September 17, 2023

The Honorable Bill Cassidy, MD
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

Re: Exploring Congress' Framework for the Future of Artificial Intelligence: The Oversight and Legislative Role of Congress Over the Integration of Artificial Intelligence in Health, Education and Labor

Dear Ranking Member Cassidy:

On behalf of Premier Inc. and the providers we serve, thank you for your leadership and support of our nation's healthcare system. Premier strongly supports the development of this white paper on artificial intelligence (AI) as a positive step towards recognizing the ways in which technology can be leveraged in healthcare to reduce costs, improve quality and access, alleviate workforce shortages and advance health equity. Specifically, Premier appreciates your recognition of the potential of AI in drug development and clinical trials, disease detection and treatment and healthcare administration, and values the opportunity to provide feedback.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 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 plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, N.C., Premier is passionate about transforming American healthcare.

Premier is already leveraging AI to move the needle on cost and quality in healthcare, including:

- 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.

Premier has thought critically about the potential legislative and regulatory framework for AI in healthcare and recently published an Advocacy Roadmap for AI in Healthcare.[1] ***While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine***

Premier's detailed feedback, based on our depth of experience in using AI in healthcare, is included below.

II. PROTECTING PATIENT RIGHTS, SAFETY AND NATIONAL SECURITY

Premier supports the responsible development and implementation of AI tools across all segments of American industry – particularly in the healthcare industry, where numerous applications of this technology are already improving patient outcomes and provider efficiency. Premier sees a defined role for Congress in advancing clear statutory guidelines that will allow providers and payers to deploy AI technology to its full potential, while still protecting individual rights and safety.

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. 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" model. 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. 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 do not provide accurate insights into an ever-changing AI tool. Further, overly-intrusive disclosure requirements around data inputs or algorithmic processes could force AI developers to publicly disclose intellectual property or proprietary technology, which would stifle innovation.

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 standardized, outcomes-based assessments of AI technologies' performance, which would ***hold AI developers and vendors responsible for monitoring for any biased outcomes***. Performance reporting could incorporate results from disparity testing before and after technology deployment to ensure that bias stays out of the AI "machinery."

[1] See Appendix A.

Premier also supports the development of a standardized risk assessment, drawing on the extensive groundwork already laid by the National Institute of Standards and Technology (NIST) in the AI Risk Management Framework. An AI risk assessment should identify potential risks that the AI tool could introduce, potential mitigation strategies, detailed explanations of recommended uses for the tool and risks that could arise should the tool be used inappropriately. Premier urges Congress to consider a nuanced approach to risk level classification for the use of AI tools in healthcare. While there are some clinical applications of AI technology that could be considered high risk, it is certainly true that not all healthcare use cases carry the same level of risk. For example, the use of AI technology to reduce administrative burden or improve workflow in a hospital carries a much different level of risk and very different safety considerations than the use of AI technology to treat patients. 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 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 protect patient rights and safety. This is particularly important given the sensitivity of health data.

III. DRUG RESEARCH, DEVELOPMENT AND MANUFACTURING

Premier appreciates the Ranking Member's acknowledgement of the many ways that AI technology can be leveraged in drug research, development and production. Congress and the Administration must work collaboratively to pre-empt uncertainty and responsibly govern the deployment of emerging technologies in these areas in a patient-centered manner. Premier specifically recommends timely legislative and/or regulatory guidance for the use of AI in clinical trials and drug manufacturing.

Opportunities for AI in Clinical Trials

Premier sees particular promise for the use of AI in streamlining processes and expanding patient access in clinical trials.

Identifying trial participants: One of the biggest challenges facing health systems that seek to participate in or enroll patients 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, while also improving patient and geographical diversity in trials to address health equity.

Generating synthetic data: AI, once trained on real-world data (RWD), 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 to optimize trial designs, model the possible 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 cost for decentralized clinical trials. Further, synthetic control arms in clinical trials can help increase trial enrollment by easing patient fears that they will receive a placebo. To encourage continued innovation, clear guidance is needed from Congress and/or the Food and Drug Administration (FDA) on the process

for properly obtaining consent from patients for the use of their RWD to produce AI-generated synthetic control arms in clinical trials.

Opportunities for AI in Drug Manufacturing

Premier sees potential for AI to transform at least three key segments of the drug manufacturing process: component supply chain, advanced process control, and quality monitoring.

Supply chain visibility: Premier believes the application of AI can advance national security by helping build a more efficient and resilient healthcare supply chain. Specifically, AI can enable better demand forecasting for products and services, such as drug components, through analysis of historical and emerging clinical and patient data. As the COVID-19 pandemic demonstrated, the ability to understand and react to shortages poses a critical challenge to healthcare providers; AI enables better planning and response time to national or regional emergencies. AI can drive better inventory management by automating the monitoring and replenishment of inventory levels. Healthcare providers can leverage AI to better manage suppliers through faster more efficient contracting processes and by monitoring of supplier key performance metrics. As Premier works to combat drug shortages, the most effective remedies begin with supply chain visibility and reliable predictions that allow manufacturers to plan for and respond to shortages or disruptions – this crucial element of the drug manufacturing process presents a key value-add opportunity for AI technology.

Advanced process control: Another significant value-add for AI in the drug manufacturing process is in the development and optimization of advanced process control systems (APCs). Process controls typically regulate conditions during the manufacturing process, such as temperature, pressure, feedback and speed. However, a recent report found that industrial process controls are overwhelmingly still manually regulated, and less than 10 percent of automated APCs are active, optimized and achieving the desired objective. These technologies are now ready to transform drug manufacturing on a commercial scale; however, challenges still remain to widespread adoption. Premier strongly believes that the FDA should issue clear guidance that supports the industry-wide transition to AI-powered APCs. Such technologies offer drug manufacturers the opportunity to assess the entire set of input variables and the effect of each on system performance and product quality, automating plant-wide optimization. This application of AI technology can transform the physical manufacturing of drugs and pharmaceuticals, leading to cost-savings and increased resiliency, transparency and safety in the drug supply chain.

Quality monitoring: AI can also provide value-add to drug manufacturing in the field of quality monitoring and reporting. Current manufacturing processes provide an immense volume of data from imagers and sensors that, if processed and analyzed more quickly and efficiently, could transform approaches to safety and quality control. AI models trained on this data can be used to predict malfunctions or adverse events. AI can also perform advanced quality control and inspection tasks, using data feeds to quickly identify and correct product defects or catch quality issues with products on the manufacturing line. Taken together, these capabilities can improve both the accuracy and speed of inspections and quality control, helping companies to reliably meet regulatory requirements and avoid costly delays that disrupt the drug supply chain.

IV. TRAINING THE HEALTHCARE WORKFORCE OF THE FUTURE

Premier believes technology can and should work alongside and learn from healthcare professionals, ***but current technology will not and should not replace the healthcare workforce.***

To ensure clinical validity and protect patients, Premier reiterates 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.

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 healthcare workforce training programs provide comprehensive AI literacy training***. Healthcare workers deal with high volumes of incredibly nuanced data, research and instructions – a growing percentage of which may be supplied by AI. This is particularly true for applications of AI in drug development, where manufacturers and quality control specialists may be reviewing high volumes of AI-powered recommendations or insights and making rapid decisions that affect the safety of patients. 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 and provider liability. Additionally, clear, risk-based guidance on which uses of AI technology in healthcare require human review and decision-making is essential.

Additionally, watermarking or provenance data/systems for AI-generated content were a component of the voluntary commitments recently announced by the Administration. 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, drug manufacturers 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 overreliance 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. In the drug manufacturing process, it is important that workers evaluating a supply chain disruption prediction, optimization recommendation, or quality control report know that the data or recommendation is AI-generated and evaluate it effectively.

V. CONCLUSION

In closing, Premier appreciates the opportunity to respond to your white paper on AI. . If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Committee 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.

PREMIER®

PREMIER'S ADVOCACY ROADMAP FOR THE 118TH CONGRESS: ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Premier supports the responsible development and implementation of artificial intelligence (AI) tools across the healthcare industry, where AI is already demonstrating its ability to help improve patient outcomes and provider efficiency. AI holds great potential for empowering the healthcare workforce, mitigating supply chain shortages, advancing health equity and driving higher-quality care. While Premier embraces AI's potential, we also acknowledge that trust – among patients, providers, payers, policymakers and suppliers – is critical for the responsible adoption of AI tools in healthcare settings. To earn trust, AI tools must be subject to clear statutory, regulatory and subregulatory guidelines that ensure transparency and protect individual rights and safety.

While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine.

OPTIMIZING THE VALUE OF HEALTHCARE

Providers, both acute and non-acute, continue to experience significant fiscal challenges stemming from a combination of increased labor costs, record inflation and lagging reimbursement rates that do not account for these unprecedented financial challenges.

Promote the use of AI in value-based care to amplify delivery system transformation. AI tools hold immense potential for identifying the highest-risk patient populations, as well as the best ways to deploy clinical resources to serve them. Innovative payment models allow resource flexibility to invest in technology such as AI to shift the paradigm of population health management.

Advance the use of AI in healthcare quality programs and measurement. Providers, payers and the federal government can all benefit from technology resources that look deeper than descriptive data. Premier will continue to work with our federal partners to demonstrate transformative use cases for AI in Medicare and other quality programs.

Create opportunities for AI to support the overburdened healthcare workforce. Premier will advocate for federal healthcare workforce programs that leverage AI to identify root causes of healthcare workforce shortage and train the clinical workforce on how to best leverage AI technology to optimize workflows and patient care.

BUILDING RESILIENT HEALTHCARE SUPPLY CHAINS

Premier advocates for policies that create visibility and transparency into the healthcare supply chain. Premier's goal is to ensure that every provider in the country has access to the right product, at the right time, at the right quality and at the right price for patient care.

Advance the use of AI to provide visibility into drug and medical supply chains. Premier will advocate for federal programs and financial incentives to increase the use of AI for medical supply chain insights, including the source of raw materials, to enhance national security and preparedness.

Provide AI-driven insights to build resilient supply chains. Premier will operationalize AI insights to inform federal policymaking and preparedness while bolstering supply chain resiliency, including strengthening supply chain integrity.
Leverage AI-driven tools to predict drug and device shortages. Premier will operationalize AI insights to inform federal policymaking related to drug and device shortages, including opportunities for the Food and Drug Administration (FDA) to leverage private sector AI algorithms to proactively predict shortages.

Incorporate AI into advanced manufacturing techniques. Premier will advocate for policies that support the incorporation of AI into advanced manufacturing techniques to support diversification of supply chains and manufacturing resiliency.

TECH-ENABLING HEALTHCARE

Premier advocates for policies to advance technology that will enhance patient safety and quality improvement, facilitate secure and timely communication and data exchange among healthcare stakeholders, and produce actionable and reportable data.

Improve trust and transparency for healthcare AI solutions. Premier will pursue trustworthy AI standards, including transparency in algorithmic decision-making, focusing accountability on the outputs and outcomes of AI technology.

Encourage AI innovation and competition. Premier will work with government partners to encourage policies that promote innovation in AI and the ability of U.S. companies to compete with international counterparts.

Support the use of clinical decision support technology. Premier will advocate for federal policies that advance the adoption of clinical decision support technologies, including continued support for accelerated approvals for physician-developed tools.

ELIMINATING GAPS IN HEALTHCARE

Premier advocates for policies that address the disparities in access to and quality of healthcare experienced by vulnerable communities and populations.

Support innovation in clinical trial recruitment and operations, ensuring all populations have access to breakthrough medical technology. Premier will work with the FDA to ensure clear and consistent guidance allowing for innovative uses of AI to identify and recruit patients for trials, construct control arms using real-world data, and develop synthetic data to improve trial design and safety.

Support the incorporation of novel digital endpoints into clinical trials. Premier will work with the FDA and industry partners to find ways to harness the analytical power of AI to incorporate novel digital endpoints and previously unavailable inferences into clinical trials, strengthening evidence available about new drugs and devices.

Prevent bias from hindering AI's effectiveness. Premier will work across government and industry to incorporate standards and regulations designed to detect and prevent bias in AI systems, including data standards, ongoing disparity testing, quality controls and outcome monitoring, and a risk-based framework for AI deployment in healthcare.

Click here to download Premier's Advocacy Roadmap.

For more information on Premier's advocacy agenda, please contact:
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