February 17, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care
90 Fed. Reg. 60108 (December 23, 2025)

Dear Secretary Kennedy:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the request for information related to accelerating the adoption and use of artificial intelligence (AI) as part of clinical care. ACS CAN advocates for evidence-based public policies to reduce the cancer burden for everyone. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. By engaging advocates across the country to make their voices heard, ACS CAN influences legislative and regulatory solutions that will end cancer as we know it, for everyone. We are providing comments through the lens of cancer patients.

There are currently more than 18.6 million Americans living with a history of cancer.[1] In 2026 in the U.S., approximately 2.1 million new cancer cases are expected to be diagnosed, and more than 626,000 people are expected to die from the disease.[1] Applications incorporating AI are being developed, and some already deployed, that can improve screening and detection, diagnosis, direct and assess treatment, and advance personalized medicine.[2] For example, integrating AI use in radiological image analysis has been shown to improve efficiency, accuracy and consistency in detection and diagnosis.[3,4] Molecular diagnostics are rapidly advancing through the integration of AI, facilitating earlier detection and treatment monitoring.[5]

Additionally, AI shows promise for enhancing care in rural areas that lack specialty providers, through the use of telemedicine, remote expert support for providers, and easing the need for local site infrastructure through automated administrative tools.[6,7] Technologies such as AI-enabled remote symptom monitoring may similarly expand access to care for rural populations and improve consistency in diagnosis and treatment.[8,9]

Although these advances show promise, practical obstacles like cost and infrastructure requirements may prevent smaller or rural health care sites from implementing these tools,[10] and it has been shown that these sites are less likely to evaluate AI tools for problems like partiality.[10] We

are also concerned about the potential negative impact of the use of AI in utilization management (including prior authorization), coverage determinations, and claims management that could impede timely access to evidence-based care.[11] In 2023, a lawsuit was filed against Cigna Healthcare alleging use of an automated AI-based system led to improper denial of hundreds of thousands of pre-approved insurance claims.[12] As the Cigna example has demonstrated, absent sufficient oversight, AI algorithms can be improperly used to deny care.

While there may be great potential for responsibly developed AI applications to improve clinical care, clinical operations, benefit patients, and improve health outcomes, AI applications should be reviewed to ensure proper safeguards for protecting patient access to medically necessary care. AI advances that help reach these goals while preserving patient safety, privacy, and access can impact patient care in positive and significant ways. Currently, patients and providers have low trust that AI will be used responsibly and that health care systems will protect patients from AI-related harms[13] – and this trust is essential for the transformative potential of AI advances to be realized.[14] This assurance requires the implementation of regulatory guardrails and guidance to ensure that clinical applications (whether provider- or patient-facing) have a transparent evidence base that confirms safety and effectiveness and that human review and oversight are included.

Regulation

Currently, a patchwork of regulations, guidance, and state laws creates a complex and potentially inconsistent system, challenging developers and providers to navigate a diverse range of requirements and potentially exacerbating inequity in access to effective AI applications and, ultimately, medical care. Individual patients may also be adversely impacted when the mosaic of laws and regulations obscures patient awareness of their rights, especially if a patient is being treated in a state different from their residence. Access to responsibly vetted, proven effective and safe AI applications may differ for patients living in different states.

We support a risk- and evidence-based approach to oversight that prioritizes patient safety and privacy, ensures that medical claims of effectiveness are verified, and is adaptable such that it can keep up with change and innovation. A clear regulatory framework should differentiate oversight based on risk. This can facilitate easier development and implementation of minimal-risk applications, such as for drug discovery and clinical trial facilitation and eligibility determinations, while focusing appropriate oversight of health care professional- and patient-facing tools such as those used for image analysis, clinical (or patient) decision support, health chatbots, and symptom checkers.

We urge the Department of Health and Human Services (HHS) to develop and implement oversight mechanisms throughout HHS agencies that require evidence of efficacy and patient safety prior to deployment, utilize appropriate validation studies of the intended use patient populations, ensure that when appropriate, use of AI tools is meaningfully disclosed to patients, specify the extent of

qualified human engagement and review while implemented, and require creation and use of effective adverse event reporting and post-approval monitoring systems across the programs and regulatory responsibilities the Department oversees. HHS should also promulgate regulations that provide clear standards as to the entity (or entities) to be held accountable in cases where AI applications result in patient harm. Any regulatory framework should prioritize patent safety and protection of patient health information.

The implementation of a clear and robust oversight framework should be conducted through a formal process with public engagement that includes a wide set of stakeholders such as patient advocates, provider groups, issuers, manufacturers, and others in the health care system. This engagement is essential for creating trust among patients and providers that AI tools are safe and effective components of their care.

For medical products reviewed by the Food and Drug Administration (FDA), the ability of AI tools to learn and adapt in real-world settings means that it is imperative that oversight require full transparency from developers, include mechanisms for ongoing feedback and monitoring during clinical use, and that the FDA create clarity around the types of changes that would and would not trigger further post-approval review.

Reimbursement

In utilization management, AI tools are already widely used to make prior authorization and coverage decisions,[15] in spite of mixed evidence that they improve efficiency, accuracy, staff experience or other metrics.[16] For example, from a patient perspective, AI could exacerbate problems with coverage claims denials: appealing a denial would be especially difficult if the basis for denial was not revealed by the AI algorithm, and/or the human operator was unable to explain the AI decision.[17]

ACS CAN encourages HHS and the Centers for Medicare & Medicaid Services (CMS) to create clear and consistent regulatory guardrails to ensure transparency and accountability when AI tools are deployed in utilization management and prior authorization processes, and provide assurance that final decisions to approve or deny care or coverage are made by qualified human professionals and based on sound evidence-based clinical judgement. These guardrails should apply formally to the federal programs that HHS oversees and be monitored for adherence across other non-governmental commercial coverage. Ongoing review systems should be put in place to monitor evolving technology and ensure that oversight remains relevant.

When the Medicare statute was written, many of today's technologies were not even imaginable, and consequently many AI tools in current use and development do not fit into traditional statutory benefit categories to qualify for coverage. Medicare coverage policies and payment pathways play a critical role in shaping patient access to these advances, determining whether beneficiaries can

receive new cancer care innovations and how quickly they can access them. Currently, there is an average 5.7-year delay between FDA approval and Medicare coverage of new technologies.[18] It is vital that CMS ensures viable, timely coverage and reimbursement pathways to prevent cost from becoming a barrier to care for patients and to incentivize investment in new technology.

AI applications are being used in all facets of the U.S. health care system – beyond the Medicare program. As HHS contemplates future action with respect to the use of AI applications, it must ensure that existing patient protections (including the appeals and exceptions process) remain a viable, human-mediated option for patients to access medically necessary services. HHS must also ensure that when making coverage determinations, regulated entities maintain human oversight over AI applications.

Research and Development

HHS has an important role in supporting the development of responsible AI, and we urge the National Institutes of Health (NIH) to take an active role in fostering research-based initiatives that can have a positive impact. The creation of clear guidance for investigators can ensure responsible and transparent use of AI in federally sponsored research and clinical trials. Public-facing tools and educational resources provided on the NIH website can help inform patients and providers. Funding from NIH can fill important gaps in research areas that would typically be unsupported by industry, such as childhood cancer and comparative effectiveness research.

AI applications can enhance almost all areas of the clinical trial lifecycle, and clear guidance and support from NIH can facilitate development of tools that improve elements such as trial design, participant identification and recruitment, decentralization of trial activities and sites, and efficient data analysis. Of course, many potential enhancements are accompanied by risks, including exacerbating disparities and concerns about patient privacy and data security, reinforcing the need for appropriate guardrails and guidance to accompany these advances.

Similarly, AI can accelerate drug discovery, research, and testing, including applications in identifying drug targets, designing and screening candidate compounds, modeling pharmacokinetics and pharmacodynamics, and streamlining and optimizing drug manufacturing. NIH can play a critical role in supporting research aspects not typically pursued by industry, such as using AI to identify additional indications for approved drugs, advancing pediatric drug development, and AI applications that guide development of clinical trial portfolios and methodology to maximize efficient testing of new drugs or uses.

Conclusion

Thank you again for the opportunity to provide comments on the request for information related to accelerating the adoption and use of artificial intelligence as part of clinical care. If you have any questions, please do not hesitate to contact Sharon Shriver, Senior Analyst at

Sharon.Shriver@cancer.org.

Sincerely,

Lisa Lacasse, MBA
President
American Cancer Society Cancer Action Network

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