

August 1, 2023

Laura Greene and Terence Tao
Co-Leads, PCAST Working Group on Generative AI
White House Office of Science and Technology Policy
Attention: Generative Artificial Intelligence (AI)

Submitted via email to: pcast@ostp.eop.gov

Re: Generative AI

Dear Ms. Greene and Mr. Tao,

Premier Inc. appreciates the opportunity to submit comments to the President's Council of Advisors on Science and Technology (PCAST) regarding strategies for identifying and promoting the beneficial deployment of Generative Artificial Intelligence (AI), as well as guardrails to mitigate associated risks. As described, this Generative AI Working Group will help inform the Biden-Harris Administration as it develops a National AI Strategy, charting a path for the United States to harness the benefits of emerging AI technologies.

Premier appreciates PCAST's commitment to leveraging generative AI to benefit the American public, while remaining mindful of the potential threats that AI could pose to individual safety and national security if misused. Premier applauds the actions that the federal government has already taken to responsibly advance the development and use of AI.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

Premier also has several AI assets, including but not limited to:

- Stanson Health, a subsidiary of Premier, designs technology to reduce low-value and unnecessary care. Stanson leverages real-time alerts and relevant analytics to guide and influence physician's decisions through Clinical Decision Support technology, providing higher-quality, lower-cost healthcare. Stanson's mission is to measurably improve the quality and safety of patient care while

reducing the cost of care by enabling context-specific information integrated into the provider workflow.

- Premier's PINC AI™ Applied Sciences (PAS) is a trusted leader in accelerating healthcare improvement through services, data, and scalable solutions, spanning the continuum of care and enabling sustainable innovation and rigorous research. These services and real-world data are valuable resources for the pharmaceutical, device and diagnostic industries, academia, federal and national healthcare agencies, as well as hospitals and health systems. Since 2000, PAS researchers have produced more than 1,000 publications which appear in 264 scholarly, peer-reviewed journals, covering a wide variety of topics such as population-based analyses of drugs, devices, treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.
- Conductiv, a Premier purchased services subsidiary, harnesses AI to help hospitals and health systems streamline contract negotiations, benchmark service providers and manage spend based on historical supply chain data. Conductiv also works to enable a healthy, competitive services market by creating new opportunities for smaller, diverse suppliers and helping hospitals invest locally across many different categories of their business.

II. BENEFITS OF GENERATIVE AI IN HEALTHCARE

Premier believes that AI has the potential to improve health outcomes for patients, enable providers, and drive innovation in clinical trials.

Workforce: The healthcare industry faces extensive, well-documented workforce challenges. A recent Premier [PINC AI analysis showed](#) hospitals' labor expenses jumped 16.6 percent on a per-paid-hour basis between October 2020 and April 2022. Healthcare workforce programs could leverage AI to identify root causes of healthcare workforce shortages and train the clinical workforce on how to best leverage AI technology to optimize workflows and patient care.

Innovating in Clinical Trials: Premier anticipates that AI and machine learning (ML) methods will provide a groundbreaking innovation platform for decentralized clinical trials, which we discuss at length in our [recent comments to the FDA](#). The potential uses of AI to facilitate decentralized clinical trials include:

- **Generating Synthetic Data:** AI, once trained on real-world data, has the capability to generate synthetic data and patient profiles that share characteristics with the target patient population for a clinical trial. This synthetic data can be used to simulate clinical trials, modeling the potential effects or range of results of a novel intervention, and predict the statistical significance and magnitude of effects or biases. Ultimately, synthetic patient data can help optimize trial design, improve safety and reduce costs for drug development.
- **Identifying Trial Participants:** One of the biggest challenges facing health systems that seek to participate in clinical trials is identifying and enrolling patients in a timely manner. Delays in meeting trial enrollment targets and timelines can increase the cost of the trial. AI tools have the ability to analyze the extensive universe of data available to healthcare systems in order to identify patients that may be a match for clinical trials that are currently recruiting. This application of natural language processing systems can make developing new drugs less expensive and more efficient.
- **Synthetic Control Arms:** Given the availability of quality real-world data through electronic health records, claims data, home health devices and other sources, synthetic control arms may soon become standard practice in many clinical trials. Synthetic control arms can increase the power of trial populations by eliminating the need for a control population and can help increase trial enrollment by easing patient fears that they will receive a placebo. The FDA has already recognized the value of real-world data to support development of drugs and biologics, and this may soon be a source of major innovation in drug and device development.

Innovating in the Public Service: Premier recommends that agencies within the federal government pursue public-private partnerships to develop standards and regulations that support U.S. AI innovation and ensure that American workers, businesses, and the economy benefit from AI development. Premier and other private companies at the cutting edge of AI technology development can offer real-world insights into the ways AI is being used in hospitals and healthcare facilities across America, as well as the challenges that providers face with implementation, financing, and regulation. One of the most significant challenges the federal government faces while developing AI regulations for the healthcare industry is understanding how healthcare providers actually use AI technology and the processes providers are using on the ground to implement new AI systems and procedures. In order to effectively regulate AI, the government must be responsive to real-world challenges and be strategic about which stages of the implementation and operations process regulations target. Partnerships with industry experts can help ensure that regulations are effective, promote patient safety and value of care, and help tackle some of the biggest challenges facing the American healthcare sector.

Supply Chain and National Security: Premier believes the application of AI in the healthcare supply chain sector will advance national security priorities by building a more efficient and resilient healthcare supply chain. Specifically, AI can improve demand forecasting for products and services through faster and more accurate analysis of historical and emerging clinical and patient data. As the COVID-19 pandemic showed, the ability to understand and react to shortages of products and services (such as ventilators, masks, and oxygen services) poses a critical challenge to healthcare providers and AI should enable better planning and response time to national or regional emergencies. AI will also provide better inventory management by automating the monitoring of inventory levels and their replenishment. Further, AI will help healthcare providers manage their suppliers better by allowing for faster more efficient contracting, by identifying the highest quality and most cost-effective suppliers, and by monitoring of supplier key performance metrics.

III. MANAGING RISKS OF GENERATIVE AI IN HEALTHCARE

Question 3: What technologies, policies, and infrastructure can be developed to detect and counter AI-generated disinformation?

Question 5: How can we help everyone, including our scientific, political, industrial, and educational leaders, develop the skills needed to identify AI-generated misinformation, impersonation, and manipulation?

Premier strongly supports AI policy guardrails that include standards around transparency and trust, bias and discrimination, risk and safety, and data use and privacy:

Promoting Transparency. Trust – among patients, providers, payers and suppliers – is critical to the development and deployment of AI tools in healthcare settings. In order to earn trust, AI tools must have an established standard of transparency. Recent policy proposals, including [those proffered by the Office of the National Coordinator for Health Information Technology](#) (ONC), suggest transparency can be achieved through a “nutrition label” or “model card.” This approach seeks to demystify the “black box” of an AI algorithm by listing the sources and classes of data used to train the algorithm and/or used as an input. Unfortunately, some versions of the “nutrition label” approach to AI transparency fail to acknowledge that when an AI tool is trained on a large, complex dataset, and is by design intended to evolve and learn, the initial static inputs captured by a label would not provide accurate insights into an ever-changing AI tool. Premier recommends that AI technology in healthcare should be held to a standardized, outcomes-focused set of metrics, such as accuracy, bias, false positives, inference risks, recommended use, and other similarly well-defined values. Outcomes, rather than inputs, are where AI technologies hold potential to drive health or harm. Thus, Premier believes it is essential to focus transparency efforts on the accuracy, reliability and overall appropriateness of AI technology outputs in healthcare to ensure that the evolving tool does not produce harm.

Mitigating Risks. It is important to acknowledge potential concerns around biased or discriminatory outcomes resulting from the use of AI tools in healthcare, as well as potential concerns around patient safety. Fortunately, there are several best practices that Premier and others at the forefront of technology are already following to mitigate these risks. First, we reiterate Premier's recommendation for a "model card" style assessment of AI technologies' performance, which would provide a standardized way to hold AI developers and vendors responsible for monitoring for any biased outcomes. Model card-style reporting could incorporate results from disparity testing, as recommended in the OSTP AI Bill of Rights, both before and after technology deployment.

Data Standards: Finally, Premier understands the importance of data standards, responsible data use, and data privacy in the development and deployment of AI technology. Data standards should specifically focus on objective assessment of potential sources of bias or inaccuracy introduced through poor dataset construction, cleaning, or use. These may include, but are not limited to, appropriately representative datasets, bias in data collection (e.g., subjectivity in clinical reports) or introduced by instrument performance or sensitivity (e.g., pulse oximetry devices producing inaccurate measurements of blood oxygen levels in patients with darker skin), bias introduced during curation (e.g., datasets with systemically introduced nulls and their correlation, such as failure to pursue treatment due to lack of ability to pay), and training and test data that is appropriately applicable to various patient subpopulations (e.g., data that sufficiently represents symptoms or characteristics of a condition for each age/gender/race of patient that the tool will be used to treat). Premier also supports the establishment of guidelines for proper data collection, storage, and use that sufficiently protect patient rights and safety. This is particularly important given the sensitivity of health data.

IV. DETECTING AI-GENERATED DISINFORMATION OR MANIPULATION IN HEALTHCARE

Premier has identified three specific opportunities to identify AI-generated misinformation or manipulation in healthcare:

Workforce Training: Premier believes technology can work alongside and learn from healthcare professionals, but current technology will not and should not replace the healthcare workforce. Premier would reiterate the importance of comprehensive risk assessments, recommended use, and trainings that combat automation bias and incorporate human decision-making into the use of AI technology in healthcare. The risks and safety concerns around AI technology are unique to each use case, and Premier supports the requirement of a risk assessment and mitigation plan specific to the level of risk associated with the use case. Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design. Finally, Premier acknowledges the risks of automation bias and fully automated decision-making processes. To reduce these risks, promote trust in AI technologies used in healthcare and achieve the goal of supporting the healthcare workforce through AI, Premier recommends that federal workforce training programs provide comprehensive AI literacy training for the healthcare workforce. Healthcare workers deal with high volumes of incredibly nuanced data, research, and instructions – a growing percentage of which may be supplied by AI. By ensuring our healthcare workers understand how to evaluate the most appropriate AI use cases and appropriate procedures for evaluating the accuracy or validity of AI recommendations, we can maximize the advisory benefit of AI while mitigating the risk to patients. Additionally, clear, risk-based guidance on which uses of AI technology in healthcare require human review and decision-making, similar to the principles discussed in section five of the OSTP's AI Bill of Rights, is essential.

Watermarks: Watermarking or provenance data/systems for AI-generated content were a component of the [voluntary commitments](#) recently announced by the White House. Premier generally supports the development of similar metrics for scientific research or clinical decision support recommendations produced by AI technology. It is important that patients, scientists, and medical professionals understand when decisions or recommendations are made by AI so they can consciously respond and evaluate the new information accordingly.

Specifically, watermarking is one potential strategy to combat automation bias, a risk especially pertinent to the use of AI technology in healthcare. Automation bias refers to human over-reliance on suggestions made by automated technology, such as an AI device. This tendency is often amplified in high-pressure settings that require a rapid decision. The issue of automation bias in a healthcare setting is discussed at length by the FDA in [guidance](#) on determining if a clinical decision support tool should be considered a medical device. Premier suggests that future guidance or standards for the use of AI should consider automation bias in risk assessments and implementation practices, such as workforce education and institutional controls, to minimize the potential harm that automation bias could have on patients and vulnerable populations, including to mitigate any potential risk of AI used in unintended settings or built on biased datasets.

End-User Specific Explainability: Premier has commented repeatedly about the importance of ongoing testing to determine accuracy and prevent bias in AI applications. Additionally, Premier has advocated for transparency into when information or recommendations are generated by an AI system. However, the concept of transparency cannot be completely disentangled from the concept of explainability. The PCAST Working Group on Generative AI will likely receive many comments urging them to incorporate explainability; however, Premier urges the members of the Working Group to carefully tailor explainability requirements to the end user of the AI system. While Premier's recommendations for a "nutrition label" or "model label" represent the type of explainability that might be valuable to a patient or healthcare system, it is important to remember that different uses of AI, such as for clinical decision support or clinical trial design, have different end users who may need a higher degree of visibility into how the AI system reaches a decision and the factors it considers.

V. CONCLUSION

In closing, Premier appreciates the opportunity to respond to PCAST's comment solicitation for managing the risks of generative AI. If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Administration in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com or 334.318.5016.

Sincerely,



Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.