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May 6, 2024

The Honorable Ami Bera, MD
172 Cannon House Office Building
Washington, DC 20515

Dear Representative Bera:

Thank you for your leadership and opportunity to respond to your request for information on the current state of artificial intelligence (AI) in the health care industry.

As North America's largest technology trade association, the Consumer Technology Association (CTA®) is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA is the trade association representing the more than 1300 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA is a leading voice on emerging technology issues, including artificial intelligence (AI), and their impact on the consumer technology industry. CTA has released a *National AI Policy and Regulatory Framework*; consumer research on the level of awareness and interest regarding AI and its applications; seven AI standards, including a voluntary consensus-based industry standard that identifies types of bias, sources of bias, and bias management practices for health care applications; and a *What is Health AI* one-pager.

As outlined in CTA's *National AI Policy and Regulatory Framework*, CTA believes Congress should recognize where existing law can be leveraged to address potential concerns with the uses of AI. For example, CTA believes that in certain instances, existing law already guards against potential bias and discrimination, regardless of whether such harm is human or machine generated. Congress should recognize where such laws provide existing remedies and procedures and avoid duplication of the same. If new lawmaking is necessary, CTA urges legislators to focus on guardrails and outcomes, rather than attempting to rein in specific technologies.

CTA believes a risk-based approach is the best way to balance the nation's technological competitiveness and culture of innovation while ensuring the rights and liberties of individuals are protected. As such, CTA believes governance obligations should apply only to high-risk, defined in CTA's *National AI Policy and Regulatory Framework* as AI systems making decisions: (1) based solely on automated processing and (2) which have consequential legal or equally significant effect on individuals, or which may impact individuals' health and safety. Decisions that impact an individual's ability to obtain financial services,

education, housing, healthcare, and other essential services such as food and water should also constitute decisions that have critical legal or equally significant effect. In the case of health, CTA's *Definitions and Characteristics of Artificial Intelligence* (CTA 2089-A) defines automated/autonomous intelligence as "a category of AI-enabled software that diagnoses disease and/or sets clinical management of a patient without additional input from the health care provider."

CTA believes it is vital that the United States leads the world on AI policy, innovation, and implementation. We look forward to continuing to work with you to develop a smart and balanced approach to meeting that goal.

Specific Responses

Implementation

1. How extensively is AI currently being implemented in health care institutions and other settings across the country?

The Food & Drug Administration (FDA) has approved more than 600 AI and machine learning (ML) enabled devices, beginning in 1995. Nearly 80 percent of approved devices are in radiology. The FDA has not yet approved a product that includes generative AI or is powered by large language models; however, these products are currently in use for non-FDA regulated functions, such as clinical note summarization or composing patient messages.

2. What areas of health care are benefiting the most from AI integration, and what are the primary challenges hindering further adoption?

Benefits – Like many other industries, the U.S. health care system is struggling with increased staffing and infrastructure costs, worker burnout and shortages, and increased demand. CTA believes technology, including AI, can help address these issues.

- Workforce Issues – The Health Resources and Services Administration (HRSA) estimates that there will be a shortage of more than 68,000 primary care physicians and the Association of American Medical Colleges (AAMC) estimates a shortage of up to 86,000 physicians overall by 2036. We face a similar crisis in nursing. In October 2022, the Bureau of Labor Statistics projected that more than 275,000 additional nurses are needed from 2020 to 2030. There are almost daily reports of the staggering number of registered nurses leaving or intending to leave the profession, due to post-pandemic stress, burnout and retirements. In a March 2023 response to the Senate Health, Education, Labor, and Pensions (HELP) Committee, CTA highlighted the potential of digital health, including AI, to address health care workforce shortage issues. CTA believes that AI is showing promise in reducing provider burden and burnout. Not only are advances in AI revolutionizing the way we detect and treat diseases, but it can also streamline administrative tasks such as scheduling and clinical documentation requirements.[1,2] AI can help health care workers treat patients more efficiently and effectively and address main drivers of worker burnout.

[1] Hazarika, I. (2020). Artificial intelligence: opportunities and implications for the health workforce. *International health*, *12*(4), 241-245.

[2] https://www.fiercehealthcare.com/ai-and-machine-learning/finding-right-candidates-keeping-them-ai-aiding-healthcare-industry-meets

- Patient Engagement – AI tools can translate jargon-heavy medical information to meet patients where they are by generating visit summaries and recommendations. It might also help facilitate patient interventions, ensuring patients follow-up with referrals or treatment plans, or by helping healthcare organizations identify and engage patients who could benefit from a specific intervention the most. Always on, always available AI can help create a world of healthcare abundance, where every individual benefits from early detection, early intervention, and personalized attention. In a December 2023 blog, senior White House officials acknowledged the promise of AI to "help doctors and health care workers deliver higher-quality, more empathetic care to patients in communities across the country."

- Improving transparency and decision-making – AI may be able to consolidate and generate insights from data, which can then be used to empower consumers and healthcare organizations to make informed decisions. For example, AI tools can be used to help payer organizations to validate their provider directory data – a process that has long been manual and difficult to manage. AI tools can also be used to detect patterns in pricing or claims data, identifying areas to improve contract negotiations or flag potential instances of fraud, waste and abuse.

- Accelerate innovation – AI can accelerate the development of new treatments or diagnoses, by being used in drug discovery and diagnostic products. As we shift to more personalized medicine and treatments, AI will be crucial to helping identify patient subpopulations and ensure clinical trials are representative of the population for which the treatments are developed.

Challenges – As with all new technological advances, policymakers must consider the impact on all stakeholders and craft appropriate policies in response. Issues CTA believes should be considered in policy related to the use of AI in health care:

- AI Governance – CTA believes Congress must act swiftly to pass legislation that establishes federal baseline AI governance requirements. Small and medium-sized businesses developing AI cannot afford to keep pace with multiple differing state laws that are already being considered given lack of action from Congress. To help guide federal lawmakers on an appropriate approach to AI governance, CTA developed a *National AI Policy and Regulatory Framework*, which focuses on an approach to AI governance that encourages appropriate guardrails and outcomes and ensures that AI systems are safe, trustworthy, effective, ethical, and legal. Many aspects of CTA's Framework incorporate elements of the NIST AI Risk Management Framework, which was developed to better manage risks to individuals, organizations, and society associated with AI.

CTA also believes that industry-developed, consensus-based standards should play an important role in AI governance. CTA is an ANSI-accredited standards development organization. We currently have seven published AI standards, with the most recent being *Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (ANSI/CTA-2116).* Industry standards can be more responsive to quickly changing technology like AI, build upon baseline requirements and support compliance.

- Post-Market Updates for FDA-regulated AI – AI used in FDA regulated medical devices, like other software, will require updates after approval. This could be challenging given the complex

regulatory structure of the FDA. The FDA has begun to address this by issuing guidance for industry related to predetermined change control plans (PCCPs). CTA recently commented on FDA's draft *guidance Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML) – Enabled Device Software Functions.* You can find our full comments here, a summary of our general comments is below:

Given the complexity of modern medical device software and the types of hardware that hosts or interacts with software as a medical device (SaMD), CTA recommends that FDA consider publishing additional guidance documents and resources, clarifying how PCCPs might apply in other contexts, including:

- The use of ML to identify and address software malfunctions that occur in real-world use—such as the self-testing of device functions and potential functional autonomous rectification of malfunctions in the field or self-testing against an internal quality benchmark.
- Improving the algorithmic capabilities of an existing parameter—such as via a device internal quality benchmark and its autonomous application in the field to determine the most suitable selection of data processing subroutine.
- Adding a new function that requires patient training or (self) validation if rolled out as an additional parameter with a new algorithm—such as a new feature of the device that would require training of a user in the field.
- Ways to manage AI/ML-driven changes to a device or drug product while it is still in clinical trials.
- The use of AI/ML in developing personalized medical products—such as the use of algorithms to tailor devices to individual patients.

- Managing Bias – While bias is often used to point to potential negative consequences of the use of AI, different types of bias may be used in health to reach outputs that are more relevant to a specific population. However, it is essential that there are practices in place to mitigate the use of AI for the purposes of discrimination or to exacerbate inequities.

Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (CTA/ANSI-2116) is a voluntary standard that identifies types of bias, sources of bias, and bias management practices for health care applications of AI. The types of bias defined include societal bias, algorithmic bias, and model bias. The voluntary standard also includes ways to manage bias, as well as health care use cases at risk.

Bias management is a prime example of where industry-developed, consensus-based standards should play an important role. While federal requirements should be in place for high-risk AI systems, standards can be more reactive to fast-changing technology and development practices and provide important guidance for industry looking to develop AI solutions in an ethical and effective manner.

- Funding/Reimbursement – Many Medicare beneficiaries are in fee-for-service models, which could limit the adoption of AI. Medicare reimbursement for covered CPT codes is calculated with an equation that factors in physician time and acuity of services and practice expense. AI tools, given the fact they often streamline provider practices and are intended to reduce time spent on services, do not factor well into this existing equation. If AI tools are not properly

reimbursed, innovation may be stifled, and provider adoption may be slow.

- Data privacy – The adoption of AI solutions is also impeded by the current patchwork of data privacy laws. While HIPAA covers health data held by covered entities such as health providers and payers and their business associates, if patients choose to upload their data to an AI-powered tool of their choosing, that tool would likely not be covered by HIPAA. Similarly, an AI tool likely wouldn't be covered under HIPAA if it were powered by health or biometric data generated by wearables like a smartwatch. CTA supports a comprehensive national privacy law that would address the gap in privacy law for health data outside of the clinical setting. Importantly, the effectiveness of an AI tool with a specific patient population is tied to how well that population was reflected in the AI's training or testing data; unfortunately, the current privacy law patchwork discourages the data sharing that is essential to minimizing bias and ensuring health equity in AI.

3. What are the various applications of AI in clinical or operational contexts?

CTA recently convened a group of health associations including AdvaMed, AHIP, American College of Cardiology, Alliance of Community Health Plans, Blue Cross Blue Shield Association, Coalition for Health AI, Council of Medical Specialty Societies, and Digital Medicine Society to publish a one-pager entitled *What is Health AI. What is Health AI* details a number of health AI use cases:

- Administrative processes: AI can streamline administrative processes like scheduling and patient intake, claims processing, or care referral tracking. Predictive AI models can be used to identify instances of fraud as well as patterns for workforce optimization. Generative AI chatbots may be used to provide contextual, personalize, and just in time education about their health or upcoming or past procedures, and help consumers make decisions about coverage or treatment.

- Operational support: AI can support healthcare operations, including quality measure data collection and analyses or business management tools.

- Clinical decision support (CDS): CDS tools, or software that can help physicians analyze patient data and interpret clinical guidelines, can be used to generate individualized recommendations for patient care plans. Some CDS tools are regulated by the FDA as medical devices, and some are "Non-Device CDS." The FDA has provided examples of Non-Device CDS software functions include evidence-based clinician order sets for an HCP to choose from, tailored for a particular condition, disease, or clinician preference; matching patient-specific medical information from records or reports to reference information (e.g., clinical guidelines) that is routinely used in clinical practice; and drug-drug interaction and drug-allergy contraindication notifications to avert adverse drug reactions.

- Population health interventions: By analyzing data sets of patient populations, AI tools can target interventions for those who would benefit from them the most.

- Medical devices: AI can be used as a medical device to aid in the treatment, cure, prevention, mitigation, and diagnosis of disease. For example, a doctor may use an AI-

enabled device to analyze medical images (e.g., from ultrasound or CT scan) to help identify features or patterns that may not be apparent to the human eye.

- Drug discovery: AI can be used to identify new molecules for the development of drugs or new treatments based on existing drugs.

4. How does AI distinguish itself from other health care technologies? How does AI support existing health care technologies?

AI has become an umbrella term that encompasses predictive algorithms, machine learning algorithms, large language models, and generative AI. Each of these technologies is different, not only in how they function, but in how they are implemented and the use cases they can each support. For predictive use cases, AI may operationally be indistinguishable from other sophisticated algorithms, i.e. researchers may identify a relationship between a certain rhythm and a particular cardiac abnormality; machine learning might have simply been a data analysis tool to identify that complex relationship. Dynamic AI algorithms take this a step further by adapting to new data. Large language models (LLMs) and generative AI differ in that rather than made a prediction based on set inputs, they take in text queries (or "prompts") and generate text responses. These LLMs can be trained to summarize large quantities of text, generate drafts of text, and engage in question-and-answer sessions with patients.

Given its adaptability and scale, AI can and is being built into other health technologies to help provide more personalized patient experiences, predict future disease based on risk factors, and identify potential clinical trial participants. For example, many telehealth solutions now have AI "assistants" that help patients navigate services and improve the overall experience.

AI also distinguishes itself from other health care technologies because in many cases, the technology itself is performing the 'work' that a human would do or has done in the past. How these technologies will (in some instances) replace the work that is today performed by humans such as auxiliary personnel, clinical staff, non-physician providers, and doctors, if very important to understand and incorporate in future policymaking.

5. What measures can be employed to guarantee proper reimbursement and coverage for AI technologies in health care?

Ultimately, reimbursement for AI should be determined by several different factors, including how is it being used, by whom, in what setting, and what are the expected outcomes. As previously stated, CMS has yet to propose a useful framework for how it plans to reimburse for emerging technologies such as AI and ML. CMS' "Transitional Coverage for Emerging Technologies" program as proposed would only apply to "certain FDA-designated Breakthrough Devices that fall within a Medicare benefit category."

CTA is concerned this limitation would exclude AI/ML because software as a medical device (SaMD) does not qualify for any CMS benefit category because medical device software is not considered to be durable medical equipment (DME) and not considered a direct practice expense (PE) under the CMS valuation methodology for physician services. Within those services, CMS broadly and incorrectly categorizes "computer software" —whether SaMD or off-the-shelf word processing—as "indirect" PE, thus mostly a non-allocable expense. This issue of categorizing all software (whether medical device software or not), as non-allocable indirect PE is an ongoing challenge for medical device software

manufacturers and developers. CMS itself has stated "that as the data used in our PE methodology have aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology."

Medical devices are not an "other expense" akin to "administrative labor" or "office expenses." Neither is SaMD an "other expense" because SaMD is, by law, a medical device SaMD is subject to the same regulatory oversight by the Food and Drug Administration (FDA) as hardware medical devices. The legal, regulatory, and financial burdens incumbent of a SaMD manufacturer (i.e., developer) are no less stringent than those of hardware medical device manufacturers. Under the law, SaMD is a medical device no different than hardware, thus it's incorrect to consider SaMD as an "other expense" and not "medical equipment" (which need not be physical hardware) a direct practice expense. CMS must distinguish and appropriately categorize SaMD away from mere "computer software" indirect PE but properly categorize and account for SaMD as direct PE under "medical equipment."

Efficacy, Accuracy, and Transparency

8. What guardrails or accountability mechanisms could be set to ensure end-to-end transparency?

Transparency is an important component of AI that helps ensure trust. ANSI/CTA standard *The Use of Artificial Intelligence in Health Care: Trustworthiness* (ANSI/CTA-2090) states that a requirement of trustworthy AI includes documentation that provides clear information on:

- Level of autonomy of the application. This includes a description of what functionality the application will automatically perform, what functionality is dependent on user-approval, and what functionality is provided for informational purposes only.

- Requirements for safe use of the application by the user regarding supervision of the technology, including specific safeguards to be employed when using fully autonomous AI technology or when using AI at any autonomy level when providing clinical care in clinical situations where the risk of harm is elevated.

- Controllability of AI functions. It is important that humans working with the AI function and who are responsible for results are able to interact with the ML/AI to get optimal results and reduce risks. This requires:

    - Explaining how to invoke or request the AI system's services when needed.
    - Explaining how to dismiss or ignore undesired AI system services.
    - Explaining how to edit, refine, or recover when the AI system is wrong.

Further, CTA's *National AI Policy and Regulatory Framework* states "Deployers of high-risk AI Systems must provide plain language explanations of how the AI system was designed and how it operates and produce insights about the basis of its decisions. In certain situations, Developers and Deployers of AI systems may be required to provide information about what data was collected to train the AI system. When an AI system is interacting directly with consumers (such as a chatbot or other case where it could be mistaken for a human) and engaged in high-risk applications, then Deployers of AI systems should disclose that fact, as appropriate."

Federal policy should focus on important safeguards and requirements for high-risk AI systems, and industry-developed, consensus-based standards should play an important role in addressing issues such as managing bias and transparency for all AI systems.

9. How can we ensure guardrails are put in place to mitigate risks such as disparate impact from racial, ethnic, and other biases?

As previously stated, industry, consensus-based standards can play an important role in helping organizations put guardrails in place to mitigate risk such as disparate impact from racial, ethnic, and other biases. ANSI/CTA standard *Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias* (ANSI/CTA-2116). Recommendations for AI developers to minimize societal bias include:

- Collect diverse data from an appropriately sized sample.
- Use explainable AI, or AI that is designed for transparency and interpretability. Techniques used to understand how the AI application is making decisions and identifying biases that may be present include feature importance analysis, counterfactual explanations, and sensitivity analysis.
- Regularly evaluate and monitor the performance of the AI application. This includes measuring the performance of the AI application on a diverse set of data, as well as evaluating the outcomes of the decisions the AI application is making.
- Implement fairness constraints to ensure that the AI application does not discriminate based on certain characteristics. This includes setting specific constraints or using techniques such as adversarial training to ensure the AI model(s) within the application is robust to different types of bias.
- Collaborate with diverse stakeholders, including human experts such as health care professionals, patients, academics, and other experts to ensure the AI application is meeting the needs of the intended population and not causing harm to any specific group.

Ethical and Regulatory Considerations

13. How can the use of AI in health care provide benefits while safeguarding patient privacy in clinical settings?

While HIPAA provides strong privacy protections for the use of AI in clinical settings, CTA urges Congress act swiftly to pass comprehensive national privacy legislation to address privacy concerns that arise when patient data is used to power AI outside of clinical settings.

14. What regulations, policies, frameworks, and standards should entities utilizing AI adhere to, and what mechanisms are in place or should be in place to supervise and enforce them?

CTA believes Congress should recognize where existing law can be leveraged to address potential concerns with the uses of AI. For example, CTA believes that in certain instances, existing law already guards against potential bias and discrimination, regardless of whether such harm is human or machine generated. Similarly, existing law already address liability for harm from products used in a medical

setting, regardless of whether the device is FDA-regulated or whether it uses AI. Congress should recognize where such laws provide existing remedies and procedures and avoid duplication of the same. If new lawmaking is necessary, CTA urges legislators to focus on guardrails and outcomes, rather than attempting to rein in specific technologies.

CTA also believes a risk-based approach is the best way to balance the nation's technological competitiveness and culture of innovation with ensuring the rights and liberties of individuals are protected. As such, CTA believes governance obligations should apply only on high-risk AI systems making decisions: (1) based solely on automated processing and (2) which have consequential legal or equally significant effect on individuals, or which may impact individuals' health and safety. Decisions that impact an individual's ability to obtain financial services, education, housing, healthcare, and other essential services such as food and water should also constitute decisions that have critical legal or equally significant effect.

Other Considerations

17. Are there legislative measures that Congress can take to ensure access to safe, reliable AI healthcare services?

In addition to passing a comprehensive national privacy law and passing legislation to provide guardrails for high-risk AI applications, Congress should ensure federal agencies are taking a risk-based approach to regulating the use of AI in health care. A risk-based approach to regulation is essential to ensure AI developers do not face undue and expensive regulatory burden and can continue to innovate. On December 13, 2023, Dr. Micky Tripathi, National Coordinator for Health Information Technology, Office of the National Coordinator for Health IT (ONC), Department of Health and Human Services, testified in front of the House Energy & Commerce Committee that ONC is specifically *not* taking a risk-based approach to requirements for AI applications that interact with certified health information technology in their Health Data, Technology, and Interoperability HTI-1 Final Rule. This is directly counter to not only the widely accepted risk-based approach to AI regulation, but it also goes against the risk-based approach to broader health regulation. With federal agencies set to release additional guidance documents and regulations related to President Biden's AI Executive Order, Congress should exercise its oversight authority to ensure federal agencies are taking a risk-based approach to regulation.

Conclusion

Thank you for the opportunity to provide input on critical issues raised in your request for information on the state of AI in health care. We look forward to continuing to work with you to ensure a balanced policy approach that allows emerging technology, like AI, to be fully leveraged across health care to improve patient outcomes and reduce provider burden and health care costs.

Sincerely,

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