May 28, 2024

Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology
Attention: *2024-2030 Federal Health IT Strategic Plan*: *Draft for Public Comment*
U.S. Department of Health and Human Services
330 C Street SW
Floor 7
Washington, DC 20201

RE: 2024-2030 Federal Health IT Strategic Plan

Dear Dr. Tripathi,

On behalf of the over 90,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) *2024-2030 Federal Health IT Strategic Plan*: Draft for Public Comment on March 28, 2024.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS is dedicated to improving the care of the surgical patient and setting standards of care in an optimal and ethical practice environment. As such, we understand the critical role technology plays in achieving this mission. This includes the need for policy to ensure health information technology (health IT) supports high-quality patient care, maintains the security of patients' electronic health information (EHI), and provides support to care teams and other stakeholders to drive positive change. With our decades of experience aggregating and evaluating data and leveraging these data to support implementation of quality programs, we believe we can offer key strategic insights to ONC. Our comments are detailed below.

Overview

The ACS appreciates the ONC's efforts in putting together this well-organized and thorough Strategic Plan. It raises a multitude of common issues that continue to present barriers to the uptake and expansion of health IT. The goals and objectives presented in this strategy are expansive and would address the health IT needs of various stakeholders. The ACS sees great opportunity in leveraging health IT to provide meaningful

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information about care to patients; support the care team in tracking and improving patient care; and create more efficiency and coordination in the health care system.

Today, health IT is viewed as a tool or enabler for finding solutions to the fragmented healthcare system. As ONC finalizes its initiatives for the next five years, we are encouraged to see that the Agency is looking beyond the current system and considering how health IT can be leveraged to enrich the transformation of healthcare to a comprehensive, coordinated, and transparent system that centers around the patient. This must include how to define episodes of care that are more meaningful to patients, clinicians, and other stakeholders, using the knowledge resources health IT generates to build care pathways and serve the entire patient journey.

When looking to the future of healthcare, the focus of health IT will be the curation of knowledge and leveraging tools, such as artificial intelligence (AI) and AI agents. Health IT can organize and present knowledge at the point of care to inform care teams for patients to better understand and find care that fits their needs, and for payers to incentivize better care. From our perspective, the future of knowledge curation will be supported by AI, not only generative AI but also AI agents and conversational AI that can extract knowledge from interactions with humans. These technologies present opportunities to support certain tasks that are currently being done by humans, ultimately removing burden from the workforce. As we look to the future, we should consider how technology can support physicians so they can work at the top of their license. This begs the question—which aspects of AI and shared intelligence require further development to support physicians and their abilities for better care? In our review of the Strategic Plan, it is clear that ONC holds the same perspective and acknowledges that health IT is no longer just supporting interoperability and data exchange but plays a major role in curating and applying knowledge for numerous use cases across healthcare.

It is also paramount that the knowledge and technology used in healthcare can be trusted by physicians, patients, and other stakeholders. To build trust, health IT, including AI, must be both clinically and technologically sound. To achieve this, these data and algorithms must be developed, trained, and tested on high-quality, highly trusted knowledge bases with ongoing surveillance once released to the public. The ACS National Surgical Quality Improvement Program (NSQIP) database is an example of a high-quality knowledge base because of the rigor and standardization of the data within the database and regular monitoring and updates. **When developing and leveraging clinical data, ONC should be collaborating with clinical experts and specialty societies who have experience working with clinical data to evaluate and test the usability, relevance, and appropriateness of health IT in the clinical setting.** Many of the same data integrity principles apply to AI algorithms. **We envision a knowledge library that specialty societies, such as ACS and others with this experience, could contribute to. A repository or library like this could house standards and validation information as well as a free, open-source sandbox environment with synthetic patient data that could be used to test the clinical and technical aspects of health IT.**

In addition, as ONC builds out their plan for knowledge management, there are various areas of healthcare to consider, such as population health, quality measurement and data tracking for improvement, standards for sharing information, research, clinical pathway development, administrative

burden reduction, and education. Many of these use cases are addressed in this Strategic Plan; however, leveraging knowledge for education and shared learning is absent. **We encourage ONC to acknowledge the importance of curating knowledge for education for continuous enrichment of our healthcare workforce.**

Goal 1: Promote Health and Wellness

ONC states that Goal 1 focuses on improving health experiences and outcomes for individuals, populations, and communities.

Objective A. Individuals are empowered to manage their health

Within this objective, ONC highlights the importance of protecting patients' EHI and ensuring they can access, use, and share their EHI without barriers. The ACS agrees that keeping patients' EHI secure and making them the sovereign owners of their data is of utmost importance as health IT continues to advance. The ACS recommends that ONC view all objectives and goals of their Strategic Plan through the lens that EHI is owned by the patient, not just those who implement or develop technology, such as electronic health record (EHR) vendors.

We must establish patients' sovereign ownership of their EHI, and all rights to use and share EHI should have to be approved by the patient. Identified patient data must always be stored and used within an environment that maintains a Health Insurance Portability and Accountability Act (HIPAA) firewall where there is a security boundary that protects the rights of the patient. It is also known that we can deidentify or clone data for use in a clinical "sandbox." When data are deidentified and used in sandboxes for research, development activities, population health tracking, etc., patients' ownership of the data would no longer apply because it is no longer identifiable. To this end, ONC and associated federal agencies should prioritize implementing policies that ensure that patients are given ownership of their data and that those who violate patients' rights and ownership of their data are penalized.

In addition to protecting patients' rights to their EHI and creating secure pathways for them to use and share their data, we also must acknowledge that patients exist in a multitude of systems. Because of this, we should be considering how to create options for patients to have centralized access to their EHI. Currently, if a patient elects to have their EHI sent to an app for the purpose of reviewing their healthcare record, they are likely to receive duplicative or incomplete information. Patients who are interested in keeping track of their record may be deterred by the amount of information and the cleaning required to make it usable. It is important that as we give patients and providers ways to bring all the information from various sources, such as provider EHR systems and patient-selected third-party apps, access to this information filters out duplication and ensures that the dots from all source systems are properly connected.

Objective B. Individuals and populations experience modern and equitable health care

To achieve this objective, ONC discusses promoting equitable access to health IT literacy resources. The ACS supports this strategy. In general, health literacy is a barrier to patients engaging in their healthcare, but as more and more health information transitions to the digital environment, we should expect health IT literacy to create similar challenges while also offering more effective and creative ways to connect with at-risk populations. Efforts to educate patients and their caregivers about how to access, share, and use EHI is an important part of the transition to creating a system centered around the patient and their needs. Also, it is key to track post-market deployment and to conduct ongoing monitoring. Digital tools can be tested for external validation, but there are many examples of tools that have led to discrimination once in the public domain, despite testing.

Objective C. Communities are healthier and safer

The strategies outlined to achieve this objective focus on leveraging public health data to address community challenges and inform action at the community level when necessary. We reiterate our previous comments that discuss the importance of trusted knowledge sources when looking to leverage data to inform initiatives to support better health of populations. We recommend that ONC collaborate with stakeholders to create standards for public health data that can help validate these data.

We also recommend that ONC consider different approaches to addressing public health, for example, by focusing on different service lines instead of broad public health issues. Overarching public health issues, such as disease prevention, screening, immunizations, and overall population health and wellness are extremely important, but there is also value in focusing on specific conditions or service lines. Knowledge can be defined for specific service lines, such as maternity care, trauma, cancer, and other conditions where specific public health principles can also be applied.

Goal 2: Enhance the Delivery and Experience of Care

ONC states that Goal 2 focuses on improving how patients and caregivers experience care, how health care providers and others across the health care continuum deliver care, and how health plans reimburse for care.

Objective A. Providers deliver safe, equitable, high-quality, and improved care

To achieve this objective, ONC plans to promote the use of health IT and other modern technology in clinical workflows by promoting interoperable data sharing through nationally adopted standards, supporting payment for high-quality, value-based care, and increasing transparency and understanding of health data that feed algorithm-based decision support tools. **The ACS is supportive of efforts to leverage data and technological advancements in health IT to align with clinical workflows and ultimately drive high-quality, high-value care. To date, most data and EHRs have been designed for documenting patient records in the context of a care setting. The initial intent of electronic records was to create a record for a service workflow and billing solution. Furthermore, these data only encompass services at the individual level, which does not show the full picture of care**

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delivery. We envision that functions of health IT can be utilized to better assess the patient goals for care and track conformance with the clinical pathways in tandem with ensuring that the patient goals are top of mind for the care team. Technology presents opportunities to create intersections between typical clinical guidelines for a condition and layer them with personalized information about each patient, such as the patient's goals and their limitations. The development of standardized data elements for non-clinical factors that influence care, such as social determinants, will also be important to realize this goal. Social determinant factors can have a major impact on executing the clinical pathway and ultimately the delivery of equitable, high-quality care.

In addition, health IT can be implemented to help care teams determine gaps in their care delivery processes and shine a light on areas where improvement is necessary. **While current workflow solutions are well suited for recording clinical care related to business transactions, we challenge ONC to think beyond the transactional nature of these systems and instead, to use health IT as a tool to support and enhance care.**

Expanding National Data Standards

We appreciate the work ONC has done to create an exchange environment through its interoperability efforts and implementation of standards, such as the United States Core Data for Interoperability (USCDI) and Fast Healthcare Interoperability Resources (FHIR). We have been supportive of the continued development of standardized data elements for bi-directional exchange of essential health information needed for care delivery, to coordinate optimal care for patients, and to help inform care team in improvement efforts. **As ONC continues to build out national data standards and standardized data elements, we thank ONC for considering incorporation of clinical orders**. Interoperable order data that shows when certain orders are made and fulfilled would allow clinicians to identify and track key laboratory tests, medications, radiology services, etc. across care settings. Having a sense of these key orders as part of the information being regularly exchanged would help clinicians better understand a patient's progress in their care journey.

Supporting Transparency and Trust

Transparency is essential to both physician and patient trust in health IT. First, there must be transparent documentation of health IT development and ongoing validation processes to ensure that products are safe and effective as the tools and data environments iterate over time. The ACS has been a pioneer in the use of data for quality improvement as demonstrated across our numerous risk-adjusted clinical data registries, such as ACS NSQIP. From this experience, we are well-positioned to offer advice and considerations for ONC in their efforts to use data to support quality and value-based care. We have learned that building a knowledge base worthy of data mining for information must hold standards of data integrity, rigor, and security so the knowledge base it generates becomes a source of truth. It is well known that searching the internet or using generative AI can lead to information, misinformation, and deceptive efforts of mis/disinformation. The importance of a trusted database, such as the ACS NSQIP, cannot be overstated.

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By ensuring that the data is high-quality and accurate, digital tools and algorithms, such as tools enabled by generative AI, can be applied and have a higher likelihood of delivering reliable, valid, and actionable information. This could come in the form of a "watermark" that confirms that a health IT product aligns with the highest clinical, quality, and regulatory standards. Groups like the ACS would be well-positioned to provide such validation for surgery.

Objective B. Patients experience expanded access to quality care and reduced or eliminated health disparities

Elements of this objective mention ONC's plans for health IT use beyond hospitals and physician offices by expanding access to behavioral health, long-term and post-acute care, and home health settings. The ACS thanks ONC for acknowledging the importance of integration between all care settings and all health and human services. Behavioral health and the management of these conditions can play a major role in patients' recovery from surgery. Integration of these data and services that are provided outside of clinical settings will only help to better inform clinical teams and other practitioners about how to better manage, prepare patients for surgery, and create more coordinated efforts in offering care.

Objective C. Health care is improved through greater competition and transparency

Patient Selection of Application

Within this objective, ONC plans to encourage pro-competitive business practices for the appropriate sharing of EHI. They state that by doing this, individuals can easily select health applications of their choice and can use applications and other health IT without special effort. In the past we have voiced concerns about these efforts. **We are concerned that patients will select applications that are untrustworthy and could be outside the protections of HIPAA, and this could put their data or other clinical systems that are required to exchange with these applications at risk. We recommend that ONC continue to work with other federal agencies to explore pathways to verify and transparently share the validity and security of applications with patients as they gain greater access to their EHI.**

Electronic Availability of Quality and Price Information

This objective also outlines a plan for making care quality and price information available electronically. The ACS is supportive of these efforts, but cautions ONC about the risk of mischaracterizing physicians, other healthcare professionals, and facilities without adequate metrics for quality and price that incorporate risk adjustment. ONC should consider the following points as they work toward achieving this objective:

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- If not effectively designed, health IT systems or other publicly available information could direct patients to facilities or providers who are not equipped to care for their needs. Inappropriately designed measures and systems can also result in perverse incentives to avoid high-risk patients or patients assumed to be more costly to the system. This can lead to clinicians referring patients to other providers, which results in access issues and poor care overall. However, data aggregated and presented in the right way can inform patients about access to care, outcomes, avoidable harms, and affordability and can assist patients in need of special care. When patients are seeking surgical services in a certain geographic location, patients should have access to general information about all surgical services, including information that defines service lines and episodes within those service lines. Since care offerings and resources vary across different facilities, it is important that information is available about the distinction of services, which can vary based on resources, technical skills, and experience.

- Instead of creating transparency around individual metrics that only focus on the care provided by one physician, the measures should be focused on attainment of the patient's goal and how the care team member contributed to the efforts of the team. Attributing measures based on shared accountability means credit is assigned to all team members for the outcomes they jointly achieved.

- To meet patients' needs, price transparency should have outputs that inform patients about total cost of care, with transparency around mean and median price. Additionally, pharmacy drug data are essential to portray the complete analysis of the cost of care. The ACS has worked with Brandeis University and the PACES Center to use open standards-based episode definitions and open logic to establish episodes of care for traditional Medicare fee-for-service using the CCW Virtual Research Data Center (VRDC). Unlike current methods used in Centers for Medicare & Medicaid Services (CMS) incentive programs, such as the Acumen methodology, PACES is open source, which drives true transparency because the cost calculations are reproducible outside of CMS.

Other useful data for determining cost and affordability include:

- Volume of services delivered over a period of time,
- Percentage of high-risk patients,
- Mean/median cost of care,
- Cost of clean versus complicated procedures,
- Ratio of observed cost versus expected cost, and more.

Objective D. Providers experience reduced regulatory and administrative burden

As part of this objective, ONC plans to leverage health IT to standardize data and processes related to electronic prior authorizations to allow for increased automation. **The ACS is supportive of efforts to streamline prior authorization (PA). From our perspective, technology is capable of automating prior authorization, but current prior authorization guidelines do not account for the complicated nature of health and the complexity of caring for patients.** Payers build PA requirements based on

guidelines for care, but the guidelines are only the first step in making care decisions. Care guidelines are developed by subject matter experts (SMEs) by exploring science and gathering evidence. However, guidelines do not always account for local resources or unique patient needs, which may impact how the care is delivered in alignment with the guidelines, and ultimately determine the care pathway. In this case, clinicians must customize the care pathway that aligns with guidelines and available resources, to determine a patient's personalized care plan. For example, patients with the same condition may have two different attitudes and goals for their care. One patient may become tired by the treatments, unwilling to travel, and lack family support, leaving the patient uninterested in continuing with treatment. Meanwhile, another patient with different circumstances might be motivated to do whatever it takes to overcome their condition. These two patient perspectives differ and their physicians' approach to their care should align with the needs and wants of the patient. However, in both instances, the guidelines for how to care for them are the same. If a clinician only followed the guidelines and did not account for the uniqueness of the patient to determine their individual care plan, they would not be adequately meeting the patients' goals. Therefore, using guidelines to determine PA requirements without accounting for the many other factors, such as local resources and the specific needs of the patient complicates the process of making appropriate care decisions. This highlights the importance of contextualizing care to patients' goals and not always relying on the exactness of applied medical science.

Goal 3: Accelerate Research and Innovation

ONC states that Goal 3 focuses on advancing opportunities for individuals, researchers, technology developers, and other health IT users to accelerate scientific discovery and innovation.

> *Objective A. Researchers and other health IT users have appropriate access to health data to drive individual and population health improvement*

Within this objective, ONC discusses a strategy to leverage existing common data elements or create new ones through collaboration with standards development organizations to improve data quality. We support strategies to leverage existing common data elements but want to highlight the burdensome nature of creating new common data elements. The current cycle that frequently recreates common data elements can require major investment and burden each time data elements are adjusted or replaced. We ask ONC to consider ways to create a collaborative environment that would outline existing common data elements to be maintained as the standard. There could be separate sets of research standards in development that can be used to supplement the common data standards, without requiring constant updates of the common data element inventory. As new research emerges and with agreement from the community at large, there should be a process in place for these supplementary data elements to replace existing common data standards.

> *Objective B. Individual and population-level research and analysis are enhanced by health IT*

This objective discusses strategies to broaden use of new technologies and analytic approaches to advance individual and population-level research. The ACS sees opportunity in applying machine

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learning and predictive modeling on sandboxes that hold synthetic patient data with similar characteristics to a real population to help physicians identify risks in their patients. By harnessing the power of data and these predictive technologies, physicians can begin to compare patients and their characteristics to testing data that was deidentified and make correlations with statistical power about which patients may also be at risk. If this information can be presented to physicians at the point of care, we can better support physicians in making important decisions about their patients while also improving the quality and efficiency of care by earlier detection of risk for disease.

> *Objective C. Researchers advance health equity by using health data that includes underrepresented groups*

Within this objective, ONC discusses their plans to address bias and algorithmic discrimination guidelines around health IT and create a more diverse representation of vulnerable communities and population in research design. **Reducing bias and discrimination in health IT is critical and must be considered when designing, training, and using health IT.** Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms or research findings, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used or should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI algorithms. The need for trusted and complete data sources for AI tools is critically important, and ensuring the algorithms and data are properly validated is crucial. If the tool is not developed and trained with data that are representative of the patient population the physicians serve, the data outputs could be inaccurate or biased. The data sources, methods of data collection, data quality, data completeness, whether the data are fit for purpose, and how the data are analyzed, must all be considered.

In addition, building a framework through collaboration with stakeholders possessing clinical and technical expertise, as well as those who work closely with these populations, such as State Medicaid groups, can help guide the development and validation of algorithms and assist in reducing bias if done with a high level of rigor. ONC should consider developing a framework that includes a checklist with certain steps that developers and researchers would have to complete to ensure algorithms have gone through rigorous testing and validation. This type of framework, coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy. By following the processes and validation criteria set forth by

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the framework, developers can ensure that the algorithms are free of significant bias and output accurate predictions.

Goal 4: Connect the Health System with Health Data

ONC states Goal 4 focuses on the policy and technology components needed to support various data needs of health IT users.

Objective A. Development and use of health IT capabilities continues to advance

This objective addresses ways to continue moving the development and use of health IT forward, including promoting mechanisms to address data governance, encouraging transparency in health IT usability, and reducing financial and regulatory barriers to innovation. As we have discussed in previous sections, allowing health IT vendors to control EHI has been problematic and stifled innovation over the years. Health IT vendors have monetized and impeded access to data in a usable format, making it difficult for providers or other stakeholders to use the data to drive improvements in clinical technologies, research, etc. With the implementation of national data exchange standards as a requirement of EHR certification, data should be available for sharing and not stored behind the firewalls of health IT vendors for them to further monetize the use of these data, especially when the patient should be the owner of their EHI, as discussed earlier.

This objective also discusses reducing financial and regulatory barriers to implementing health IT. The ACS supports efforts to reduce these barriers as the cost to not only implement and maintain a current health IT system is exorbitant, but also the cost to switch to new health IT systems presents even greater financial burden and may put end users at risk of losing information that vendors may deem under their ownership. These factors are problematic and can also stifle innovation. If an end user is beholden to a system that does not fit their needs because of the financial stress switching to a new system would put on the organization, then the potential of new systems may never be realized.

Objective B. Health IT users have clear and shared expectations for data sharing

This objective discusses ONC's plans to promote information sharing and highlights plans to advance policies related to the Trusted Exchange Framework and Common Agreement (TEFCA). The ACS has been supportive of the advancement of health information exchanges (HIE) through implementation of Qualified Health Information Networks (QHINs) under TEFCA. As the policies under TEFCA advance, we ask ONC to review how it plans to ensure compliance under TEFCA.

The HIE and QHIN environment was contemplated for simple workflow exchange, but after it was stood up it was realized that sharing the knowledge assets found in HIEs and QHINs offered more value than simple workflow exchange. Nationwide exchange of data is an important step in the transition to integrated interoperable health IT systems. Therefore, we ask ONC to consider

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how to make connections with QHINs more accessible to those who would not be able to participate because of cost, such as small physician practices or individual providers.

Finally, the ACS appreciates ONC mentioning that it plans to work towards international collaborations to support this effort. Other parts of the world have taken major strides to creating federated knowledge sharing networks. They are assembling knowledge around conditions to empower patients and assist providers and policymakers in understanding where resources can be extended. Through collaborative relationships with other countries who have moved ahead on these projects, we can learn best practices and realize opportunities for successful nationwide information sharing.

The ACS appreciates the opportunity to provide feedback to this Strategic Plan and looks forward to continuing dialogue with ONC on these important issues. If you have any questions about our responses, please contact Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

Sincerely,

Patricia L. Turner, MD, MBA, FACS
Executive Director and CEO