HEALTH INNOVATION ALLIANCE

September 22, 2023

The Honorable Bill Cassidy
Ranking Member
Senate Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Re: Exploring Congress' Framework for the Future of AI

Submitted electronically

Dear Ranking Member Cassidy,

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on your white paper, Exploring Congress' Framework for the Future of Artificial Intelligence (AI), and the included questions for comment. Overall, we encourage Congress to:

- Take advantage of the full potential for AI to combat waste, fraud, and abuse in the Medicare program;
- Use AI to reduce clinician burden, improve patient outcomes, and streamline administrative processes;
- Ensure that regulation of AI balances the need for innovation in health care, including allowing patients to access cutting-edge technologies with appropriate safeguards; and
- Educate consumers and ensure transparency of AI to create trust in the technology.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the commonsense use of data and technology to improve health outcomes and lower costs. Our members are on the front lines of innovation in health care, including implementing AI across various administrative and clinical contexts.

Combatting Waste, Fraud, and Abuse

Medicare loses up to $300 billion each year to errors, fraud, and abuse.[1] Current efforts to combat fraud have hinged on expensive, frequent audits of providers, chasing crooks after they have been paid, and requiring patients to see doctors in person before using remote care. The private sector long ago adopted artificial intelligence to combat improper payments. These models outperform government strategies because they incorporate more factors that can predict and identify fraud consistently and because it is easier and faster to retrain models to keep up with or stay ahead of fraudsters. Congress can take steps to ensure the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) have the resources necessary to identify and reduce fraud in real time through the use of AI.

Congress should act to ensure that fraud detection and prevention at CMS is modernized and incorporates new technologies like AI for all government health programs. In response to a Question for the Record you

[1] https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/

submitted to the Department of Health and Human Services' Inspector General Christi Grimm following her 2021 confirmation hearing before the Senate Finance Committee, she confirmed her commitment to "expanding HHS-OIG's use of sophisticated data analytics, including leveraging AI and ML, to proactively monitor and address fraud, waste, and abuse in HHS programs." HIA has worked with your office and others in Congress to develop legislation to make HHS good on its promise. By updating CMS's Fraud Prevention System to include AI, machine learning, and other advanced algorithmic technologies, CMS could begin to transition to a true post-service, prepayment system of fraud prevention. We look forward to working with your office to see the Medicare Fraud Reduction Act introduced and passed into law.

Reducing Clinician Burden and Administrative Costs

One of the most promising uses of AI in health care is for administrative tasks. Clinicians spend nearly 50 percent of their time on administrative tasks like documentation and authorization processes with payers.[2] Advanced algorithms can replace tedious and burdensome tasks with automated services, freeing up staff time for other purposes. HIA members are currently engaged in using AI for activities like claims adjudication after services have been delivered, streamlining document intake (like faxes) to classify files and create orders, and inputting appropriate insurance information after scanning a patient's card. These types of activities could be overhauled through the appropriate adoption of more advanced AI and related technologies. For example, prior authorization could become a completely automated activity with diminished staff time required. Responsible AI tools can compile and synthesize the information from a clinician's office required by payers to approve treatments. These types of activities are very low risk in terms of creating harm to patients or others.

Clinical decision support (CDS) software can provide clinicians with the most recent evidence based research and patient specific information to inform decisions. More consistent adoption of these technologies will lead to more standardized care and improved outcomes. Some types of CDS software have been carved out of regulation as medical devices by the Food and Drug Administration (FDA) in the 21st Century Cures Act. FDA released final guidance in 2022 that contradicts the 2016 statute, so Congress should engage in careful and thorough oversight of these policies. We urge you to support the adoption of responsible AI without inadvertently creating a regulatory environment that inhibits the ability of clinicians to use tools that can digest and distill large amounts of data, including data collected from patients, to inform healthcare decision making. Congress should encourage the adoption of these types of technologies and services to improve the health care work environment, reduce costs to the system, and improve care delivery for patients.

Ensuring Innovation, Patient Safety, and Equity

Care delivery, particularly at the hospital bedside, involves a complex system of data exchange. AI has the potential to automate and streamline many of the operations surrounding patient care like collecting information from various systems to aggregate and guide decision-making. Improved management and orchestration of care through tools like AI could lead to more consistent improved outcomes at scale. Particularly in emergencies, time can be the most critical factor, and AI has the capability of simultaneously analyzing the clinical situation and guiding personnel according to documented best practices. Additionally, AI could navigate the confusing matrix of clinical trials to help match eligible patients through their electronic health information while they're in a clinician office – this would help patients access more comprehensive care options and help clinicians deliver more complete care to their patients. Because AI is adaptive, it can adjust to the extremely dynamic environment of care delivery, monitor data from various sources, and present information to the care team more efficiently and effectively.

[2] https://www.acpjournals.org/doi/10.7326/M16-0961?articleid=2546704

A risk-based approach to AI tools would ensure the appropriate level of oversight at different levels. For example, health care is full of burdensome administrative processes where the use of AI is low risk and the impact to the health system is high. These low-risk use cases should be treated with a less strict scrutiny than other implementations where patient harm could result. Congress should work to ensure that regulators adjust to the new complexities AI presents. Despite numerous statements from the FDA that they want to be nimble, the FDA has had trouble adjusting away from its traditional review of medical products. The Pre-Cert program was terminated in September 2022 and recognized the need for a "new regulatory paradigm" for medical software and evolving technology.[3] Simply put, many types of AI adapt too often and too quickly to be subject to traditional FDA review. An AI product could not possibly be resubmitted for approval every time the product "learns" something new and adjusts, nor could the developer afford to undergo such a process. Patients and caregivers would also be denied use of these tools until each review is completed. Instead, review and approval of pre-determined change protocols may be a more realistic approach to regulation, building on the lessons from the Pre-Cert program.

This dynamic technology will require a consistent and innovative regulatory process based on risk. Consistency will require a whole of government approach to avoid duplicative and conflicting regulation. Higher-risk uses of AI should maintain human oversight, or a "human in the loop," to ensure appropriate decision-making and accountability. Patients deserve the best and safest care we can provide them, and AI has the potential to make many instances of care delivery safer and more consistent. However, high-risk uses of AI will need to have the appropriate oversight to ensure safety. Congress should wade into the regulation of AI in health care delicately to ensure a balance of patient safety, patient access, and product innovation.

Additionally, Congress should actively encourage the use and adoption of AI technologies. A new workforce will need to be trained to implement and oversee AI adoption, and Congress should consider what federal investments will need to be made in the training of students, faculty, and clinicians in these digital technologies. Other investments will need to be made to ensure adoption across the health care system – particularly in areas that may not be able to afford the most recent technologies. By embracing aspects of AI that improve safety and consistent care delivery, the federal government can improve access to high-quality care in rural and underserved areas. Congress should consider investment in the equitable adoption of AI across communities.

Creating Trust in AI

AI has a long way to go to gain trust in health care. Congress, the administration, and the private sector need to work collaboratively to ensure patients and clinicians know what AI is and how it is developed to help establish a foundation of understanding. Transparency in the technology is important, but Congress should be cautious not to require the broad disclosure of confidential and proprietary information about new tools, systems, and devices. In cases where a review of the intellectual property embedded in a product is necessary, requisite safeguards should be in place to ensure a competitive and innovative market for AI products.

Congress should work with innovators to ensure that regulation of AI balances the potential with the risks. We caution you against policies that could stifle the development of appropriate, innovative products that assist clinicians in improving patient outcomes, experience, and care. It's worth taking the time to get this right. We look forward to working with you.

Sincerely,

[3] https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program

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