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Office of the Deputy Secretary and Assistant Secretary for Technology Policy (ASTP)
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services (HHS)

Submitted via the Federal eRulemaking Portal

Attention: HHS Health Sector AI RFI

Dear Assistant Secretary Keane:

As the leading organizations for nutrition professionals, the Academy of Nutrition and Dietetics (the Academy) and the American Society for Nutrition (ASN) appreciate the opportunity to provide comment on the Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care published in the Federal Register on December 23, 2025. Representing more than 112,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of nutrition and dietetics practitioners working across clinical care, public health, research, education, food systems, and industry. ASN is a global scientific society representing over 8,000 researchers, clinicians, and policy experts who advance nutrition science to improve public health and clinical outcomes. Collectively, these organizations represent a substantial segment of the health workforce and research community, directly engaged in the development, evaluation, and implementation of technologies and innovative tools, such as AI, in clinical care, population health, and precision nutrition.

We offer the following comments and recommendations on the RFI on accelerating the adoption and use of AI as part of clinical care.[1,2] This RFI appropriately recognizes that regulation, reimbursement, and research and development must be aligned to foster responsible, effective, and scalable adoption of AI across the health care system. We appreciate HHS's efforts to solicit concrete, experience-based feedback across these domains to support responsible, effective, and scalable AI integration into health care delivery.

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[1] Office of Management and Budget. *Accelerating Federal Use of Artificial Intelligence through Innovation, Governance, and Public Trust (M-25-21).* 2025.
[2] U.S. Department of Health and Human Services. *HHS Artificial Intelligence Strategy.* 2025.

Executive Summary:

- Federal funding for AI adoption across regulation, reimbursement, and research; without sustained investment, policy reforms alone will not achieve scalable or equitable implementation.
- Absent sustained federal investment in data infrastructure, implementation science, and workforce capacity, accelerated AI adoption risks producing fragmented, opaque, and inequitable deployment, increasing safety risks and undermining public trust rather than improving care.
- Ambiguities in HIPAA, information blocking, and clinical decision support governance disproportionately hinder the development of continuous-learning AI systems and smaller or safety-net providers.
- Current reimbursement models fail to recognize AI as an enabler of clinical infrastructure, particularly disadvantaging prevention-, nutrition-, and population health–focused AI tools.
- National data assets such as NHANES and the NIH All of Us Research Program function as essential AI infrastructure and require sustained, expanded funding to support model validity, equity, and public trust.[3,4]
- Federal investment in applied implementation science and workforce capacity is necessary to translate AI innovation into real-world clinical impact.

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

1.1 Funding as the Foundational Constraint

Across regulation, reimbursement, and research, federal policy increasingly encourages rapid AI adoption. In contrast, federal investment in the underlying public goods required for AI success, longitudinal datasets, representative population surveillance, implementation science, and workforce capacity, has not kept pace with AI's growth. This creates a structural paradox: AI tools are expected to improve productivity, reduce burden, and enhance outcomes, yet the foundational infrastructure required to validate, monitor, and sustain those tools remains fragile or under-resourced.

As a result, regulatory uncertainty, reimbursement inertia, and uneven adoption are not solely policy design problems; they are predictable consequences of underinvestment in health care. Addressing this funding gap should be viewed as a prerequisite to achieving HHS's stated goals of public trust, safety, innovation, and health system transformation.

[3] National Institutes of Health. *All of Us Research Program Strategic Vision.*
[4] Centers for Disease Control and Prevention. *National Health and Nutrition Examination Survey (NHANES): Program Overview.*

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.

2.1 Regulatory Barriers Affecting AI Adoption in Clinical Care

2.1.1 HIPAA Privacy Rule and Secondary Use of Data (45 CFR Parts 160 and 164),

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule presents unresolved challenges for AI systems that require ongoing model training, validation, and updating. Ambiguity remains regarding whether secondary data use for model retraining constitutes health care operations, research, or a hybrid activity requiring additional authorization or institutional review board oversight. This uncertainty disproportionately affects smaller health systems and safety-net providers, which lack the necessary legal and compliance resources to interpret evolving expectations.

These challenges reflect a deeper mismatch between existing governance frameworks and the nature of AI-based systems. Unlike traditional statistical analyses, which are hypothesis-driven and executed once at study completion, AI systems require iterative development, repeated evaluation, and ongoing performance monitoring. Treating AI as a static analytic output rather than a continuously evolving system creates regulatory ambiguity and discourages responsible model updating, even when such updating is necessary to maintain accuracy and mitigate bias.

Without clear guidance, health care organizations may limit or avoid continuous-learning AI models, even when such models are essential to maintaining accuracy, mitigating bias, and ensuring clinical safety. HHS should consider issuing guidance or establishing safe harbors clarifying permissible AI-related secondary data use under 45 CFR §164.506, particularly for de-identified, federated, or privacy-preserving learning approaches. [5]

2.1.2 Information Blocking and AI-Generated Outputs (45 CFR Part 171)

The information blocking regulations raise unresolved questions about whether AI-generated outputs, such as predictive risk scores, decision-support insights, or model-derived features, constitute electronic health information subject to access, exchange, and use requirements.[7] Uncertainty regarding enforcement expectations discourages deeper integration of AI into electronic health record (EHR) workflows and creates hesitation among developers and health systems.

HHS, through ONC, should clarify how AI-generated artifacts are treated under existing information-blocking rules and consider how future United States Core Data for Interoperability (USCDI) expansions may incorporate AI-relevant data elements without stifling innovation or exposing clinicians and organizations to unintended compliance risks.

[5] 45 CFR 164.506 -- Uses and disclosures to carry out treatment, payment, or health care operations. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.506

2.1.3 Governance, Liability, and Accountability for Clinical Decision Support

For non-medical device AI tools used in clinical decision support, there is no harmonized federal framework addressing liability, documentation standards, clinician reliance thresholds, or audit expectations. This governance gap contributes to inconsistent adoption and undermines clinician trust.

HHS could play a constructive role by supporting model governance frameworks, safe-harbor pilots, and consensus standards that clarify accountability while preserving clinician judgment and autonomy. Importantly, these efforts require dedicated funding to support real-world testing, evaluation, and refinement.

2.1.4 Interoperability and Data Management Constraints

Interoperability limitations and fragmented data governance represent material barriers to the safe and effective deployment of AI in clinical care. AI systems depend on access to longitudinal, high-quality, and standardized data across care settings, yet health data remain siloed across EHR vendors, public health systems, payers, and federal programs. Inconsistent data models, limited adoption of standardized terminologies, and variable data quality constrain model performance and generalizability, particularly for nutrition, prevention, and population health applications.

While ONC has advanced interoperability through the United States Core Data for Interoperability (USCDI), many data elements critical to AI, such as nutrition intake, social determinants of health, functional status, and longitudinal outcomes, remain inconsistently captured or poorly standardized.[6] HHS should prioritize sustained investment in data harmonization, standards development, and infrastructure that enable AI tools to operate across systems without the need for bespoke integration efforts. Absent such investment, interoperability requirements risk becoming unfunded mandates that further disadvantage smaller and resource-constrained providers.

Without dedicated investment in applied implementation science, AI systems are likely to be deployed unevenly across care settings, validated inadequately on local populations, and monitored inconsistently after deployment. These implementation failures represent safety risks, not merely inefficiencies, as models that perform well in development environments may degrade or behave unpredictably in real-world clinical contexts.

2.1.5 Transparency, Explainability, and the "Black Box" Challenge

Lack of transparency in AI model development and operation, often referred to as the "black box" problem, poses challenges for clinician trust, patient acceptance, and effective regulatory oversight. Clinicians are expected to integrate AI-generated insights into clinical decision-making; however, they frequently lack access to information regarding model training data,

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[6] United States Core Data for Interoperability (USCDI). Interoperability Standards Platform (ISP). Published September 30, 2025. https://isp.healthit.gov/united-states-core-data-interoperability-uscdi

performance characteristics across populations, known limitations, or mechanisms for error detection and mitigation.

HHS should consider policy approaches that promote proportional transparency for AI used in clinical care, including expectations for disclosing the model's purpose, data provenance, validation methods, and performance monitoring, without requiring disclosure of proprietary source code. Clear federal expectations regarding explainability and documentation would reduce uncertainty for developers and users alike, support informed clinical use, and mitigate risk without stifling innovation.

These transparency requirements must be paired with federal investment to support evaluation infrastructure, post-deployment monitoring, and clinician education. Without funding to operationalize transparency, disclosure requirements alone are unlikely to significantly improve safety or trust.

2.2 Reimbursement Barriers to AI Adoption

2.2.1 AI as Enabling Infrastructure Rather Than a Billable Service

Current reimbursement systems are primarily designed to compensate for discrete services and human labor, rather than supporting infrastructure that enhances care delivery across episodes, settings, or populations. Many AI tools function as clinical infrastructure, supporting prevention, care coordination, risk stratification, and quality improvement, yet they often lack reimbursement pathways under fee-for-service and even many value-based models.

Absent explicit recognition of AI as a covered enabling technology, health systems face difficulty justifying investment, particularly when financial returns accrue over long time horizons or outside traditional billing constructs. CMS should explore demonstration models and payment reforms that treat AI-enabled clinical infrastructure as a component of high-value care, both allowable and incentivized.

2.2.2 Structural Disincentives for Prevention, Nutrition, and Population Health AI

AI reimbursement pilots and payment reforms have disproportionately focused on imaging, diagnostics, and acute care applications. In contrast, AI tools supporting prevention, nutrition, social determinants of health, and population health management remain structurally disadvantaged, despite their potential to reduce long-term costs and improve outcomes.

This imbalance is particularly problematic for emerging fields, such as precision nutrition and personalized preventive care, where AI-enabled insights rely on longitudinal data and early intervention. CMS should explicitly include AI-driven nutrition risk identification, intervention targeting, and monitoring within innovation models, chronic care management pathways, and value-based arrangements.[7]

[7] Centers for Medicare & Medicaid Services. *Innovation Center Models and Value-Based Care Initiatives.*

As a result, AI tools that support early nutrition risk identification, longitudinal dietary monitoring, or population-level prevention are often not deployed, even when evidence suggests long-term cost savings and improved outcomes, because financial returns are misaligned with short-term reimbursement structures.

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

10.1 Research and Development Investment Priorities and Concerns of Programs at Risk of Defunding with Direct Impact on AI and Nutrition

Several federal programs critical to AI readiness, nutrition science, and population health are vulnerable to funding instability. Reductions in these programs would directly impair the development, validation, and equitable deployment of AI tools in clinical and community settings. These include: the CDC's Nutrition, Physical Activity, and Obesity (NPAO) Program, which supports population-level nutrition surveillance and intervention evaluation; the Agency for Healthcare Research and Quality (AHRQ), which plays a central role in implementation science and real-world evaluation of health technologies; USDA Food and Nutrition Service (FNS) data systems, including SNAP and WIC, which generate essential data for AI applications addressing food insecurity and diet quality; and the CMS Innovation Center (CMMI), which provides a primary mechanism for testing AI-enabled payment and care delivery models.[8,9,10,11]

10.1.1 NHANES as National AI Infrastructure

The National Health and Nutrition Examination Survey (NHANES) is not merely a public health surveillance tool; it is a foundational national infrastructure that can be utilized for training, validating, and auditing AI models related to nutrition, metabolic health, chronic disease, and health disparities.[12] Funding instability or reductions in NHANES directly undermine this data collection infrastructure for the purposes of publicly available information for AI generalizability, bias detection, and equity.

HHS should ensure sustained and expanded funding for NHANES, including modernization efforts that support higher-frequency data collection, digital phenotyping, and linkage with EHR and claims data to enhance AI readiness.

[8] Centers for Disease Control and Prevention. *Nutrition, Physical Activity, and Obesity Program Overview.*
[9] Agency for Healthcare Research and Quality. *Health Services Research and Implementation Science Portfolio.*
[10] U.S. Department of Agriculture, Food and Nutrition Service. *SNAP and WIC Data and Research Initiatives.*
[11] Centers for Medicare & Medicaid Services. *Center for Medicare and Medicaid Innovation: Strategy and Model Portfolio.*
[12] National Health and Nutrition Examination Survey. National Health and Nutrition Examination Survey. Published December 18, 2024. https://www.cdc.gov/nchs/nhanes/index.html

10.1.2 Expansion and Domain Deepening of the All of Us Research Program

The NIH All of Us Research Program represents a critical national investment in precision medicine. The All of Us Research Program represents a new paradigm of big data sharing in healthcare that supersedes individual small investigator run RCTs. However, its potential to support AI-driven clinical care will remain limited without expanded funding for cohort retention, longitudinal follow-up, and domain-specific data collection, particularly in nutrition, lifestyle exposures, and food systems.

Targeted expansion of All of Us to support precision nutrition, metabolomics, and AI-enabled lifestyle modeling would significantly strengthen the evidence base for equitable AI deployment in clinical care. In addition, funding improvements to the cloud environment in the All of Us Researcher Workbench infrastructure will reduce technical barriers to data queries and AI-prediction of non-communicable disease states within this incredible data source.

10.1.3 AI Readiness Requires Labor

Importantly, AI-readiness is not a default property of datasets. Transforming raw population data into AI-ready inputs requires substantial investment in data engineering, preprocessing, harmonization, and quality control. These activities require skilled personnel and sustained funding yet are often invisible in traditional research budgets and reimbursement models. Underinvestment in this labor directly compromises model validity, generalizability, and equity.

10.1.4 Applied Implementation Science for AI

Federal AI research funding has heavily emphasized algorithm development and proof-of-concept studies, while underinvesting in implementation science, workflow integration, clinician training, and patient trust.[13,14] Without funding to understand how AI performs in real-world care settings, many promising tools remain confined to academic or pilot environments.

HHS should prioritize grants, cooperative agreements, and public-private partnerships focused on the applied implementation science of translating AI from concept to sustained clinical use.

E. Federal Workforce Capacity

Finally, federal agencies themselves require sustained funding to recruit, train, and retain AI-literate staff capable of evaluating technologies, overseeing post-market performance, and engaging meaningfully with the private sector.

Federal oversight of AI in clinical care depends on internal workforce capacity with sufficient AI literacy and domain expertise. Agencies require staff capable of evaluating model development

[13] Agency for Healthcare Research and Quality. *Artificial Intelligence in Health Care: Implementation and Evaluation Considerations.*

[14] U.S. Food and Drug Administration. *Measuring and Evaluating AI-Enabled Medical Device Performance in the Real World.* Digital Health Center of Excellence.

practices, assessing post-deployment performance, interpreting probabilistic outputs, and engaging with developers on issues of bias, drift, and validation. Without sustained investment in federal workforce development, regulatory frameworks risk becoming procedural rather than substantive, limiting their ability to ensure safety, equity, and accountability.

F. Public–Private and Public–Academic Partnerships to Build AI Infrastructure Capacity

Despite growing interest in accelerating the adoption of artificial intelligence in clinical care, the availability of personnel with deep technical expertise in data engineering, data science, and AI systems remains a binding constraint. Individuals with the skills required to design, maintain, and monitor AI-ready data infrastructure are in limited supply within academic and public-sector settings, and private industry is able to offer substantially higher compensation and career pathways that federal agencies and universities cannot realistically match. As a result, critical functions such as data preprocessing, pipeline development, system integration, and post-deployment monitoring are often under-resourced or unevenly supported in publicly funded research and clinical environments. This workforce imbalance constrains the federal government's capacity to steward AI responsibly, not because of a lack of interest or policy intent, but because the underlying technical labor required to operationalize AI at scale is structurally misaligned with existing funding and staffing models.

Sustained federal investment in AI adoption for clinical care will require workforce and infrastructure strategies that are both scalable and fiscally responsible. In particular, the limited supply and high cost of experienced data engineers, data infrastructure specialists, and AI systems engineers pose a practical constraint on the federal government's ability to build and maintain AI-ready data ecosystems through direct hiring alone.

To complement and strengthen permanent federal staffing models, HHS should also prioritize creating structured public–private and public–academic partnership approaches that enable shared investment in AI-relevant public goods while preserving public oversight and accountability. These partnership models can expand federal capacity without requiring the government to compete directly with private-sector salaries.

Specifically, HHS should consider the following partnership mechanisms:

- Cost-shared personnel models, in which federal funds support partial effort for data engineers and infrastructure specialists embedded in academic or industry settings to develop and maintain AI-ready public infrastructure.
- Term-limited fellowship and rotation programs that allow experienced technical professionals to contribute to federally supported AI infrastructure and governance efforts for defined periods, while maintaining career continuity outside permanent federal service.
- Jointly governed infrastructure projects focused on shared, reusable assets such as data preprocessing pipelines, harmonization frameworks, quality control systems, and post-deployment monitoring tools that support safe and equitable AI deployment across care settings.

- These partnership-based models are particularly well suited to the functions that are most essential for AI readiness but often underfunded, including data engineering, data curation, system integration, and ongoing performance monitoring.

In addition to direct funding, non-monetary incentives can further strengthen participation in these partnerships, including:

- Access to unique federal data assets, such as nationally representative population datasets and longitudinal health data, made available under clear governance, transparency, and conflict-of-interest safeguards.
- Structured pilot and evaluation pathways that allow AI tools developed using public infrastructure to be tested, audited, and refined in real-world clinical environments prior to broader adoption.
- Recognition and leadership opportunities for participating partners through named programs, public attribution, and involvement in standards-setting and governance activities.
- By investing in partnership-based capacity-building models, HHS can extend the impact of federal funding, accelerate AI readiness across the health system, and strengthen national stewardship of AI-enabled clinical care without expanding permanent federal headcount. These approaches complement, rather than replace, direct federal investment in workforce development and are essential to building durable, trustworthy AI infrastructure at scale.

V. Summary of Recommendations

HHS should prioritize the following actions to accelerate responsible AI adoption in clinical care:

1. Establish sustained federal funding streams that support AI-relevant public goods, including longitudinal population datasets, implementation science, data engineering, and workforce development, recognizing these as prerequisites for safe and equitable AI adoption.
2. Issue regulatory guidance clarifying the permissible use of secondary data for AI model training and updating under HIPAA (45 CFR Parts 160 and 164).
3. Clarify the treatment of AI-generated outputs under information blocking regulations (45 CFR Part 171) and future USCDI expansions.
4. Modernize CMS payment models to recognize AI as an enabler of clinical infrastructure, with explicit inclusion of prevention-, nutrition-, and population health-focused AI tools.
5. Protect and expand funding for NHANES and the NIH All of Us Research Program as core national infrastructure for AI.
6. Increase federal investment in the implementation science of applied AI, real-world evaluation, and clinician and patient engagement.

7. Strengthen federal agency workforce capacity to oversee, evaluate, and steward AI deployment across the health sector.
8. Optimize public and private partnership pipelines and knowledge sharing opportunities for maximum data sharing, precision and broadening technological innovation.

V. Conclusion

HHS has an opportunity to shape a health sector AI ecosystem that is innovative, trustworthy, and equitable. Achieving this vision will require aligning regulatory clarity and payment reform with sustained federal investment in data infrastructure, research, implementation capacity, and workforce development. Without such investment, AI policy risks remaining aspirational rather than operational.

Thank you for considering these comments. We appreciate HHS's leadership in advancing the responsible adoption of AI and look forward to continued engagement on these critical issues. Please do not hesitate to contact Kelly Horton, the Academy's Senior Vice President of Public Policy and Government Relations at khorton@eatright.org with any questions or requests for additional information.

Respectfully submitted,

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