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Health AI Collaborative: Policy Considerations for a New Congress and Administration

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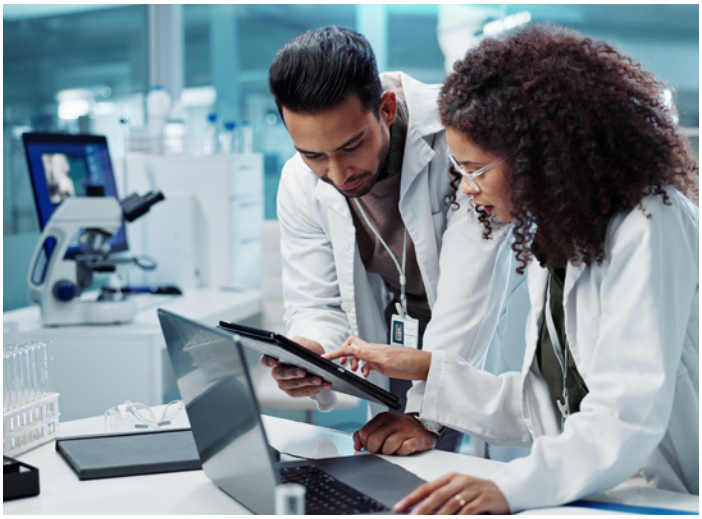
As the use of AI in healthcare advances, so do conversations about ensuring AI-enabled solutions are trustworthy and are used responsibly. Different levels of understanding and a lack of common definitions of AI can cause confusion and lead to ineffective policy. Healthcare leaders – in policy, industry, and academia – need to use the same language and reach a similar level of knowledge to avoid these outcomes.

The Health AI Collaborative, a group of associations representing the diverse stakeholders of the healthcare industry, are aligned on the following expanded AI policy positions:

1. **AI is Not a Monolithic Technology –** AI is not a monolithic technology; it is an umbrella term that encompasses a variety of techniques for algorithm and model development that span a spectrum of complexity. AI-enabled tools have many use cases in healthcare, with differing regulatory and policy considerations depending on the application.
2. **Regulation of AI Should Be Risk-Based –** Just as there is no "one-size-fits-all" definition of AI, there should not be a "one-size-fits-all" approach to regulating it. Policies regulating AI should consider sector-specific needs and factors such as end users and impact -- and calibrate regulatory oversight to both the specific levels of risk and benefits the AI technologies may pose.
3. **AI Policy Should Be Streamlined and Adaptable –** Before "reinventing the wheel" with new laws, the federal government should use existing authorities and consider adapting current policies and frameworks to cover any existing gaps. The AI regulatory landscape should not be overlapping, confusing, or conflicting. Any new policies should be streamlined with existing regulations when appropriate and allow for flexibility as technology continues to evolve.
4. **Policymakers Should Leverage Industry Expertise –** Regulators should align with the policies and best practices outlined in consensus-based standards that reflect industry-wide input, including national and international standards. Due to rapidly evolving technologies, any new policies should also be developed in public-private partnerships (whether formal or informal) to ensure policies are robust and reflect the expertise and experience of all stakeholders.
5. **Trustworthy AI Is Transparent –** Transparency is essential to patient-centered care. AI-enabled solutions and tools should offer transparency with the appropriate level of information necessary to ensure the safe, effective, and responsible use of the tool. Transparency policies in AI should not require the publication of proprietary information or trade secrets.
6. **AI Technologies Should Improve Equity, Not Exacerbate Disparities –** AI-enabled solutions and tools should promote access to care and improve health equity. They should be developed and deployed responsibly and mitigate against unwanted bias.
7. **Data Needs to be Accessible –** Robust and trustworthy AI requires large, high-quality data sets that are representative of the target patient population. Access to data or resources to ensure data quality should not be a barrier to innovation.
8. **Robust Federal Data Privacy Protections Are Essential –** A preemptive, comprehensive federal data privacy law needs to be a foundational element of any comprehensive AI framework.
9. **All Health AI Regulations Should Return to the North Star –** Health AI policies should be crafted to create a better and more secure healthcare system for patients and providers. AI in healthcare can be a tool to achieve the quintuple aim when applied responsibly.



Our mission is to create a common understanding of the use of artificial intelligence in the healthcare system. The Health AI Collaborative is a multi-stakeholder industry group that has convened to develop and share resources with policymakers to assist in charting a thoughtful course for the safe, trustworthy, and effective use of innovative AI applications in health care.

As the use of AI in healthcare advances, so do conversations about ensuring AI-enabled solutions are trustworthy and are used responsibly. Different levels of understanding and a lack of common definitions of AI can cause confusion and lead to ineffective policy. Healthcare leaders – in policy, industry, and academia – need to use the same language and reach a similar level of knowledge to avoid these outcomes.

The Health AI Collaborative, despite our diverse perspectives and roles in the healthcare industry, are aligned on the following AI policy positions:

AI is Not a Monolithic Technology

Part of the reason it is so difficult to reach a consensus on how to define and discuss AI is because it is not a monolithic and stagnant type of technology. As explained in the Health AI Collaborative's "What is Health AI?" brief, there are some types of AI technologies, like predictive AI models, that are more established and in some cases, have been used for decades, whereas generative AI-enabled tools and solutions are newer and continuously evolving.

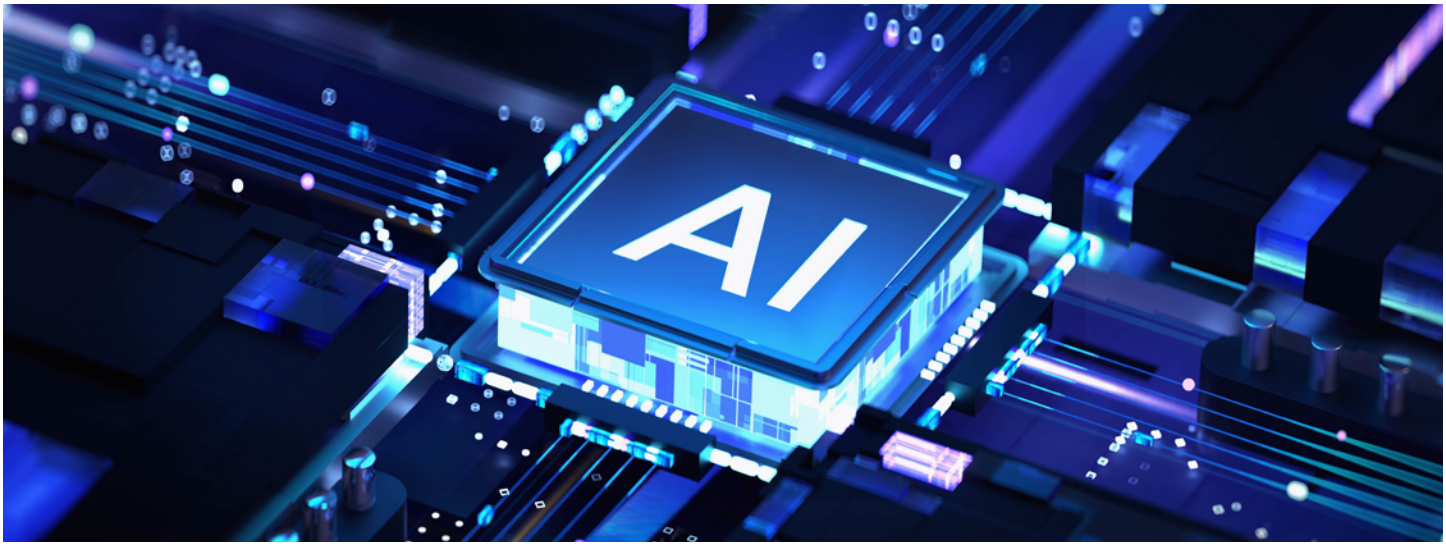
We need a common understanding for policymakers to incorporate this nuance into future regulatory and legal frameworks for the use of AI in healthcare, including clear, consensus-based definitions on what the frameworks are looking to address. If not, it may lead to creating policies that stifle innovation.

AI Regulations Should Be Risk-Based

Factors such as type of AI employed, intended purpose, user population, and use environment pose different risk considerations and may carry different degrees of risk. Any new policies should reflect this by applying a risk-based approach. Guardrails on AI in high-risk applications should be crafted in a way that does not interfere with the use of longstanding or low-risk applications. A risk-based approach ensures that regulation of AI strikes the right balance between promoting innovation, protecting individuals' rights, and advancing safe and effective care.

Using AI in healthcare poses unique and specific risks and opportunities compared to other sectors. For example, health data can be sensitive, and some AI-enabled tools and solutions may impact patient care decisions. Thus, there should be appropriate oversight that reflects those risks while also acknowledging the sector-specific protections that already exist in healthcare. An example of an existing regulation includes Health Insurance Portability and Accountability Act (HIPAA) provisions related to protected health information. Additionally, the FDA has already reviewed and authorized nearly 1,000 AI and machine learning-enabled medical devices under its existing authority.

Should a one-size-fits-all policy be applied to AI regulation, it could conflict with these regulations, and also interfere with the sector-specific opportunities that the use of AI in healthcare brings, such as improving access to new treatments and reducing workforce burden.



AI Policymaking Should Be Streamlined and Adaptable

Healthcare organizations already navigate a myriad of rules and regulations with which to comply. The federal government should leverage these policies first when figuring out how to regulate AI in healthcare to avoid adding new, potentially conflicting requirements that will also increase compliance costs. Should new lawmaking or rulemaking be necessary, however, it should be streamlined and adaptable to ensure it is not a barrier for the pace of innovation.

Policymakers Should Leverage Industry Expertise

The federal government must consult diverse perspectives and leverage stakeholder experience and expertise to promote effective and appropriate best practices for using AI in healthcare, many of which are already being developed in the private sector.

Industry experts have also dedicated years, resources, and research towards developing existing standards and frameworks that establish industry-wide best practices, including internationally. To avoid spending more time and resources on similar activities, the federal government should draw on what already exists and is already being operationalized – when crafting new regulatory frameworks.

Trustworthy AI Is Transparent

Trust in new technologies often comes with knowledge about how they were developed and how they are intended to be used. Transparency can help foster trust and encourage adoption by providing the essential and meaningful information necessary to ensure the safe, effective, and responsible use of the AI-enabled tool. Existing standards and frameworks, such as the ANSI/CTA The Use of Artificial Intelligence in Health Care: Trustworthiness standard, ISO 42001, and NIST's AI Risk Management Framework, call for specific instances of transparency within AI development.

Health AI transparency policies that help patients or providers make informed decisions should not infringe upon proprietary information.

AI Technologies Should Improve Equity, Not Exacerbate Disparities

AI-enabled tools and solutions should work to mitigate unwanted bias and not exacerbate existing disparities in access and outcomes given its potential for large-scale application. On the other hand, they can also be used to promote and expand access to care for rural and underserved communities. These goals can be achieved when AI models are developed and trained on quality datasets that are representative of the target population and unwanted bias is mitigated. Policymakers should promote the responsible use of AI to advance health equity and protect specific populations from adverse outcomes.

Policymakers should also consider the different types of bias AI models use, as not all are negative. Some models may use intentional biases for targeted specialization and outcomes, and AI developers should be able to preserve the ability to deploy this when appropriate.

Data Needs to be Accessible

AI models are only as good as the data they are trained on, the testing they go through, the tuning and adjustments made, and filters, safeguards, and operations they are subject to. It is a well-understood problem that obtaining high-quality data in healthcare is complicated. Despite decades of investment, interoperability among healthcare organizations is still not as advanced as it should be. When data does flow among organizations, it is often disorganized, incomplete, subject to contractual or regulatory use restrictions, and in several different formats or standards.

Healthcare organizations dedicate immense resources and time towards aggregating and "cleaning" datasets to ensure that AI models achieve appropriate and accurate outputs. Not all organizations have the same resources to access data for AI model training. Policymakers should consider policies that support greater access to healthcare data for appropriate uses. These policies should also consider supporting lower-resourced organizations that want to benefit from AI-enabled tools and solutions, but do not currently have the time, expertise, or finances at the ready. There will also be significant need for workforce readiness, training, and support to ensure AI is deployed effectively and safely.

Robust Federal Data Privacy Protections are Essential

AI models require large amounts of data to run. In healthcare, this data is often granular, sensitive, and with the rise of new healthcare technologies, does not always fall under the purview of HIPAA protections. Robust data protection measures must be implemented to ensure the responsible use of AI, particularly where the AI falls outside of existing health privacy laws and regulation. The patchwork of existing state and federal protections also creates a confusing and sometimes conflicting regulatory landscape that is difficult for technology developers to navigate. Policymakers should consider privacy frameworks that build off existing protections, like HIPAA. If new privacy frameworks do not align with what already exists, this could add to the complexity – creating unmanageable privacy requirements for some organizations (i.e., HIPAA covered entities).

Innovation in AI is enmeshed with privacy considerations – to make an AI model more fine-tuned and specific, it will need to be trained on diverse and specific data sets. Datasets with more granular and specific detail may improve a model's performance but may also increase risks to patient privacy. At the same time, AI technologies may help reduce privacy risks – they can help with data encryption and deploy other privacy-preserving techniques.

A preemptive, comprehensive federal data privacy framework that complements existing requirements will help balance AI innovation with the need to create baseline privacy protections for patients.

All Health AI Regulations Should Return to the North Star

The Health AI Collaborative believes that when applied appropriately, AI-enabled tools and solutions can help the healthcare sector achieve the quintuple aim: reimagining a healthcare system into one that simultaneously works to improve health, patient experience, lower costs, improve clinician well-being, and reduce health disparities. This North Star, to make healthcare work better for patients and providers in a responsible manner, should be the driving force of any new policies regarding health AI as well.

AI in healthcare is not without risk; however, now is not the time to be driven by fear of change. Instead, policies and guardrails must be developed with excitement behind the potential for AI to change healthcare for the better in mind. Centering this goal will ensure we establish common-sense policies that prioritize real outcomes for real people and positions America in a global leadership position.

Developed in collaboration with:

- AdvaMed
- AHIP
- Alliance of Community Health Plans
- American College of Cardiology
- Association for the Advancement of Medical Instrumentation
- Blue Cross Blue Shield Association
- Coalition for Health AI
- Consumer Technology Association
- Council of Medical Specialty Societies
- Digital Medicine Society