

July 7, 2023

Nik Marda Chief of Staff, Tech Division White House Office of Science and Technology Policy Attention: OSTP-TECH-2023-0007

Submitted electronically to: http://www.regulations.gov

Re: Request for Information: National Priorities for Artificial Intelligence (OSTP-TECH-2023-0007)

Dear Mr. Marda,

Premier Inc. appreciates the opportunity to submit comments to the White House Office of Science and Technology Policy (OSTP) regarding the request for information (RFI) to develop National Priorities for Artificial Intelligence (AI). As described, this RFI 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 and mitigate the risks of emerging AI technologies.

Premier appreciates OSTP's commitment to leveraging AI to advance equity, promote economic growth and innovate in public service, while remaining mindful of the potential threats that Al 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. Premier specifically requests that OSTP consider the following in developing a National AI Strategy:

- Promote transparency by holding AI technology to publicly-reported metrics based on outcomes, not on inputs;
- Mitigate risks of bias and discrimination by requiring publicly reported disparity testing results, both before and after technology deployment;
- Incorporate guidelines for AI risk assessments that identify potential risks, potential mitigation strategies, detailed explanations of recommended uses for the tool and risks that could arise should the tool be used inappropriately;
- Establish data standards that include an objective assessment of potential sources of bias or inaccuracy introduced through poor dataset construction, cleaning, or use;
- Establish guidelines for proper data collection, storage and use that sufficiently protect patient rights and safety:
- Prevent inappropriate or unintended use of AI technologies by requiring developers to clearly describe recommended and prohibited use cases;
- Mitigate risk of automation bias through comprehensive risk assessment and workforce training efforts:
- Avoid across-the-board freezes on AI technology development, which would put American companies at a competitive disadvantage globally;
- Require agencies with sector-specific jurisdiction over Al policy to hire technologists with Al-specific expertise to incorporate into current industry and legal regulatory frameworks; and
- Engage in public-private partnerships with AI industry experts to ensure any regulatory framework reflects the cutting edge of AI technology.

Our detailed recommendations are included below.

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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. COMMENTS ON NATIONAL PRIOIRITIES FOR ARTIFICIAL INTELLIGENCE

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. Clear statutory, regulatory and

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subregulatory guidelines will better prepare providers and payers to deploy AI technology to its full potential, while still protecting individual rights and safety.

Protecting Rights, Safety, and National Security

[In response to questions 1, 2, and 3.]

Premier strongly supports Al 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" model. This approach seeks to demystify the black box of an Al 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. Further, overly-intrusive disclosure requirements, around either data inputs or algorithmic processes, that would force AI developers to publicly disclose their intellectual property or proprietary technology may 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 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.

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 Al Risk Management Framework. An Al Risk Assessment should identify potential risks that the Al 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 also urges OSTP to adopt a nuanced approach to risk level classification for the use of Al tools in healthcare. While there are some clinical applications of Al 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 Al 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 Al technology to treat patients.

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

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(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.

[In response to question 4.]

Premier believes the application of AI in the healthcare supply chain sector will advance overall national security by helping build a more efficient and resilient healthcare supply chain. Specifically, AI should help with better 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.

Protecting and Empowering Underserved Communities

[In response to questions 10 and 12.]

Premier believes that AI technology must be developed and deployed with special attention towards algorithmic discrimination for vulnerable, underserved communities. While AI has immense potential to improve medical care, enable providers and increase the availability and accessibility of critical healthcare services, developers and users of AI technologies must be conscious of unique challenges introduced by data limitations, inappropriate or unintended use of AI technologies and potential automation bias among medical professionals.

Premier has unique expertise in harnessing.data to improve care for underserved populations. PINC AI Applied Sciences has assembled a HIPAA-compliant database containing over one billion data points representing 25 percent of U.S. hospital inpatient and outpatient discharges drawn from a geographically diverse collection of over 1,000 U.S. hospitals over the past twenty years. PINC AI Applied Sciences has used this data to <a href="https://idea.com/idea.co

It is also critical to ensure that AI tools are used as intended to limit bias, discrimination or other adverse impacts. Premier understands that an AI technology or dataset that is highly accurate for one patient, subgroup or condition may not provide the same insight or accuracy for another. Premier strongly recommends that any standard or certification of AI technology include a requirement that developers provide a detailed description of the intended use cases for the tool or device. Users should then be required to only use that device for certified use cases. In many cases, AI technologies are highly specialized. The dataset that an AI device is trained on may be representative of a particular population, condition, procedure, or specialty; however, there should be no assumption that the same dataset is representative for use cases beyond that design.

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Automation bias is another 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 Food and Drug Administration (FDA) in <u>guidance</u> 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.

Promoting Economic Growth and Good Jobs

[In response to question 18.]

The healthcare industry faces extensive, well-documented workforce challenges. 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. Premier envisions several ways in which AI could help alleviate labor costs and shortages and enhance the healthcare workforce, including through increased efficiency, reduced administrative burden, and improved quality of care at lower costs.

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 comprehensive training on automation bias. 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.

[In response to question 19.]

Several recommendations were proposed by lawmakers during a recent Senate Judiciary Committee hearing on AI, including freezing AI development for up to six months while regulators develop a framework for AI and establishing a new regulatory body to govern AI. Premier believes that proposals to freeze AI development would unnecessarily stifle innovation, hamper the U.S. economy, and place U.S. companies at a disadvantage against international competitors.

Al technology in healthcare is not new; rather, the pace of development has rapidly accelerated and innovation has occurred in major bursts over the past year. This rapid pace of innovation has led to increased competition, both within the U.S. and internationally. A freeze on Al development equates to a self-imposed setback for American companies currently in fierce competition on a global scale. It would also put startups and new companies at a disadvantage, slowing the pace of innovation. Additionally, a development freeze would limit the economic boost projected to come from the integration of new Al technologies into sectors such as healthcare.

Premier also opposes the creation of a new federal agency to regulate and govern AI, which would increase confusion and introduce inefficiency to AI governance and put U.S. companies at a competitive

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disadvantage. The time it would take to establish, staff, and determine the jurisdiction of a new agency would leave the healthcare industry and AI innovation and development in regulatory limbo for far too long to be tenable. Even after it is created, a new agency would lack the sector-specific expertise and regulatory relationships necessary to effectively regulate and govern AI at the scale necessary in today's economy. Rather, Premier recommends that agencies with sector-specific jurisdiction (e.g., Department of Health and Human Services, Department of Transportation, Department of Commerce) make an active effort to hire technologists with AI-specific expertise to incorporate into current industry and legal regulatory frameworks. Additionally, AI regulatory jurisdiction should be incorporated into the existing agency structure, and each federal agency should be tasked with establishing AI regulatory frameworks within a reasonable timeframe to enable innovation and reduce uncertainty across the U.S. economy.

Innovating in Public Services

[In response to questions 25 and 26.]

Premier recommends that agencies within the federal government pursue public-private partnerships to develop standards and regulations that support U.S. Al innovation and ensure that American workers, businesses, and the economy benefit from Al development. Premier and other private companies at the cutting edge of Al technology development can offer real-world insights into the ways Al 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 Al regulations for the healthcare industry is understanding how providers actually use Al technology and the processes providers are using on the ground to implement new Al systems and procedures. In order to effectively regulate Al, 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.

III. CONCLUSION

In closing, Premier appreciates the opportunity to respond to OSTP's RFI on National Priorities for Al. 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.