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February 23, 2026

Dr. Thomas Keane
Assistant Secretary for Technology Policy
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street S.W.
Washington, DC 20201

Submitted electronically via regulations.gov

> Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care [RIN 0955-AA13]

Dear Assistant Secretary Keane:

The Academy of Managed Care Pharmacy (AMCP) thanks the Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology (ASTP/ONC) and the Department of Health and Human Services (HHS) for the opportunity to provide comments in response to the "Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care [RIN 0955-AA13]."

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Artificial intelligence has the potential to meaningfully improve clinical decision-making, care coordination, and administrative efficiency across the health care system. However, realizing these benefits at scale requires a policy environment that balances innovation with patient safety, clinician accountability, and equity. Despite significant private-sector investment and rapid technological advancement, adoption of AI in clinical care remains uneven and constrained by regulatory uncertainty, fragmented data infrastructure, unresolved governance questions, and misaligned payment policies. Addressing these barriers will be essential to ensuring that AI is deployed responsibly, supports clinical judgment, and delivers measurable value to patients, clinicians, and payers.

Barriers to Innovation and Adoption

Adoption of artificial intelligence (AI) in clinical care has accelerated rapidly, often outpacing clinicians' capacity to integrate these tools safely and effectively. Global AI spending is

projected to reach $2.5 trillion in 2026,[1] underscoring both the scale of investment and the urgency of addressing adoption barriers. The most significant obstacle is concern about patient harm and professional liability when AI-generated recommendations diverge from clinical judgment. Regulatory ambiguity around the boundary between clinical decision support and regulated medical devices further discourages developers and health systems. Clinicians also face practical challenges related to clinical workflow integration, interoperability, safeguarding data, and reimbursement. Many AI applications with demonstrated technical promise fail to scale or generalize across care settings because no established reimbursement framework exists to support their routine use in clinical care.

Regulatory, Payment, and Programmatic Priorities

AMCP urges HHS to clarify regulatory boundaries across FDA, ONC, and CMS to reduce uncertainty and promote responsible innovation. Clear, coordinated guidance distinguishing non-device clinical decision support from Software as a Medical Device would reduce adoption risk under existing frameworks (e.g., 21 CFR Parts 800–898; 45 CFR §170.315). Modernization of payment policy is also essential to support appropriate clinical use of AI. Medicare and Medicaid should better recognize and reimburse AI-enabled services that improve diagnostic accuracy, efficiency, and quality, including through updates to 42 CFR Parts 410 and 414 and alignment with value-based programs such as the Medicare Shared Savings Program (42 CFR Part 425).

Support for Private Sector Innovation

HHS can best support private sector innovation by enabling, rather than duplicating, industry-driven accreditation, certification, and testing frameworks. Endorsing consensus-based standards for model validation, bias assessment, and post-deployment monitoring, developed in collaboration with standards-setting organizations, would promote safe and effective AI use while avoiding unnecessary regulatory duplication and preserving flexibility for innovation.

Governance and Administrative Hurdles

Within health care organizations, adoption decisions are most influenced by clinical informatics leaders, quality and safety executives, and medical governance bodies. Effective AI governance models should be distinct from typical data governance and have rely on clearly defined, rigorously tested frameworks to ensure appropriate data stewardship, oversight, and accountability.

Administrative hurdles, including procurement processes, privacy and security compliance under HIPAA (45 CFR Parts 160 and 164), challenges integrating AI tools into electronic health record (HER) systems, workforce concerns relating to job displacement, implementing education and training programs, and the absence of mature governance models to support AI oversight and accountability, further impede adoption.

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[1] Gartner, Press Release: Gartner Says Worldwide AI Spending Will Total $2.5 Trillion in 2026 (Jan. 2026). Available at https://www.gartner.com/en/newsroom/press-releases/2026-1-15-gartner-says-worldwide-ai-spending-will-total-2-point-5-trillion-dollars-in-2026

Interoperability and Data Access

Enhanced interoperability is foundational to advancing the safe and effective use of AI in clinical care. Expanded access to longitudinal, multi-setting data, including unstructured clinical notes, imaging metadata, and outcomes data, would broaden market opportunities and accelerate the development and evaluation of AI tools. Limited availability and standardization of unstructured data is a significant constraint on AI applications in health care.

Gaps in clinical data, often driven by beneficiary movement across plans or care settings, can impede clinician access to critical information at the point of care. In these circumstances, clinician judgment remains essential to contextualize incomplete data and should not be supplanted by AI-generated recommendations. Continued advancement of HL7 FHIR, expansion of the United States Core Data for Interoperability (USCDI) (45 CFR §170.213), and the development of standardized benchmarking datasets are therefore essential to support interoperability, improve data continuity, and enable responsible AI deployment.

Patient and Caregiver Considerations

Patients and caregivers are most receptive to AI solutions that improve access, accuracy, personalization, and continuity of care while reducing administrative burden. Importantly, patients expect AI to support, but not redefine, their role in clinical decision-making. Applications such as ambient or live AI clinical documentation tools can strengthen the clinician-patient relationship by allowing clinicians to focus on patient engagement rather than documentation, thereby enhancing the care experience. Patient experience may also be meaningfully improved when AI streamlines administrative processes such as prescription refills, prior authorization, and scheduling.

At the same time, patients and caregivers have expressed persistent concerns regarding data privacy, bias, transparency, and the potential erosion of the clinician–patient relationship. Successful AI adoption must therefore augment, rather than replace, human clinical judgment and preserve the relational aspects of care.

Research and Evidence Base

HHS should prioritize research addressing generalizability across populations and care settings, bias identification and mitigation, human–AI interaction, post-market surveillance, and the impact of AI on clinician workload and burnout. While existing literature demonstrates performance gains in narrow or task-specific applications, evidence remains limited regarding long-term clinical outcomes, health equity implications, and system-level cost savings. Economic analyses should more explicitly examine how costs, benefits, and risk are distributed across clinicians, health systems, and payers to inform sustainable adoption and appropriate payment policy.

Conclusion

Taken together, these considerations underscore the need for a coordinated federal approach that clarifies regulatory expectations, strengthens interoperability and data continuity, supports appropriate governance models, and modernizes payment policy to reflect the realities of AI-enabled care. HHS is uniquely positioned to enable this progress by aligning the roles of FDA, ONC, and CMS; endorsing consensus-based standards; advancing evidence generation; and ensuring that reimbursement and value-based programs appropriately recognize clinically

meaningful AI applications. With thoughtful policy design, AI can be integrated into clinical care in a manner that enhances quality, protects patients, supports clinicians, and promotes sustainable innovation across the health care system.

AMCP appreciates your consideration of AMCP's concerns and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer