

October 27, 2025

Stacy Murphy
Deputy Chief Operations Officer/Security Officer
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

RE: Request for Information; Regulatory Reform on Artificial Intelligence (FR Doc. 2025-18737)

Dear Ms. Murphy:

The Healthcare Leadership Council (HLC) and the Confidentiality Coalition appreciate the opportunity to submit comments to the White House Office of Science and Technology Policy in response to the [Request for Information](#) (RFI) on regulatory reform on Artificial Intelligence (AI). Our members are eager to provide input to help inform your effort to identify existing Federal statutes, regulations, agency rules, guidance, forms, and administrative processes that unnecessarily hinder the development, deployment, and adoption of AI technologies, particularly in healthcare, within the United States. We strongly urge the creation of a risk-based federal policy that preempts conflicting state laws and streamlines regulations, ensuring a consistent national approach that reduces barriers and supports innovation in AI.

HLC is an association of CEOs and C-suite executives from all sectors of healthcare working to shape the future of the U.S. healthcare system. HLC is the exclusive forum for the nation's healthcare industry leaders to lead on major, sector-wide issues, generate innovative solutions to unleash private sector ingenuity, and advocate for policies to improve our nation's healthcare delivery system. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors/wholesalers, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

The Confidentiality Coalition is a diverse alliance dedicated to balancing the protection of confidential health information with the need for efficient, interoperable systems that enhance healthcare delivery. The Coalition's aim is to safeguard the privacy of

healthcare consumers while improving the essential flow of information necessary to deliver high-quality, timely, and effective care and facilitating the development of innovative medical interventions.

Overview: AI and Healthcare

For decades, AI has been a valuable tool in healthcare, recognizing patterns that help guide clinical research, care delivery, medical supply chains and more. As more sophisticated machine-learning algorithms and generative AI have emerged, human elements of healthcare can be augmented even further to serve patients and communities. AI-enabled capabilities have the potential to sharpen the accuracy of diagnoses, improve clinical decision-making, detect public health threats, and enable earlier disease intervention. The scope for applications ranges beyond immediate patient care from administrative tasks to improving efficiencies to predictive analytics to help forecast disease outbreaks.

Principles To Guide Further Action

To inform your effort to develop appropriate policy frameworks to enable innovation while safeguarding the public interest, the Healthcare Leadership Council and the Confidentiality Coalition share our principles for the responsible development and use of AI in healthcare as you consider future action, in Addendum 1.

These principles support the intent to advance AI developments in support of better healthcare. Specifically, they emphasize the need for cooperation between regulators and stakeholders to balance innovation with individual rights and patient safety. Our principles call for a federal standard that preempts state regulation, is risk-based, harmonizes privacy standards for all information used, and promotes appropriate transparency. Risk assessments should be flexible, tailored to specific use cases, and align with established frameworks such as the National Institute of Standards and Technology's (NIST) AI Risk Management Framework.

The benefits of unleashing AI can be realized by allowing innovation to enhance the roles of scientists, clinicians and caregivers; assessing applications from a risk-based approach; developing a federal uniform standard; and adhering to privacy and security protections. Further, steps to harmonize requirements across business sectors and improve agencies' collaboration, along with increasing accountability, transparency, clarity, and comprehensiveness are imperative. We urge you to consider existing regulations that apply to AI enabled solutions and to leverage critical collaborative opportunities with the private sector to enable innovation and promote benefits for developers, deployers, and ultimately patients.

Instructive Use Cases Demonstrate the Potential



As AI continues to revolutionize healthcare, our member organizations are driving innovation. A collection of sample use cases detailed in Addendum 2 provide instructive examples of private-sector AI advancements in healthcare that:

- ✓ Facilitate the access and distribution of resources,
- ✓ Improve diagnostic capabilities and sharpen prognoses,
- ✓ Enhance clinical decision-making,
- ✓ Refine research and spur therapeutic development, and
- ✓ Bolster staff efficiencies and efficacies.

These AI tools illustrate both the breadth and opportunity of private sector ingenuity in leveraging AI.

Barriers and Burdens to Remove

HLC and the Confidentiality Coalition strongly support the removal of unnecessarily burdensome requirements that restrict the development and deployment of AI; we share your goal of enabling the growth of private-sector AI innovation and advancements to improve health. The emerging patchwork of regulations at the federal and state level is, perhaps, the most significant threat. Private sector companies currently navigate complex and potentially conflicting regulatory and legal frameworks pertaining to data science use in healthcare and beyond. Additionally, there is uncertainty regarding best practices and the risk of a state-by-state patchwork emerging without federal guidance. The myriad requirements create confusion and inconsistencies that stifle innovation, increase compliance burdens, and hinder the seamless adoption of evidence-based AI-driven advancements – underscoring the essential need for a clear, cohesive federal framework to provide regulatory certainty.

Establishing a comprehensive federal policy that preempts, deters, and possibly places a temporary moratorium on the adoption of conflicting state laws is likely the single most effective way to address barriers to AI adoption in healthcare. A comprehensive federal policy would ensure a consistent, nationwide approach and deter the widespread adoption of a state-by-state approach that hinders innovation and is resulting in an uneven set of standards being adopted across states. At the same time, a federal framework should be flexible enough to adapt to rapid AI innovation and secure enough to reduce the unnecessarily complex aspect of a fragmented approach.

Conclusion

HLC and the Confidentiality Coalition appreciate the opportunity to respond to the RFI on regulatory reform and AI. We stand ready to partner in the effort to remove barriers



to the most effective uses and widescale adoption of AI in the united goal of improving outcomes for patients. Thank you for considering our comments on this RFI.

We welcome the opportunity for continued collaboration and stand ready to leverage the expertise of our private sector members to strengthen and develop effective, forward-looking solutions. If you have any questions, please do not hesitate to contact me at ckeane@hlc.org or (202) 449-3441.

Sincerely,

A handwritten signature in dark ink, appearing to read "Clara Keane". The signature is fluid and cursive, with the first name "Clara" and last name "Keane" clearly distinguishable.

Clara Keane
Director of Policy

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Addendum #1

Principles for the Responsible Development and Use of Artificial Intelligence in Healthcare

Introduction

Artificial intelligence (AI) is rapidly evolving, and improving healthcare delivery, augmenting research and development across drugs and medical devices, aiding diagnoses, assisting intricate procedures, streamlining administrative tasks, and identifying individuals who could benefit from additional health services. AI's full potential in healthcare can only be achieved with collaboration between private and public sector stakeholders to foster continued innovation. Our members have collaboratively developed the principles below to guide a policy framework governing the use of AI in the healthcare field.

Principles

Benefits and Innovation. The use of AI tools in healthcare lowers costs, reduces human error, increases access to care, augments existing clinical practices, alleviates clerical and administrative burden, and improves health outcomes. For example, AI enables review and translation of mammograms thirty times faster than human review with 99% accuracy and reduces the need for unnecessary biopsies.¹ The benefits of existing tools represent only the first step in realizing AI's potential to revolutionize healthcare and patient outcomes. It is therefore essential that regulators, stakeholders, and AI experts work together to ensure any regulation or policy takes a risk-based, patient centered approach that supports and nurtures developing AI technology innovations, while recognizing industry-specific differences and needs.

Risk-based Approach. Regulatory agencies and organizations using AI should adopt a risk-based oversight approach to AI applications. Risk assessments should be tailored to use cases and should be entity-dependent assuming there is a baseline, agreed-upon floor to align with consensus-based risk management frameworks such as the AI Risk Management Framework (AI RMF) developed by the National Institute of Standards and Technology (NIST). Oversight processes adopted by organizations using AI should routinely identify potential risks, possible mitigation strategies, and recommended uses for the tool(s). Regulators should avoid imposing duplicative compliance requirements, or those that conflict with existing requirements, that create an unworkable operating environment and consider organizations that follow a

¹ See <https://www.pwc.com/gx/en/industries/healthcare/publications/ai-robotics-new-health/transforming-healthcare.html>, referencing the California Biomedical Research Association. New Drug Development Process. <http://www.ca-biomed.org/pdf/media-kit/fact-sheets/CBRADrugDevelop.pdf>

framework such as the NIST AI RMF to be adopting best practices. It is important to permit flexibility in assessing and allaying risk to enable companies to tailor risk mitigation to the unique considerations of each AI use case - as opposed to prescriptive requirements to guide AI oversight.

Federal Standards. Any regulatory framework(s) for AI applications should be developed and applied at the federal level, while reducing regulatory compliance costs and creating a safer environment for long-term investment. A single national standard that preempts state laws in this area will avoid conflicting, patchwork requirements and facilitate compliance without unduly restricting innovation.

Privacy and Security. Personal information used in AI should be subject to robust privacy and security protections at the federal level. This involves adhering to existing health data privacy and security protections in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and applying equivalent protections for non-HIPAA health data, by establishing baseline privacy protections for the processing of non-HIPAA personal information that often comprise the datasets used to train, validate, and test AI models. Privacy considerations should be integrated into AI tools from the start to reflect the importance of data minimization and use limitations. Individuals should have the right to be informed about the collection and use of their personal information, and the right to access, correct and, if feasible, delete their personal information.

Congress should establish a single national standard for the use of personal information not already subject to HIPAA that encompasses use in AI applications by entities also not regulated by HIPAA. Security safeguards, which may be based on guidelines such as those provided in the NIST Cybersecurity Framework and RMF, should protect against data breaches, data poisoning, exfiltration of models or training data and other threats that could expose the data used or alter the use, behavior, or performance of an AI application.

Harmonization. Federal agencies such as the Food and Drug Administration (FDA), the U.S. Equal Employment Opportunity Commission (EEOC), and the Federal Trade Commission (FTC) should collaborate to align the federal government's approach to the regulation of AI. This will allow organizations subject to the authority of different federal agencies to harmonize their AI implementation approach, to avoid confusion, support innovation, and achieve greater compliance.

While agencies may approach this technology from varying regulatory angles, whether in safety, privacy, consumer protection or otherwise, they should take a patient-centered approach and reach sufficient alignment so that compliance with one framework will not result in violation of, or inability to comply with, another. Failure to coordinate regulatory frameworks will not only create interpretation and compliance burdens but will slow AI development and deployment, and stifle innovation by creating a regulatory patchwork incompatible with the way health is delivered.



Any additional requirements on HIPAA-covered entities must balance the need to protect patient privacy while not adding unnecessary burden to the regulated entities. Alignment enables consistency to ensure requirements are complimentary. Additionally, conflicts between federal agencies' regulation of AI will hamper U.S efforts to lead globally in the regulation of AI. Other countries want to adopt a framework for the regulation of AI that harmonizes across business sectors and regulatory areas, rather than having to deal with discordant or conflicting requirements.

Accountability. Health organizations that use AI should determine and establish a risk-based structure of accountability that extends across its partnerships to ensure that their AI use cases are deployed in a responsible, fair, and consistent manner. This includes developing, implementing, and documenting principles, policies, procedures, and an internal collaborative governance structure and controls to oversee the development and use of AI applications. These controls should include quality control parameters for the data used as well as criteria against which the performance of the AI applications is monitored, evaluated, and re-evaluated, as needed, at regular intervals throughout the lifecycle to ensure that AI can be iteratively enhanced and adapt within the risk framework. Accountability should extend to the highest levels of management and should include key elements such as risk assessment, training, monitoring, and internal sanctions.

Transparency. Transparency is essential to build trust in AI technology. While organizations should protect their intellectual property or proprietary technology, they should also disclose when they are using AI tools in high-risk applications rather than instances where it is used for administrative or clerical purposes. Organizations should not be required to reveal the inner workings of their AI systems to the public or regulatory agencies, nor is there any benefit in doing so. The detailed disclosure of either data inputs or algorithmic processes would not be meaningful to patients, providers, or payers, would force AI developers to disclose their intellectual property or proprietary technology, could create AI vulnerability risks, and may limit innovators' willingness to work with the already highly regulated healthcare industry on meaningful AI applications.

Explainability. Developers of AI applications for use in healthcare must be able to explain to users how a decision is made by a high-risk AI application in a way that is sufficiently understandable to those users. Users should be able to gauge the context in which an algorithm operates and understand the implications of the outcomes. Users should in turn be able to explain the role of algorithms to individuals affected by AI-assisted decisions. Explanations should be meaningful and useful, tailored to the audience, and calibrated to the level of risk.



Addressing Adverse Bias and Discrimination. There are instances where AI applications have been found to be biased, as the underlying, especially historical, data sets may lack representative or accurate data. Organizations should take comprehensive steps to identify and mitigate potential sources of harmful bias across the lifecycle of their model development, and where reasonable and appropriate for specific models, align with industry-developed standards. Ongoing inclusion of sensitive personal data or data of vulnerable groups in AI training data is critical where such data is relevant for the intended use and/or population can help alleviate and remedy biases, so all patients may benefit from the advances from AI in healthcare.

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Sample Use Cases of Innovative AI Advancements in Healthcare

Access & Distribution		
Company	Link	Description
Cardinal Health	<u>Inside Cardinal's new AI-Driven Warehouse & Fulfillment Center</u>	Cardinal is combining two facilities into one single distribution and fulfillment center, wherein robotics and technological systems will coordinate processes such as inbound/outbound and automatic storage.
IQVIA	<u>IQVIA AI for Good</u>	Support Antibiotic Stewardship (ASP) to identify inappropriate antibiotic prescribing: Using AI and IQVIAs National Medical and Prescription Claims Data geographic hotspots for, and characteristics of, inappropriate prescribing were identified and helped inform state and local health departments to support targeted ASP programs.
Johnson & Johnson	<u>Six ways Johnson & Johnson is using AI to help advance healthcare</u>	J&J is using AI models to accurately predict supply and demand while identifying and responding to various risks that can impact J&J's ability to manufacture and deliver products to patients. These algorithms analyze historical data on patient demographics, demand fluctuations and supplier performance, along with real-time events that may disrupt the supply chain, to ensure customer needs are met with reliable supply.
Mount Sinai	<u>Assessing calibration and bias of a deployed machine learning malnutrition prediction model within a large healthcare system</u>	Mount Sinai studied its MUST-plus to evaluate current calibration and bias at the time and gave itself recommendations to improve thereafter.



Improved Diagnoses/Prognoses		
Company	Link	Description
Epic	Exploring Generative AI Adoption	Outpatient note summarization helps clinicians quickly review recent changes for a patient prior to an outpatient visit. UMCG found the AI summaries to be comparable to physician-created summaries in terms of completeness, correctness, and trustworthiness, but it took the physicians seven minutes to write them on average while it took AI just over 15 seconds.
IQVIA	IQVIA AI for Good	Reduced uncontrolled asthma by 17% using real world data and AI algorithms to predict patients at high risk of being undiagnosed or untreated, allowing providers to improve their outreach and treatment.
	IQVIA AI for Good	Identifying misdiagnosed Type 1 Diabetes patients to avoid life threatening complications: Using a predictive AI diagnostic model, those with T1D most likely to be diagnosed with T2D were highlighted, which alerts clinicians to ensure that treatment is accurate to each patient, avoiding complications that could be life threatening, such as diabetic ketoacidosis.
Johnson & Johnson	Six ways Johnson & Johnson is using AI to help advance healthcare	Driving greater precision in measuring disease severity and treatment response: J&J is applying AI/ML to data sets – from digital images to videos to sound recordings – to identify novel biomarkers and clinical endpoints that can help us develop and deliver the right medicines for the right patients at the right time – across oncology, immunology and neuroscience.
Mayo Clinic	Tomorrow's Cure: AI Powered Stethoscopes Improve Access to Heart Care	The AI Powered Stethoscope captures electrocardiogram data and heart sounds to lower the diagnostic gap in detecting peripartum cardiomyopathy and provide a safe noninvasive screening test.
	Mayo Clinic accelerates personalized medicine through foundation models with Microsoft Research and Cerebras Systems	In a multi-partnership, foundation models (pre-trained AI models amendable to a wide array of tasks) are being used for a genomic-purpose, which is to personalize care such that an AI model can know things to specifically look individual-to-individual based on risk.
Mount Sinai	AI-enhanced algorithm improves diagnosis of REM sleep behavior disorder	Sleep studies have been previously limited by the necessity of research-grade 3D cameras, but an automated machine learning method can analyze video recordings with just a 2D camera.
	Artificial Intelligence May Expedite Prognoses in Cancer Care	AI can deduce information by image alone, helping to profile cancer in ways that highlight high-risk features and probability of metastasis.



Enhancing Clinical Decision-Making and Efficiency

Company	Link	Description
Amazon	<u>Amazon and Memorial Sloan Kettering Cancer Center leap toward AI-driven drug discovery</u>	A partnership sees Memorial Sloan running large language models through Amazon Bedrock and SageMaker to amplify data quality, which will allow for better monitoring of cancer status in patients as well as shrink the time required for the early stages of drug development.
	<u>AI 'frees up time for patient care,' says Amazon Pharmacy's Vin Gupta</u>	Amazon Pharmacy's goal is to eliminate menial work for doctors and clinicians such that they can focus more fully on patient interaction and counseling.
Epic	<u>Mayo AI Message Responses</u>	In Basket Art (short for Augmented Response Technology) automatically drafts text for a potential response to the patient's medical advice request MyChart message based on the text of the message and information from the patient's record. Initial pilots at Mayo Clinic showed that In Basket Art saves nurses around 30 seconds per message and drafts more empathetic responses.
	<u>Ambient Listening Helps Primary Care Doctors Finish Notes Faster</u>	Ambient listening technology documents notes and queues up orders to improve the overall patient-physician experience. Third-party ambient listening vendors integrate with Epic so that doctors can spend less time on documentation, have fewer feelings of burnout, and refocus on the vital human component of patient-centered care.
IQVIA	<u>IQVIA AI for Good</u>	Predicting Risk of Stroke: The use of AI for Atrial Fibrillation patients decreased stroke incidence by 22% through algorithms that used real world data to identify the patient risk level. Allowing a streamlined approach to clinician intervention.
	<u>IQVIA AI for Good</u>	Developing Diabetes and Cardiovascular care bundles for countrywide deployment: Developed 14 AI algorithms across diabetes, CVD, and strokes to be used by physicians to identify patients at-risk and allowed treatment to occur earlier in the care continuum. Use of these 14 AI algorithms improved care management, reduced costs of care, AND identification of neuropathy was documented to be five times more accurate than standard practice.



Enhancing Clinical Decision-Making and Efficiency (continued)

Johnson & Johnson	<u>Six ways Johnson & Johnson is using AI to help advance healthcare</u>	Harnessing AI for electro-anatomical mapping of the heart: During catheter ablation procedures for atrial fibrillation, it is critical for electrophysiologists to “see” inside the heart. J&J's CARTO™ 3 System – the leading 3D heart mapping system features AI to reconstruct the left atrial anatomy of the heart. By eliminating the need for manual contouring, the system represents a new approach to anatomy creation, improving the efficiency of the procedure workflow.
Mount Sinai	<u>AI Can Reliably Predict Efficacy of Immune Checkpoint Inhibitor [(ICI)] Therapy</u>	Machine learning model SCORPIO “remains a highly accessible model for predicting ICI efficacy and can aid clinical decision-making when use alongside other assessments.”
Mount Sinai	<u>Mount Sinai awarded the Hearst Health Prize for an AI-driven nutrition application</u>	AI-driven nutrition application NutriScan AI more quickly detect signs of malnutrition in hospitalized patients and informs treatment for them.
	<u>Implementing a Machine Learning (ML) Screening Tool for Malnutrition: Insights from Qualitative Research Applicable to Other ML-Based Clinical Decision Support Systems</u>	ML tool Malnutrition Universal Screening Tool (MUST), when properly implemented, can serve as a key example of effective ML-based clinical decision support systems (CDSS), highlighting a switch from older CDSS to the most modern ML approach.
Oracle	<u>Oracle Health Clinical AI Agent (CAA)</u>	Oracle Health’s AI-powered voice recognition technology records key elements of the physician-patient encounter to interpret the information, accurately inputs a draft note into the Oracle Health EHR, and enables the physician to quickly review and approve the clinical documentation produced.
Senior Helpers	<u>Richland business leans on AI, tech to keep seniors in their own homes Tri-Cities Area Journal of Business</u>	flexHome utilizes smart sensors to build pattern recognition on a senior patient/client’s activity such that AI will alert family or the needed authorities if a deviation indicates a senior is having a medical emergency like a fall.
Vizient	<u>Augmedix Awarded Vizient Contract for Ambient AI Documentation Solutions</u>	Clients of Vizient will soon be able to access Augmedix services for drafting medical notes, meant to alleviate menial tasks and emphasize patient interaction and counseling.



Research & Development

Company	Link	Description
IQVIA	<u>NVIDIA and IQVIA Build Domain-Expert Agentic AI for Healthcare and Life Sciences</u>	NVIDIA AI Foundry and its accompanying platform plays a key role in the development of IVQIA Healthcare-grade AI that will give rise to new treatments quicker in the clinical trials and launch phases of drug research.
Merck	<u>AI optimizes the quest for small molecules - Merck.com</u>	In the lead optimization phase of drug discovery, the use of machine learning accelerates the data consensus on things like all possible combinations of molecules such that new possible drugs are found sooner and pushed forward more quickly.

Staff Efficiency/Efficacy

Company	Link	Description
Amazon	<u>Revolutionizing Real-World Evidence: How Generative AI Can Simplify Data Exploration</u>	Generative AI allows medical evidence to be sourced outside of just clinical trials to provide timely, relevant, and necessary data to clinicians and doctors.
	<u>Amazon Pharmacy Improved Prescription Processing Time by 90% with Gen AI</u>	A HIPAA-compliant digital platform uses generative AI for data entry and validation which speeds the process of approving and assigning doctor-approved prescriptions to the pharmacy counter.
	<u>Five ways Amazon Pharmacy uses AI to make getting medications more convenient for customers</u>	Alongside improving prescription processing time, AI can forecast demand, provide real-time insurance estimates, answer questions ahead of an agent and conduct batching decisions.
Envision Healthcare	<u>How Envision Healthcare Is Incorporating AI into Radiology Workflow Healthcare Innovation</u>	By partnering with Aidoc, Envision Healthcare models the radiology workflow after the Amazon service model where ED physicians may order a study through on-site systems that will more promptly monitor a patient's case.



Staff Efficiency/Efficacy (continued)		
Company	Link	Description
IQVIA	IQVIA AI for Good	Surfacing hidden risk factors to prioritize engagement of social workers: NorthShore – Edward-Elmhurst Health used the IQVIA AI solution for health NLP that flags patients with health factors, allowing ED social workers to assess 56% more patients with health needs.
	How AI is shaking up compliance in the life sciences industry - IQVIA	AI is being used to comb pages and pages of law/regulation to then outline how companies may navigate compliance.
Johnson & Johnson	Six ways Johnson & Johnson is using AI to help advance healthcare	Analyzing the operating room for efficiency and physician learning: AI automates snippets of surgical video to speed up the process of surgeons reviewing their work and adjusting accordingly.
Mayo Clinic	Mayo Clinic launches Mayo Clinic Digital Pathology to modernize pathology, speed medical breakthroughs	With the help of AI-gnostics, Mayo Clinic data and expertise is being combined with machine learning to shift pathology away from analogy processes to digital ones.
Surescripts	Touchless Prior Authorization Remove manual work & reach determinations faster	Clinical determinations regarding prior authorization of medications can be automated when AI is fed an electronic medical record within the purviews of the pharmacy benefit manager.

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