February 23, 2026

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

RE: RIN 0955-AA13; Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care

Submitted electronically via regulations.gov.

Dear Secretary Kennedy,

The National Rural Health Association (NRHA) appreciates the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Request for Information (RFI) on accelerating the adoption and use of artificial intelligence (AI) as part of clinical care. NRHA commends HHS, the Office of the Deputy Secretary and the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) for seeking broad, experience-based input on how federal regulation, reimbursement policy, and research and development can responsibly advance AI integration in health care delivery. We welcome the Department's stated commitment to fostering innovation while protecting rural patients, maintaining public trust, and aligning federal incentives to improve productivity, reduce burden, and improve health outcomes.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

Background

AI is a rapidly evolving field within computer science focused on the development of systems designed to replicate human cognitive processes such as learning, decision-making, and problem solving with minimal human intervention.[1],[2] In rural areas in particular, where health care systems face unique barriers including limited infrastructure, workforce shortages, geographical isolation, and longer patient access times, AI could help bridge gaps in access and quality of care, streamline

[1] Krittanawong C, Zhang H, Wang Z, Aydar M, Kitai T. Artificial intelligence in precision cardiovascular medicine. J Am Coll Cardiol. 2017;69(21):2657-2664. doi:10.1016/j.jacc.2017.03.571

[2] Guo J, Li B. The application of medical artificial intelligence technology in rural areas of developing countries. Health Equity. 2018;2(1):174-181. doi:10.1089/heq.2018.0037

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health care delivery, enhance diagnostic precision, and ensure continuous care. [3,4,5,6] To effectively deploy and promote AI-driven health care tools in rural areas, it is paramount to address potential biases, ensure strong data security, and promote transparency and interpretability of AI systems.[7] Federal initiatives such as the National Institutes of Health's Bridge2AI program[8] exemplify current governmental efforts to integrate AI within rural health care, aiming to improve access and health outcomes for underserved populations.[9] To better ensure that AI policy advances innovation without exacerbating geographic disparities, NRHA offers the following responses to the RFI's regulatory, reimbursement, research, and implementation questions.

Regulation

HHS should establish enforceable standards governing development, validation, quality assurance, post-market monitoring, and transparency requirements for AI-enabled medical devices and non-device clinical decision support tools. NRHA also recommends that HHS create a dedicated regulatory coordination office to align related activities by FDA, CMS, NIH, and other federal oversight agencies.[10] While the Food and Drug Administration has issued draft guidance regarding AI-enabled device software functions and lifecycle management, these recommendations remain non-binding. Rural facilities often lack expertise and legal resources to independently evaluate vendor claims or conduct robust validation.[11] Mandatory rural-representative validation should be required to mitigate algorithmic bias and ensure generalizability. Clear delineation of shared responsibility among manufacturers, clinicians, and facilities is also necessary to reduce malpractice uncertainty, particularly in settings where governance infrastructure and access to legal counsel are limited.

HHS, through ASTP/ONC, should establish enforceable guidelines for algorithmic transparency, data provenance, auditability, and accountability, and require human-in-the-loop oversight for high-impact clinical uses. Transparency, explainability, and human oversight

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[3] Wilson NW, Couper ID, De Vries E, Reid S, Fish T, Marais BJ. A critical review of interventions to redress the inequitable distribution of healthcare professionals to rural and remote areas. Rural Remote Health. 2009;9(2):1060.
[4] Stolarchuk C, Anshu, Kumar P, et al. Optimizing healthcare delivery: strategies for workforce retention and resource allocation. J Surg Spec Rural Pract. 2025;6(1):3-8. doi:10.4103/jssrp.jssrp_7_25
[5] Lekadir K, Frangi AF, Porras A, et al. FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence in healthcare. BMJ. 2025;380:r340. doi:10.1136/bmj.r340
[6] Olugboja A, Agbakwuru EM. Bridging healthcare disparities in rural areas of developing countries: leveraging artificial intelligence for equitable access. In: Proc IEEE Int Conf Artif Intell Comput Data Sci Appl (ACDSA). 2024:1-6. doi:10.1109/ACDSA59508.2024.10467443
[7] National Academy of Medicine. An artificial intelligence code of conduct for health and medicine: Essential guidance for aligned action. Adams L, Fontaine E, Matheny M, Krishnan S, eds. Washington, DC: National Academies Press; 2025. doi:10.17226/29087
[8] National Institutes of Health. Bridge to Artificial Intelligence (Bridge2AI). Accessed July 9, 2025. https://commonfund.nih.gov/bridge2ai
[9] US Department of Health and Human Services. Strategic plan for the use of artificial intelligence in health, human services, and public health. Published 2025.
[10] Warraich HJ, Tazbaz T, Califf RM. FDA perspective on the regulation of artificial intelligence in health care and biomedicine. JAMA. 2025;333(3):241. doi:10.1001/jama.2024.21451
[11] US Food and Drug Administration. Artificial intelligence-enabled device software functions: lifecycle management and marketing submission recommendations. Draft guidance. Published 2025. Accessed July 9, 2025.

are essential components of trustworthy AI governance. National and international consensus frameworks emphasize that AI tools must function as decision-support systems within broader clinical and organizational contexts, not as substitutes for professional judgment. In rural communities, concerns about opaque "black box" algorithms, surveillance, automation, and loss of human interaction may undermine community acceptance.[12] Additionally, legal and ethical scholarship highlights unresolved questions regarding liability allocation in AI-influenced decision-making. HHS should provide guidance clarifying accountability and consider safe harbor frameworks for providers who appropriately rely on certified AI systems within established standards of care.

Infrastructure limitations further complicate regulatory considerations. The FCC's broadband data demonstrate persistent connectivity gaps in rural and Tribal areas, which directly constrain the safe deployment of cloud-based AI tools.[13] In addition, the environmental footprint of AI infrastructure, including high electricity and water demands for data center, poses sustainability risks for resource-limited rural regions.[14] Regulatory and procurement policies should therefore incentivize low-energy, resource-efficient AI architectures appropriate for rural environments.

Reimbursement

AI-enabled remote patient monitoring and predictive analytics have shown promise in managing chronic diseases such as diabetes, cardiovascular conditions, and cancer in rural settings.[15] Evidence indicates that AI systems can achieve expert-level performance in diagnostic domains including dermatology and diabetic retinopathy screening.[16] AI-enhanced telehealth platforms can triage, analytics, and specialist access, while predictive tools may flag early deterioration and enable proactive outreach.

While AI tools demonstrate clinical promise, rural facilities operating on thin margins cannot absorb upfront capital, licensing, training, and integration costs without predictable payment pathways. Without explicit Medicare and Medicaid reimbursement codes for AI-supported services, such as remote monitoring, predictive analytics, ambient documentation, and diagnostic support, rural providers face significant financial risk in adopting this technology.

HHS should establish clear reimbursement pathways for validated AI-supported services and ensure payment parity across rural and urban settings, including under critical access hospital (CAH) and rural health clinic (RHC) specific payment methodologies. Integration of AI tools into value-based models, such as chronic care and population health initiatives, can align incentives with improved outcomes.

Research & Development

HHS supports one of the world's largest health research ecosystems and can translate AI innovation into deployable clinical tools in which rural inclusion must be embedded. AI

[12] Adus S, Macklin J, Pinto A. Exploring patient perspectives on engagement in the development of AI applications in health care. BMC Health Serv Res. 2023;23(1):1163. doi:10.1186/s12913-023-10098-2
[13] Federal Communications Commission. 2020 broadband deployment report. Published 2020.
[14] Wang Q, Li Y, Li R. Ecological footprints, carbon emissions, and energy transitions: the impact of artificial intelligence. Humanit Soc Sci Commun. 2024;11:1043. doi:10.1057/s41599-024-03520-5
[15] Nwankwo EI, Emeihe EV, Ajegbile MD, Olaboye JA, Maha CC. Integrating telemedicine and AI to improve healthcare access in rural settings. Int J Life Sci Res Arch. 2024;7(1):59-77. doi:10.53771/ijlsra.2024.7.1.0061
[16] Ting DSW, Cheung CYL, Lim G, et al. Development and validation of a deep learning system for diabetic retinopathy and related eye diseases. JAMA. 2017;318(22):2211-2223. doi:10.1001/jama.2017.18152

models rely on large, high-quality datasets; however, rural health data are often sparse, siloed, and lack interoperability, and rural populations are frequently underrepresented in model development.[17] As a result, AI tools optimized for urban workflows may not align with rural care delivery structures, increasing the risk of degraded performance or inappropriate recommendations in small clinics and decentralized networks.[18] Sparse and siloed rural datasets limit algorithm performance and increase the risk of bias. HHS should fund rural-inclusive, de-identified national datasets with diverse geographic and demographic representation and require rural validation studies prior to large-scale deployment. Community-based participatory research approaches can strengthen trust and ensure AI tools reflect the social, cultural, and logistical realities of rural care delivery.

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Workforce readiness is equally critical.[19] Rural clinicians face limited training opportunities and technical support shortages. Expanded HRSA and Department of Labor funding for AI literacy, micro-credentialing, and continuing education programs tailored to CAHs and RHCs would improve implementation capacity. Pilot programs and demonstration initiatives like rural-focused CMS Innovation Center models or Rural AI Centers of Excellence would provide structured environments to test workflow integration, assess clinical outcomes, evaluate cost impacts, and monitor unintended consequences.

Individual questions to be addressed:

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

In rural settings, barriers are structural, financial, legal, and technical. First, AI systems rely on large, high-quality datasets; however, rural data are frequently sparse, fragmented, and siloed across institutions with limited interoperability. Rural populations, often older and medically complex, are underrepresented in training datasets, which can reduce model performance and introduce bias when tools are deployed in rural environments.[20] Second, infrastructure constraints remain substantial. Persistent broadband gaps, poor connectivity quality, outdated hardware, and limited IT staffing capacity hinder deployment of cloud-based AI tools and ongoing maintenance. These constraints increase implementation costs for vendors and providers alike. Third, workforce readiness presents a major barrier. Rural providers often perform multiple roles and have limited access to AI literacy training, technical support, or data science expertise. Without training and workflow integration support, adoption may be unsafe or unsustainable. Fourth, liability and regulatory ambiguity deter innovation. Questions regarding responsibility when AI-influenced decisions result in patient harm remain unresolved. Rural facilities frequently lack internal compliance and legal infrastructure to navigate these risks. Finally, reimbursement uncertainty and thin operating margins significantly limit capital investment capacity. Even promising tools cannot be adopted if payment pathways are unclear or misaligned with rural payment methodologies.

[17] Hains L, Kovoor JG, Stretton B, et al. When one size does not fit all—artificial intelligence in Australian rural health. Aust J Rural Health. 2025;33(3). doi:10.1111/ajr.70037

[18] Nong P, Adler-Milstein J, Apathy NC, Holmgren AJ, Everson J. Current use and evaluation of artificial intelligence and predictive models in US hospitals. Health Aff (Millwood). 2025;44(1):90-98. doi:10.1377/hlthaff.2024.00842

[19] Igwama GT, Nwankwo EI, Emeihe EV, Ajegbile MD. The role of community health workers in implementing AIbased health solutions in rural areas. Int J Biol Pharm Res Updates. 2024;4(1):1-7. doi:10.53430/ijbpru.2024.4.1.0026

[20] Hains L, Kovoor JG, Stretton B, et al. When one size does not fit all—artificial intelligence in Australian rural health. Aust J Rural Health. 2025;33(3). doi:10.1111/ajr.70037

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.

HHS should prioritize enforceable validation standards and transparency requirements for AI-enabled tools used in clinical care. Rural-representative, validated datasets should be required to ensure safety and performance across diverse populations. Payment policy modernization is equally critical. HHS should establish explicit Medicare and Medicaid reimbursement pathways for AI-supported services, including remote patient monitoring, predictive analytics, ambient documentation technologies, and AI-assisted diagnostics. Payment methodologies for CAHs and RHCs should reflect the unique financial structure of rural facilities to avoid disadvantaging them relative to urban systems.

Programmatically, HHS should invest in rural demonstration models through CMS Innovation Center authority and HRSA programs to evaluate workflow integration, outcome improvements, and cost impacts in real-world rural contexts. Workforce development grants and AI literacy initiatives tailored to rural clinicians and IT staff are also necessary to operationalize adoption safely.

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?

For non-device AI tools like generative AI documentation systems, triage algorithms, or predictive risk stratification platforms, novel governance questions arise regarding accountability, indemnification, and data use. Legal scholarship highlights ambiguity in determining responsibility when AI recommendations influence clinical decisions.

Additional implementation concerns include secondary data use and model retraining practices, cybersecurity vulnerabilities in under-resourced environments, and contractual power imbalances between rural providers and technology vendors. Cybersecurity breaches increased 84% between 2018 and 2021, and rural ransomware attacks frequently result in system downtime and ambulance diversion.[21] When expanding interoperability and AI adoption, adoption methods must simultaneously strengthen cybersecurity capacity in rural hospitals to protect patient trust and ensure continuity of care. Rural institutions often lack leverage to negotiate indemnification clauses or audit vendor training practices.

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?

HHS can support private sector innovation by aligning certification programs with enforceable AI governance standards, recognizing accredited evaluation entities, and incentivizing validation in rural and underserved populations. Clear, predictable regulatory pathways reduce uncertainty and investment risk. Additionally, seed funding and demonstration partnerships between rural providers

[21] Neprash HT, McGlave CC, Rydberg K, and Henning-Smith C. Understanding the Rise of Ransomware Attacks on Rural Hospitals. UMN Rural Health Research Center Policy Brief. June 2024. https://rhrc.umn.edu/publication/understanding-the-rise-of-ransomwareat-tacks-on-rural-hospitals

and technology developers can facilitate co-design of AI tools tailored to rural workflows. Federal coordination across FDA, CMS, NIH, and ASTP/ONC would reduce fragmentation and provide a coherent national framework.

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?

AI tools have demonstrated strong performance in diagnostic domains such as dermatology, with studies showing performance comparable to medical experts when validated appropriately. Remote patient monitoring systems and predictive analytics have improved chronic disease management and enabled earlier detection of deterioration in rural populations. AI-enabled documentation tools have also reduced administrative burden and cognitive fatigue among clinicians. However, AI tools have fallen short when deployed without rural validation, adequate workflow integration, reimbursement alignment, or provider training. Overreliance on consumer-grade AI platforms may introduce privacy and data governance risks, particularly where digital literacy is limited. Performance degradation due to biased training data remains a significant concern.

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?

AI adoption decisions are typically influenced by executive leadership, chief medical officers, chief information officers, compliance officers, and governing boards. In rural hospitals and clinics, administrative leadership may be consolidated among fewer individuals, increasing decision-making burden. Primary hurdles include capital investment constraints, limited IT personnel, vendor contracting complexity, cybersecurity compliance requirements, and integration with legacy EHR systems. Without technical assistance and external support, rural administrators may be hesitant to adopt complex technologies.

9. What challenges within health care 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?

Rural patients frequently seek improved specialty access, reduced travel burdens, earlier diagnosis, and enhanced chronic disease support. AI-enhanced telehealth and predictive monitoring systems may directly address these needs. At the same time, patients express concerns regarding trust, data privacy, algorithmic bias, automation replacing human interaction, and lack of transparency in AI-generated recommendations. Community engagement, participatory design approaches, and plain-language education are essential to building trust and acceptance.

Ultimately, while AI presents transformative opportunities to strengthen clinical care delivery, rural communities remain concerned about being left behind in yet another wave of health system innovation. Rural hospitals, clinics, and patients cannot meaningfully participate in the next generation of AI-enabled care without first securing the foundational infrastructure necessary to support it including reliable broadband connectivity, modernized health IT systems, cybersecurity protections, sustainable reimbursement pathways, and a trained workforce capable of implementing and overseeing these technologies. We respectfully urge the Department to ensure that investments in AI innovation are matched with parallel investments in rural readiness and capacity building.

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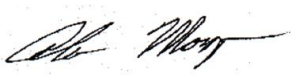
National Rural Health Association

NRHA appreciates the Administration's recognition of rural communities throughout this RFI and thanks you for keeping rural health at the forefront of national AI policy discussions. We look forward to continued collaboration to ensure that rural providers and patients are full participants in, and beneficiaries of, the rapidly evolving AI landscape. If you have any questions or wish to discuss further, please contact Marguerite Peterseim (mpeterseim@ruralhealth.us).

Sincerely,



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