February 23, 2026

Office of the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW, Washington, DC 20201

Submitted electronically at www.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:

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Request for Information regarding actions the Department of Health and Human Services (HHS) can take to accelerate the adoption of artificial intelligence (AI) in clinical care.

ASCO represents more than 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are committed to ensuring that AI-enabled discoveries are translated into equitable, evidence-based tools that lead to improved patient outcomes available to all patients.

ASCO appreciates the "OneHHS" approach that coordinates a unified, division-wide AI strategy to eliminate information silos and promote the transformative potential of AI. Our support for this unified strategy is deeply rooted in our own foundational work. In May 2025, ASCO issued principles for the responsible use of AI in oncology which we believe provides a compatible roadmap for a coordinated federal framework.[1]

ASCO offers the following recommendations and detailed responses to HHS' questions:

Q1: What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

Promote Regulatory Alignment. ASCO believes that the absence of a flexible

[1] https://cdn.bfldr.com/KOIHB2Q3/as/g5jsnp7g2b6m28j67j97smff/2025-ASCO-AI-Principles

federal regulatory framework remains a primary barrier to innovation. In the current environment, a patchwork of state laws and legal challenges is emerging that may interfere with federal AI action plans and limit the competitive intent of AI adoption in clinical care. ASCO urges HHS to support nimble regulatory mechanisms that address AI's risks while enabling a more efficient, accessible, and affordable health care system. We urge HHS to work collaboratively with all stakeholders to advance a flexible regulatory approach that prioritizes the health and well-being of patients.

Eliminate Data Silos and Improve Technical Interoperability. The limited ability to curate large, complex data sets remains a major impediment to the accuracy of AI systems. To fully recognize the potential of AI in clinical care, we must address existing interoperability gaps across the entire health information technology (HIT) continuum. Massive volumes of high-quality data are required to support AI reliability; currently, limited or poor-quality data sets can lead to suboptimal model performance and research conclusions that perpetuate inaccuracy. While electronic health records have improved data collection, we must incentivize data sharing across the care continuum, including community practices, academic settings, laboratories, and payers to derive new clinical insights and improve the efficiency of care delivery.

Leverage Privacy-Enhancing Technologies (PETs) for Data Exchange. To overcome the technical hurdles inherent in large-scale data sharing, ASCO recommends that HHS leverage PETs, such as federated learning and differential privacy. These technologies enable the analysis of decentralized medical data without the need to move raw patient information, effectively bypassing the interoperability bottlenecks that currently stifle multi-institutional research. Overall, HHS should pursue a comprehensive use of real-world data and real-world evidence (RWD/E) by leveraging insurance claims, patient registries, and digital health solutions through these secure, decentralized frameworks.

Address Resource Constraints. Implementation costs remain prohibitive for many oncology practices. While broad adoption could lead to systemic savings, there is limited economic analysis of AI's financial impact on individual organizations. Existing modeling methods and reporting standards may be insufficient to assess cost-effectiveness, creating an AI digital divide where only resourced institutions can afford cutting-edge tools, potentially affecting rural and underserved populations. Closing the technological gap for small and rural practices will require dedicated funding and the technical infrastructure necessary for sustainable AI integration must be prioritized.

Confront Validation and Evaluation Challenges. ASCO urges HHS to support the creation of robust evaluation tools rooted in harmonized data governance and accountability frameworks. To bridge the gap between high-level federal oversight and practical clinical application, HHS should encourage researchers to adhere to established international guidelines, such as SPIRIT-AI and CONSORT-AI. These standards ensure that clinical trials for AI systems are as transparent and reproducible as those for traditional medical interventions. In exploring pre- and post-deployment evaluation, HHS should explore the use of digital twins and synthetic data. HHS might also consider standardized documentation methods like applied model cards or AI "nutrition labels" to provide technical clarity on model performance and limitations.

Q2: 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.

Mandate Transparency and Oversight of AI Tools. HHS must prioritize rigorous transparency mechanisms and oversight of AI tools, particularly those used by payers for prior authorization. Current regulations are insufficient on their own to protect consumers from "black box" payer algorithms that can lead to accelerated claims denials and delays in lifesaving care. These mandates incentivize effective AI by shifting the market toward high-value, explainable AI. When payers are required to cite the specific clinical evidence and data sources used by an algorithm, it incentivizes the development of AI that prioritizes accuracy over cost-containment.

To ensure patient safety, ASCO recommends that HHS implement frameworks for regular auditing of training data sets and mandate that payers cite all evidence used by AI in reaching coverage determinations. Furthermore, regulatory agencies should conduct continuous monitoring to detect if AI tools are being used to disproportionately deny specific types of care. It is essential that any AI-derived denial is immediately escalated for clinical peer review, ensuring that automated efficiency never overrides professional medical opinion. This oversight must extend to third-party vendors to prevent payers from exploiting liability loopholes through external partnerships.

Strengthen Post-Market Surveillance. ASCO's principles assert that clinician comfort with AI tools depends on continued evidence of safety and effectiveness. Currently, the FDA has limited ability to monitor technology once it's on the market, complicated by the potential for AI model degradation or drift. We urge HHS to address resource restraints within the FDA and support reporting mechanisms that monitor AI performance throughout its lifecycle, including the deployment of regulatory sandboxes and/or assurance labs for transparent and localized testing.

Q3: 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?

Clarify Legal Uncertainty. Liability and uncertainty serve as a significant deterrent to clinical adoption. Physicians are less likely to use AI in high-complexity cases when they perceive a risk of malpractice liability for deviating from an algorithm. The fundamental responsibility for treatment decisions remains with clinicians, and this must be understood by all users of AI technologies. To address this, HHS should play a proactive role in addressing novel accountability structures. ASCO recommends that HHS explore the establishment of legal "safe harbors" for providers who use AI tools certified through HHS-approved

assurance labs or sandboxes. This would mitigate the malpractice fears that currently hamper the integration of non-device clinical decision support tools into routine care.

Q5: How could HHS support accreditation, certification, or credentialing for the development and use of AI in clinical care?

Support the Workforce through AI literacy. To mitigate the risk of clinician deskilling, HHS should collaborate with medical societies to develop AI-literacy benchmarks and credentialing. Providing clinicians with the tools to critically audit AI outputs can ensure that human expertise remains the primary safeguard in oncology. HHS could also support a federal certification program for AI tools that can be validated against diverse, representative data sets that reflect the unique local and demographic contexts of specific communities in which AI tools are deployed.

Q8: 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.

Prioritize Adoption of Technical Data Standards. To accelerate AI development in oncology, HHS should prioritize adoption of minimal Common Oncology Data Elements (mCODE) and Fast Health care Interoperable Resources (FHIR) standards for all AI-enabled health information exchange. Mandating these universal technical standards through financial leverage will compel EHR vendors to eliminate data silos and create a common language for disparate systems. This approach reduces the manual burden of data abstraction, allowing AI developers to scale innovations more rapidly across diverse clinical sites. While FHIR provides the building blocks for interoperability, HHS must address implementation gaps to ensure high-quality data is readily accessible.

Q9: What challenges within health care do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care?

Bridge the AI Digital Divide. ASCO believes that the integration of AI in clinical care must be fundamentally patient-centered, focusing on bridging the AI digital divide to ensure that technological advancements do not inadvertently widen existing gaps in access to care. This divide is primarily driven by the risk that algorithms trained on non-representative or high-resource datasets will scale skewed data points, leading to inappropriate interpretations for underserved, rural, and diverse populations who are frequently excluded from the data lifecycle. It is essential that HHS proactively incentivizes the deployment of these technologies in community oncology practices and rural settings, ensuring that innovative AI tools do not remain concentrated solely at well-resourced academic medical centers.

Q10: Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

Prioritize AI Research for Clinical Integration. ASCO recommends that HHS prioritize research that fosters a comprehensive real-world data framework and focuses on human-in-the-loop interactions.

This includes implementation science research to evaluate the longitudinal impact of AI on the oncology workforce, specifically identifying and mitigating deskilling among early-career clinicians. We must develop proficiency benchmarks to ensure that while AI enhances efficiency, the fundamental diagnostic precision of the oncologist is preserved. Furthermore, HHS should fund the development of deflationary AI technologies, such as AI-assisted clinical trial matching, that integrate seamlessly into EHRs and reduce administrative burden.

Ensure Collaborative Research and Development and Safety Safeguards. HHS should pursue collaborative development through mechanisms such as Cooperative Research and Development Agreements (CRADAs) to integrate AI into care delivery. These partnerships are essential for scaling innovation, but they must be coupled with strict safety safeguards as we move toward more complex systems. While ASCO supports innovation in semi-autonomous or agentic AI, these transitions should be approached with extreme caution to ensure that fully autonomous systems do not replace sensitive clinician-patient interactions. Consequently, any agentic AI used in oncology must not be permitted to autonomously perform clinical functions or modify prescriptions without the direct, final approval of a clinician.

Conclusion

AI has the potential to make clinical recommendations and decision support readily available to every clinician, thereby smoothing unwarranted variations in care and enabling all patients to receive high quality, evidence-based care. In addition to improving outcomes, AI could also eliminate cost of unwarranted variation--for all stakeholders. ASCO appreciates the opportunity to provide feedback on this critical request for information. As the use of AI continues to expand within oncology, it is imperative that federal strategy remains grounded in clinical evidence, transparency, and the protection of the patient-clinician relationship. We look forward to working with HHS to ensure that AI serves as a tool for professional empowerment and improved patient outcomes across the cancer care continuum.

Respectfully submitted,

Lynn M. Schuchter, MD, FASCO
Chair of the Board
Association for Clinical Oncology