

May 23, 2024

Dr. Micky Tripathi
National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building
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Washington, DC 20201

Submitted electronically to: <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2>

RE: Draft 2024-2030 Federal Health IT Strategic Plan

Dear Dr. Tripathi:

Premier Inc. appreciates the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) regarding its Draft 2024-2030 Federal Health IT Strategic Plan. Premier applauds the ONC's commitment to improving health experiences and outcomes for patients, advancing health equity and innovation and modernizing the nation's public health infrastructure. Premier shares many of ONC's goals for addressing the policy and technology components essential for meeting diverse data requirements of all health IT users. In our comments, Premier specifically recommends that ONC consider:

- Conducting adequate and inclusive real-world testing of new standards – with input from provider end-users – before the standards are codified in rulemaking;
- Advancing standardization, transparency and automation of the electronic prior authorization process while working closely with providers and other end-users who have been piloting new technology standards;
- Holding artificial intelligence (AI) technology in healthcare to a standardized, outcomes-focused set of metrics that promote transparency and mitigate bias;
- Working across the Department of Health and Human Services (HHS) to leverage ONC's data resources to validate providers' certified electronic health record technology (CEHRT) adoption and use while limiting administrative burden; and
- Continuing to standardize and harmonize practices and standards for the collection and use of data on social determinants of health.

Our recommendations are described in greater detail below.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 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's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 2.7 billion hospital outpatient and clinic encounters and 177 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 is focused on leveraging cutting-edge technology to move the needle on cost and quality in healthcare, including:

- Premier's PINC AI Clinical Decision Support (CDS) designs AI-enabled technology to reduce low-value and unnecessary care. PINC AI CDS leverages natural language processing AI technology to read unstructured data such as physician notes in electronic health records and ties together unstructured data with established practice guidelines to generate real-time alerts and relevant analytics, guiding physician's decisions toward higher-quality, lower-cost healthcare. PINC AI CDS'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 AI-powered solutions that span the continuum of care and enable sustainable innovation and rigorous research. Our services and real-world data drive research and quality improvement in pharmaceutical, device and diagnostic industries, academia, federal and national healthcare agencies, as well as hospitals and health systems. PAS leverages Premier's robust data resources to design and deploy AI-powered solutions for clinical trial recruitment, and to help collate disparate patient records to tell a complete patient story, leading to higher-quality care.
- 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's award-winning PINC AI Supply Chain Disruption Manager (SCDM) builds resilience and mitigates risks to the healthcare supply chain by harnessing machine learning AI technology to predict when critical drugs, devices and other medical supplies are anticipated to become unavailable up to six weeks in advance of a supply chain disruption. SCDM allows hospitals and health systems to access clinically approved alternative products to avoid delays in care or quality, and it allows for communication to federal agencies and other partners about pending shortages to help proactively develop mitigation strategies.

II. INTEROPERABILITY AND DATA SHARING THROUGH REAL-WORLD TESTING

The development of new health IT standards and their adoption into regulatory requirements can be highly beneficial for both solving existing, known challenges and creating more uniformity in how health information is gathered, shared and used. Premier appreciates ONC's intent to collaborate across public and private sectors on health IT standards' maturity, adoption and use. Premier also strongly support ONC's goal of improving alignment and automation of data collection and reporting, which will reduce the administrative burden and costs associated with federal requirements.

Premier also agrees with the need to develop, align, test and implement data standards to increase interoperability. **Premier believes that adequate and inclusive testing of standards should be done before they are promulgated in regulations.** Although ONC references real-world performance throughout the draft Strategic Plan, real-world testing requirements that are included in ONC's certification

rules are most helpful for assessing how health IT products perform **after** implementation – this is not the same as real-world testing in advance of codifying requirements in regulation. Additionally, **Premier encourages ONC to include a diverse set of end-users from various settings and sizes of healthcare organizations in all phases of real-world testing of standards.** Premier also recommends that ONC work closely with CMS, other relevant federal agencies and the broader health IT stakeholder community to identify the most critical elements for the successful real-world testing of standards.

III. INTEGRATING HEALTH IT INTO CLINICAL WORKFLOWS

To limit the burden and cost of implementing new technologies and standards, it is critical that they be integrated as seamlessly as possible into existing clinical workflows. Premier strongly supports ONC's objective to promote the use of health IT in clinical workflows and to provide support for healthcare professionals for easier adoption, implementation and secure use of health IT. Premier commends ONC for recognizing the need for resources and support focused on users of health IT. Providers, hospitals and health systems could particularly benefit from tailored assistance that accounts for – and builds on – the varying existing capabilities of the organization(s). Premier recommends that ONC offer open-door forums for end-users to identify needed resources and technical assistance, enabling both federal agency staff and technology vendors to outline actionable steps for streamlining and improving implementation of health IT.

Premier appreciates ONC's continued commitment to streamlining electronic documentation requirements to reduce administrative burden and improve the quality of patient health records, including standardizing data and processes related to electronic prior authorization. Prior authorization is intended to protect patient safety and lower costs by putting guardrails in place to avoid inappropriate care. However, too often it can also limit timely patient access to medically necessary services and be costly, time-consuming and burdensome for healthcare providers. For example, the HHS Office of the Inspector General (OIG) issued an alarming [report](#) finding that Medicare Advantage plans often denied or delayed patients' access to medically necessary services and burdened physicians, even though the requests met Medicare coverage rules. These inappropriate denials were due in large part to human error during the manual claims processing reviews. **A main culprit is a lack of standardization, transparency and automation of the prior authorization process.**

Greater engagement with the health IT end-user community will help create a better understanding of the effort needed to operationalize technology solutions and business processes needed to interact with payer systems. For example, the Health Level Seven (HL7) DaVinci Project was granted as "exception from use of adopted standards" to test whether Fast Healthcare Interoperability Resources (FHIR) based standards will reduce the cost, complexity and burden associated with electronic prior authorization transactions.¹ CMS required reporting of the pilot's findings no later than July 14, 2024. **Premier recommends that ONC and other federal partners make the pilot results publicly available and work with health IT end-users to evaluate the results in light of any on-the-ground implementation challenges that providers may be experiencing, ensuring that the implementation of FHIR for electronic prior authorization and other purposes may be conducted smoothly and successfully.**

IV. LEVERAGING ARTIFICIAL INTELLIGENCE IN HEALTHCARE TECHNOLOGY

ONC notes in its draft Strategic Plan that the federal government plans to prioritize promoting education, outreach and transparency about the use of AI. 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 the federal government in advancing clear regulatory guidelines

¹ Letter from Christine Gerhardt, Director, National Standards Group, CMS to Sagan S. Moodley, Chair, HL7 Da Vinci Project Steering Committee dated April 14, 2021.

that will allow providers and payers to deploy AI technology to its full potential, while staunchly 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 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.”

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.

V. LEVERAGING EXISTING DATA RESOURCES TO REDUCE PROVIDER BURDEN

As part of its [2024 Medicare Physician Fee Schedule](#) rulemaking, the Centers for Medicare & Medicaid Services (CMS) finalized several policies pertaining to CEHRT utilization requirements for ACOs, Alternative Payment Model (APM) Entities and their participating practices. Premier is concerned that two of the finalized policies could significantly increase burden and jeopardize participation in the Medicare Shared Savings Program (MSSP) and other Medicare Advanced APMs, with a disproportionate impact on small practices and the beneficiaries they serve.

First, CMS will require that all MSSP participants, regardless of Qualified Participant (QP) status or track, report Merit-based Incentive Payment System (MIPS) Promoting Interoperability (PI) data beginning with the 2025 performance year. Additionally, CMS has updated the CEHRT use criteria for all Advanced APMs from 75 percent to all eligible clinicians starting in 2025. ***Premier strongly opposed this proposal for multiple reasons, including the excess burden it places on ACOs and clinicians and the policy's contradiction to the statutory exemption from MIPS as a key incentive for clinicians to participate in Advanced APMs.*** While Premier appreciates the goal of ensuring compliance with CEHRT criteria, we believe this could be accomplished in a less burdensome manner that more closely aligns with CMS' stated goal for all Medicare fee-for-service beneficiaries to be part of care relationships with accountability for quality and total costs by 2030.

Rather than its current approach, CMS could instead validate CEHRT adoption and utilization across the ACO and APM community by: (1) instituting a "yes/no" attestation to demonstrate CEHRT adoption, use and compliance with information blocking requirements; and (2) leveraging ONC CEHRT data that are already being collected directly from certificated HIT developers, such as information from the new Insights Condition and Maintenance of Certification finalized in ONC's recent Health Data, Technology and Interoperability (HTI-1) Final Rule.

When fully implemented, ONC's new Insights Condition will require certified HIT developers to report on use of their products across four areas related to interoperability: individuals' access to electronic health information, clinical care information exchange, standards adoption and conformance, and public health information exchange. Importantly, this information will reflect real-world clinician use of CEHRT in actual clinical settings rather than check-the-box reporting. Using a yes/no attestation combined with Insights Condition metrics and other robust ONC data, ACOs will more effectively demonstrate how CEHRT is being utilized across the entire health ecosystem without the need to collect duplicative data from clinical staff, allowing them to focus on patient care. Importantly, this ONC data can be leveraged for MIPS and APMs to promote alignment across programs. Premier urges ONC to work collaboratively with CMS to use ONC's data to help CMS and HHS writ large to achieve its goals of monitoring adoption of CEHRT and preventing information blocking.

VI. COLLECTION AND USE OF SOCIAL DETERMINANTS OF HEALTH (SDOH) DATA

Achieving equity in health and healthcare requires both collecting much-needed data to identify disparities and working towards improving care delivery for better patient health outcomes. Currently, there is significant variation in the way social risk data is collected across different healthcare organizations and systems. This inconsistency can result in incomplete or inaccurate data, which can ultimately hinder efforts to address social risk factors and promote health equity. Premier has been working with our members and

various coalitions to gain insights into health disparities and effective methods of tackling them, including the collection and sharing of social risk factor data. The barriers to health equity have several components that need to be addressed and Premier believes there are three key issues that are paramount:

1. There are numerous data collection, data sharing and outcome measurement standards that confound insights into health disparities. This inhibits collaboration across organizations and sectors.
2. There is a lack of sustainable funding for health equity endeavors, including better collection of social risk data. Currently there are very few payment mechanisms that support and incentivize care transformation that addresses medical and social needs to advance health equity.
3. There is a shortage of strong forums for the sharing of data, insights and best practices across organizations and sectors.

Throughout all goals in the draft Strategic Plan, Premier is pleased to see objectives related to advancing the collection and use of standardized SDOH data, ensuring data collection involves appropriate consent for and understanding of secure sharing and use of this information, and encouraging equity, safety, and user-centered design principles in the development and use of health IT. While flexibility in screening tools and processes can allow providers to best collect this data within existing workflows and environments, the lack of standard approaches can lead to inconsistent data classifications and collection, struggles to track progress over time, and the inability to share this data across organizations and care settings to efficiently coordinate care.

Premier also appreciates the objective to harmonize common data elements for improved interoperability. Premier supports efforts to standardize and increase uniform collection and reporting of relevant data. In addition to standardization, end-users need training in how best to collect sensitive data, the tools and workflows best equipped to collect and share it effectively, and how to avoid redundant or inaccurate data collection. Finally, Premier recommends ONC continue working with CMS to support the development of standards for the collection of social risk data, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and FHIR standards. Providing resources, tools, and training will widen the opportunity for providers and other end-users to be able to collect this information and monitor impacts and interventions on health disparities and health outcomes.

VII. CONCLUSION

Premier appreciates the opportunity to comment on the ONC Draft Strategic Plan. 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,



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Premier Inc.