U.S. SMALL BUSINESS ADMINISTRATION
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February 23, 2026

VIA ELECTRONIC SUBMISSION

The Honorable Robert F. Kennedy, Jr.

Secretary

U.S. Department of Health and Human Services

Hubert H. Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201

Re: *Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care,* 90 FR 60108

Dear Secretary Kennedy:

On December 23, 2025, the Department of Health and Human Services (HHS) requested information on how the agency can accelerate the adoption of Artificial Intelligence (AI) in the clinical care space.[1]

In this response, Advocacy highlights feedback received from small entities in the clinical care space. While small businesses are increasingly adopting AI tools, significant barriers remain.[2] Small entities raised concerns about data standardization and interoperability, access to training and education, reimbursement structures, liability and safe harbor protections, and regulatory clarity.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent voice within the executive branch that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small

[1] 90 Fed. Reg. 60108 (Dec. 23, 2025).
[2] AI in Business: Small Firms Closing In https://advocacy.sba.gov/2025/09/24/ai-in-business-small-firms-closing-in/ (Sept. 24, 2025).

entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the Small Business Administration (SBA) or the Administration.

The Regulatory Flexibility Act (RFA),[3] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[5] If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis for such a determination that adequately supports its certification.[6]
Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[7]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[8] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[9]

II. Advocacy's Response to HHS' Questions

HHS posed ten questions to seek insight on how clinicians are currently using AI and the potential consequences of AI adoption. On January 28, 2026, Advocacy hosted a roundtable with over seventy participants to solicit insight from small entities on each of HHS's questions. Advocacy summarizes those views below.

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

Roundtable participants noted multiple barriers to fully integrating AI into existing systems, such as, unreliability of data quality, lack of education and training, and an inability to fully reimburse the costs associated with AI. Healthcare, specifically, will experience significant challenges in this area.

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[3] Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[4] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).
[5] 5 U.S.C. § 603.
[6] *Id.* § 605(b).
[7] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[8] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[9] *Id.*

A. Data Standardization and Quality

High-quality, interoperable data are the foundations for effective AI. Currently, the lack of consistent data standards across specialties limits AI systems' ability to interpret and transfer insights between disciplines. For example, a surgeon, physical therapist, and neuromuscular therapist may each assess the same shoulder injury differently, resulting in data that are not compatible for cross-disciplinary analysis.

Roundtable participants noted that available AI models for clinical diagnostics are trained on data drawn primarily from adult populations aged 20–40, rendering them less reliable for pediatric and geriatric use. Expanding representative datasets would support equitable AI adoption across diverse patient populations.

Roundtable participants recommended that HHS collaborate with the National Institute of Standards and Technology (NIST) to establish data standardization guidance for clinical care specialties. Harmonized data definitions would allow AI systems to generate insights usable across the continuum of care.

B. Lack of Guidance on AI Use and Interpretation

Clinicians expressed uncertainty about how to interpret AI-generated diagnostic results or understand the algorithms' weighting of variables. As AI diagnostic tools become the norm for practitioners, clinicians need to understand how AI reaches its result since the clinician is liable for any misdiagnosis. The absence of clear guidance deters adoption due to concerns over reliability and liability.

Roundtable participants urged HHS to develop interpretive guidance and transparency standards that would allow clinicians to understand the logic and limitations of AI tools. Additionally, HHS should establish standardized criteria or metrics for evaluating the reliability and performance of clinical AI technologies.

C. Training and Education

Small clinicians reported limited opportunities for AI training and stated that lack of familiarity with AI-based diagnostics creates hesitancy to adopt new tools. Small hospitals face disproportionate barriers to accessing AI-centered training due to their lack of resources. Many small hospitals and clinical offices lack dedicated AI governance structures, legal, or technical expertise and are therefore less able to assess vendor claims, manage risk, or negotiate complex AI tools and services contracts.

Roundtable participants recommended that HHS develop educational resources or continuing education programs to train clinicians on AI integration, interpretation, and create forums where hospitals can share their experiences using AI tools. This will facilitate small clinicians to adopt AI powered tools. HHS should facilitate sharing information, advice, and cybersecurity frameworks between small clinicians.

D. Reimbursement Policies

Clinicians, particularly in small and rural practices, cited reimbursement challenges as a central barrier to AI adoption. AI tools can improve efficiency but do not currently provide direct financial benefits under existing Center for Medicare and Medicaid Services (CMS) billing codes. Without updated reimbursement methods, small clinical practices often find that the productivity gains of AI-enabled tools do not justify their significant financial costs.

Roundtable participants urged HHS to examine reimbursement structures and create codes recognizing the costs of implementing AI tools. Aligning reimbursement with time and resource savings could promote wider adoption.

E. Building Trust in AI

Clinicians voiced concern about the reliability and accountability in AI-based decisions. Clinicians and patients are reluctant to rely on AI tools that may produce errors or "hallucinations." Without reliable means to systematically check the accuracy of various AI-enabled tools, clinicians are faced with uncertainty in how to analyze the results it produces. When a clinician's medical licenses are implicated when utilizing AI, the AI-enabled devices must build trust with clinicians to assure them of the accuracy of the results. Advocacy supports HHS's efforts to expand public awareness, validation processes, and transparency standards that foster trust and understanding of AI capabilities and limitations. Roundtable participants suggested that HHS should create model datasets that small clinicians can rely on to test AI-enabled diagnostic tools.

Question 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.

A. Liability and Safe Harbor Frameworks

HHS should explore mechanisms that provide liability protection or safe harbors when health systems deploy AI tools that meet recognized national standards for validation, documentation, and governance. This may include encouraging state medical licensure boards and associations to have active conversations regarding how AI tools affect the standard of care within their state. Without such protections, the promise of AI to reduce clinician burden is undermined by the expectation that providers must independently validate or override AI outputs.

B. National AI Governance and Validation Standards

Clear federal guidance on acceptable AI risk management frameworks would accelerate adoption. To establish these management frameworks, collaboration from both clinical providers and AI tool developers is needed. Using established frameworks that have buy-in from both developers and clinical deployers would provide defensible, consistent expectations across states and health systems, reducing duplicative or inconsistent internal standards.

C. Payment Policy Alignment

CMS should expand reimbursement pathways for AI-enabled diagnostics and clinical decision support, while appropriately recalibrating payment rates. For example, reimbursing certain AI-based interpretations at a lower rate but allowing higher-frequency use could address workforce shortages while maintaining safety and access, particularly for rural or small hospitals. Roundtable participants encouraged HHS to further explore how various clinician specialists utilize the efficiency and insights gained by AI. For example, roundtable participants noted that time saved by ambient scribe technologies enabled them to spend more time with patients while other specialties such as radiology noted that certain AI tools enabled them to see more cases on a daily basis. Providing clear guidance on payment policy will enable these tools to be adopted by smaller clinical practices.

Question 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?

Roundtable participants raised concerns about AI model updates that may alter diagnostic performance without clinician notice. Small clinicians questioned who bears liability when manufacturers modify underlying AI algorithms.

For AI tools not regulated as medical devices, health systems face unresolved challenges related to liability, indemnification, data governance, and accountability. Absent Food and Drug Administration (FDA) review, health providers may benefit from the accelerated innovation. On the other hand, timely and well-executed FDA review may relieve providers of the burden of independently assessing safety and appropriateness.[10]

This dynamic can slow adoption, as health systems decline to deploy tools without regulatory certainty. HHS can play a constructive role by providing voluntary guidance for oversight,

[10] Private-sector review may create opportunities for small entities to serve as standards bodies, a role they have historically filled. On private-sector drug efficacy review prior to 1962, see Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. Pol. Econ. 1049 (1973).

documentation, and accountability for non-medical-device AI used in clinical settings and by aligning guidance across the FDA, Office of the National Coordinator for Health IT (ONC), Office of Civil Rights (OCR), and CMS.

Participants also noted that HHS needs to research the consumer-facing applications enabled by AI which are not subject to Health Insurance Portability and Accountable Act (HIPAA) privacy and security frameworks. Without clear guidance or standards, many consumers are utilizing personal AI monitoring tools that are not subject to HIPAA and the protections that come with clinical practice.

Question 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)?

When clinicians look at AI tools in the clinical care space, the issue of evaluating the AI results falls on the clinician. There are no clear standards or means to test AI diagnostic tools. Robust AI benchmarking has emerged in the private and academic sectors, including standardized evaluations for clinical reasoning, diagnostic accuracy, and complex case analysis. These benchmarks provide objective, quantitative measures that could complement qualitative regulatory review.

Roundtable participants encourage HHS to review existing regulatory frameworks which could create the appropriate "sandbox" for pre- and post-deployment AI evaluation. For example, clarification regarding how existing Patient Safety Organizations (as defined under the Patient Safety and Quality Improvement Act of 2005) can provide the appropriate controlled and accountable environment for AI monitoring, evaluation, and improvement. By creating the appropriate safe harbor for evaluations, HHS could support adoption by recognizing or referencing validated benchmark methodologies, periodically updating performance thresholds to reflect technological progress, and supporting applied research through grants or cooperative agreements focused on post-deployment monitoring, bias detection, and workflow impact

Question 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?

Regulatory clarity is the most effective way HHS can support private sector accreditation and certification efforts. Clear federal expectations enable third-party organizations to develop meaningful certification programs that small health systems can rely on rather than independently validating every tool. Absent this clarity, adoption becomes dependent on internal expertise and negotiating power, which disadvantages small hospitals and safety-net providers.

Roundtable participants recommended that HHS should partner with small clinicians to promote certification programs and establish clinician-led reporting and feedback channels.

Question 6: Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential to improve health care outcomes, give new insights on quality, and help reduce costs?

Exceeding Expectations:

AI tools have exceeded expectations when it functions as time multipliers**,** particularly in administrative and clinical documentation workflows. Tools that return meaningful clinician time (minutes per encounter that compound across patient stays) deliver clear value. For example, AI-enabled chart summarization has demonstrated substantial time savings for clinicians by rapidly synthesizing patient records into actionable summaries. One small entity participant noted that their hospital saves twenty minutes of paperwork for every new patient and ten minutes for returning patients with the use of auto-transcribing and notetaking tools.

Falling Short:

AI tools are only as capable as the foundational data that it has been trained on. Roundtable participants noted AI tools perform less effectively for underrepresented subpopulations such as pediatric and geriatric patients. There are gaps in the data which AI tools are trained on which create bias and risk of misdiagnosis or treatment.

Additionally, public misuse or overreliance on AI-based self-diagnosis presents new challenges for clinicians. AI diagnostic tools have the potential to diagnose patients, but the patient must close the referral loop and complete the specialized treatments.

Question 7: Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles to the adoption of AI in clinical care?

Physicians are the most influential decision-makers in AI adoption. Frontline clinicians rapidly determine whether a tool improves the delivery of care or reduces burden, and their usage patterns determines success or failure.

Administrative hurdles include governance complexity, contracting requirements, data access restrictions, and inconsistent regulatory guidance, all of which slow deployment and disproportionately affect smaller hospitals.

Question 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, particularly provider-side data portability, would significantly expand AI innovation. While patient-directed access has improved, healthcare systems remain constrained in using their own data for AI-enabled workflows such as prior authorization, care coordination, and documentation automation. Clarifying permissible uses of health data and related regulations for operational AI under HIPAA would provide certainty to small clinicians and improve the patient and provider experience.

Question 9: What challenges within healthcare do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care? Equally, what concerns do patients and caregivers have related to the adoption and use of AI in clinical care?

Stakeholders identified AI's potential to prevent chronic disease and support patient monitoring (e.g., AI-enabled beds to prevent bedsores and cameras to detect when a recovering patient is a fall-risk). However, clinicians emphasized the need to preserve the integrity of the doctor–patient relationship and ensure that AI tools augment, rather than replace, clinical judgment

Patients and caregivers want AI to reduce administrative burden, improve access, and support more timely, accurate care. Common frustrations, such as delays related to documentation or authorization, are areas where AI could deliver tangible benefit.

At the same time, patients express concerns about privacy, transparency, and trust. Clear governance, appropriate safeguards, and communication about how AI is used in care delivery are essential to maintaining confidence.

Question 10: Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

a. Are there published findings about the impact of adopted AI tools and their use clinical care?

b. How does the literature approach the costs benefits, and transfers of using AI as part of clinical care?

Advocacy has no response to this question.

III. Conclusion

Small health care providers view AI as a promising tool for improving patient care and efficiency but face significant barriers related to data quality, reimbursement, liability, and trust. Advocacy encourages HHS to collaborate with NIST, CMS, and industry experts to develop clear guidance,

reimbursement structures, and data standards that allow small entities to adopt AI safely and effectively. Doing so will ensure that innovation in clinical AI benefits providers and patients across all practice sizes and specialties. Advocacy applauds HHS for taking the first step in developing an AI framework and seeking public input. Advocacy hopes to facilitate further conversations about the success and struggles of small entities attempting to implement AI.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel David Mullis at (202) 830-2292 or by email at David.Mullis@sba.gov.

Sincerely,

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