the road." In response, HHS should work with industry to build off of these baseline standards with industry consensus-based standards that can be more reactive to quickly evolving technology like AI.

8. Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking tools.

Enhanced interoperability focused on cancer data, genomics and imaging data would help widen opportunities, fuel research, and accelerate the development of AI. This would enable researchers and developers to link datasets that are currently siloed across institutions and platforms, ultimately improving translational research by enabling faster validation of biomarkers, treatment response prediction and real-

world evidence generation, ultimately shortening the path from discovery to clinical deployment and improving cancer prevention, diagnosis and care.

Conclusion

CTA appreciates the opportunity to respond to the Request for Information on Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care. We look forward to continuing to work with you to advance the adoption of AI in healthcare to increase efficiency, lower costs and improve patient outcomes

Sincerely,

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