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March 13, 2020

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the 32 members of the Electronic Health Record (EHR) Association, we are pleased to offer our input on the Draft 2020-2025 Federal Health Information Technology Strategic Plan.

EHR Association members serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

We appreciate the opportunity to review proposed federal health IT goals and objectives as you work to fulfill the requirements of the 21st Century Cures Act. Widespread interoperability, better patient access to their own health records, and decreased provider burden are goals that we can all support, and the members of the EHR Association remain available to you and your team to provide early input on reasonable expectations and timelines for regulations directed at these important goals.

We note that we may have additional comments or different perspectives on some of the concepts included in the Strategic Plan after reviewing the impending final rule on information blocking, interoperability and certification, but in the meantime, our comments and recommendations on specific aspects of the Strategic Plan follow.

Goal 1: Promote Health and Wellness

Objective 1a: Improve patient access to health information

The EHR Association agrees patients should be empowered with easy and efficient access to their health information and control who is able to receive and use that data. However, in order for patients to improve their outcomes or decrease costs, they must be able to understand that data. There is a need for the population to be educated about the healthcare system, such as how it works, where to access information, where their information already flows, how to become an active participant in their care, and how that care is paid for. This educational effort could be led by HHS in partnership with stakeholders across the industry, as it continues to work to ensure that patients are in charge of their own information.

The data exchange work being done with HL7 Accelerators — such as Argonaut, Da Vinci, Carin, Gravity, and Pacio — can contribute toward the goal of improving patient access to health and claims information managed by payers outside of a traditional patient portal. For example, by using FHIR-based APIs, claims and other data from payers can be accessed by the patient and the provider at the point of care. This will be beneficial for both the patient and provider, as well as save money throughout the health system as a whole, because there is less chance of repeat tests for procedures with a more complete record, and the patient can make decisions about where to receive care if they are more informed about care options, and able to move their own data if they decide to go to a different provider.

Objective 1b: Advance healthy and safe practices through health IT

We agree that health information technologies, including apps and wearables, show promise for improving the health of individuals. However, we urge the federal government to address the current gap in regulatory oversight after a consumer acquires their data from a covered entity and downloads it into a patient-facing app. What regulatory oversight exists for apps that are not obligated to adhere to HIPAA guidelines?

Although consumer apps are within the purview of the Federal Trade Commission, and while the FTC can address issues around transparency of what data may be shared with others by consumer apps, the unique privacy requirements relevant to health data requires additional tools and resources to help ensure patient data is protected in accordance with the patient's expectations. The FTC's regulatory authority and scope are not sufficient to provide robust protection to patient health information, and they are not resourced appropriately to address the volume of reported complaints if patients were to become more aware of this challenge. It is important to prioritize establishment of an appropriate approach to maintain the privacy of patient data once it is shared with a non-covered entity, such as a third-party app.

Additionally, payment models largely do not reward the application of innovative technologies, including telehealth and digital therapeutics. While there has been some progress in telemedicine in particular, there is still a need for Congress and CMS to recognize the benefits to patients of monitoring and care outside of a traditional care setting, and to pay clinicians accordingly for the time they spend supporting that care.

Objective 1c: Integrate health and human services information

We are gratified that the federal government recognizes the importance of integrated health and human services, including the value of social determinants of health. We agree with the need to strengthen community health IT infrastructure and care coordination, but note that the Strategic Plan lacks a strategy for supporting community-based organizations that do not have appropriate resources to achieve the goals laid out in the Plan. We encourage the addition of specific strategies to enable the various federal, state, territorial, regional and local agencies, tribes and community organizations to acquire the "requisite health IT infrastructure and adoption support that is needed in order to become fully integrated as a part of the care continuum."

We note that social determinants of health must be able to be captured in the electronic health record to be acted upon by the provider, where appropriate, and there currently is little standardization of such data, whether sourced digitally or provided verbally by the patient. There are various methods taking shape in this area now, such as the PREPARE form and the work the Gravity project is doing. For assessments included in §170.315 (a)(15) *Social, Psychological, and Behavioral Data,* those standards should be used or updated. As additional determinants are added, the Interoperability Standards Advisory can be used to identify the most appropriate standards.

Critically, providers must feel that they are able to act on the data after it is collected, which is something outside of the technical realm and a reflection, currently, of insufficient policy. While certain states, such as North Carolina, are testing and deploying policies that pay clinicians to consider SDOH and make available resources around food scarcity, housing and transportation, this is not yet the norm. Until the healthcare professional is empowered to act on knowledge about a situation outside of the visit, it can expose him or her to additional data capture for little benefit at best, and a sense of frustration or malaise with their inability to help the patients they are committed to caring for.

Goal 2: Enhance the Delivery and Experience of Care

Objective 2a: Ensure safe and high-quality care through the use of health IT

We applaud ONC for the strategies outlined to ensure safe and high-quality care using health IT. With that said, it is important to note that patients exist on a continuum of medical knowledge and ability to function within a system. Not all patients have the resources to understand and make use of their data, and differences in access can reinforce a divide in care stratified by socioeconomic and educational conditions.

We are also pleased that ONC has increasingly been allowed to investigate the many factors associated with Unique Patient Identifiers; while this is not a comprehensive answer to the complex challenge of patient matching, it could be one more useful tool in the patient-matching toolbox.

Lastly, we note that because inconsistencies in state and federal privacy laws pertaining to sensitive health information are obstacles both to interoperability and to enhanced privacy and security of health systems, including but not limited to limitations associated with HIPAA and 42 CFR Part 2 and laws within individual states, the EHR Association supports efforts to harmonize state and federal regulations affecting the security and privacy of health information and associated technologies. Given that patients are not limited by state

lines in where they receive their care, policymakers should strive to reduce variation in privacy laws and requirements wherever possible.

Objective 2b: Foster competition, transparency, and affordability in healthcare

EHR Association members support increased adoption of tools that promote price transparency. In fact, EHRs already support or integrate with multiple tools to help patients know the cost of their care, such as personalized estimates for a growing number of orders, services, and procedures, including integration with Real Time Benefit Tools provided by pharmacy benefit managers and health plans.

Health IT developers have supported tools to provide patients with price estimates for years. However, whether patients and providers are able to take advantage of these tools depends on a number of factors, including the availability of negotiated rate data for each of the health plans accepted by the provider organization in a machine-readable format; the extent to which connected systems have adopted content and terminology standards; and prioritization by the provider organization to complete necessary technical and workflow implementation steps and staff training. Further, there are numerous sectors of healthcare that do not exchange data, including pricing data, in a consistent, standardized way, making it difficult for patients to "compare apples to apples."

To advance price transparency, ONC should promote the adoption of standards-based interoperability to access the relevant data from different sources that allows for real-time estimate creation across stakeholders. Incentivizing broader provider adoption of these tools and ensuring data is available to generate cost estimates will greatly advance use of these tools by providers and patients.

We note, however, that shopping for care solely based on price is not enough and may lead to inappropriate selections. Patients — consumers, in this instance — should also be provided with easily comparable information about the quality of the care delivered by various healthcare institutions in their region. For example, if most private payers charge the same amount for a specific service, different patient outcomes could be the factor that helps a patient choose; conversely, someone might be willing to pay more if they are aware that Hospital A delivers outcomes at a significantly superior level than Hospital B.

Objective 2c: Reduce regulatory and administrative burden on providers

We have been appreciative of the administration's focus on reducing administrative burden, including updates to Appropriate Use Criteria, Evaluation and Management code simplification, the Promoting Interoperability strategy, and Patients Over Paperwork. What's missing from the Strategic Plan, however, is consideration of the impact — if any — each of the initiatives has had on provider workflow and clinician frustration.

ONC proposes a strategy to "monitor the impact of health IT on provider workflows." We request clarity on the intent of this strategy. How will the impact of health IT be measured separately from the impact of regulation on provider workflows? This is a concept that has been explored for some years, but it has never been something that policymakers have been able to move forward with because health IT and regulatory requirements are intrinsically interwoven at this point. We note, as we have in the past, that EHRs and other health IT are the supporting mechanisms but not the reason for many elements of the healthcare delivery experience that frustrate providers, and we believe ONC and HHS could play a helpful role in helping stakeholders understand that distinction and engage in

collaborative conversations on what specifically needs to be adjusted for real impact to be realized.

Objective 2d: Enable efficient management of resources and a workforce confidently using health IT

The EHR Association agrees that a properly trained and prepared health IT workforce is a core component of the digitized health environment. When HHS introduces regulation that affects health IT software, care delivery processes, or expectations of clinicians, it is imperative to allocate adequate time to design, develop, and test the software, as well as document for, train, and prepare users for the change. The EHR Association recommends at least 18 months between introduction and enforcement of regulatory changes (and more if the scope of changes demand it). We invite ONC, CMS, and others to engage with us early in the rulemaking process to help provide early feedback on size, scope, and timing.

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

Objective 3b: Support research and analytics using health IT and data at the individual and population levels

The EHR Association applauds ONC for outlining strategies that explore the optimal use of cutting-edge technologies (e.g., machine learning, artificial intelligence, natural language processing, and predictive modeling) to support research. We encourage ONC to coordinate challenges to foster public-private partnerships that can contribute to innovation in these areas.

Members of the EHR Association actively participate in multiple industry groups and consortia focused on leveraging health IT to support research and innovation advances, as well as optimizing the use of health IT to provide advances to systems-based approaches for improvements in public health and patient safety capabilities.

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Objective 4a: Advance the development and use of health IT capabilities

The EHR Association has long been a proponent of safety-aware, user-centered design; indeed, our Code of Conduct restates our members' commitment to such design. While we are pleased to see ONC also lend its support to these principles, we remain concerned that in ONC's vision of a digital app economy, both patient- and provider-facing apps have no such expectations. Additional focus on consumer education is needed to enable patients to make informed decisions, including how to identify consumer-focused apps that respect privacy and security in a fully transparent fashion.

Innovation in healthcare can be encouraged by development of baseline standards to support essential data access, and by collaboration among stakeholders, including the government, to advance a model of interoperability that allows flexibility to deploy additional data access and exchange mechanisms. Industry-wide adoption of standards is the critical foundation for exploration of new technologies and continued innovation in our sector.

Objective 4b: Establish transparent expectations for data sharing

To realize an ecosystem that enables a nationwide exchange of health data, policymakers and industry must prioritize development and adoption of robust standards, including implementation guides and associated testing tools.

The EHR Association is committed to the prevention of information blocking. Compliance processes for all relevant parties can be streamlined by defining specific affirmative activities that health IT developers and provider organizations can undertake to prevent information blocking — including standards-based exchange — rather than focus exclusively on requiring proof that entities are not engaged in information-blocking.

Patients have high expectations regarding the privacy and security of their health data. Policymakers should clarify and revise health privacy rules (such as HIPAA and the 42 CFR Part 2 rules) to facilitate and also protect data during consensual exchange between providers for care coordination purposes. All actors in an interoperable health IT ecosystem must be expected to maintain the confidentiality of patient health data, and standards for data-sharing should apply throughout the healthcare landscape, including third-party apps that hold patient-directed health data.

Objective 4d: Promote secure health information that protects patient privacy

Privacy and security are two separate and important considerations for all entities that hold patient data. While the current plan lays out a robust approach for focusing on the security of data shared by the patient to prevent accidental loss or leakage, it is relatively silent on the willful misuse of data by malicious or careless actors. We ask ONC to also consider means — whether through consumer protections, redress, or simply education — to help consumers protect their data and share it only with those with whom they intend to.

EHRA recognizes that the majority of healthcare-related cybersecurity breaches are due to a lack of privacy and security best practices at the user level. To improve this, we support programs that provide awareness and basic education on cybersecurity best practices for health professionals and consumers, and development of a culture that sees privacy and security as an enabler of increased patient trust, improved patient safety, and better health outcomes.

Thank you for the opportunity to share our feedback on the Draft Federal Health IT Strategic Plan. We welcome the opportunity to clarify any points we've made, and look forward to engaging in further conversation in the future.

Sincerely,

Cherie Holmes-Henry
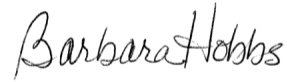Chair, EHR Association
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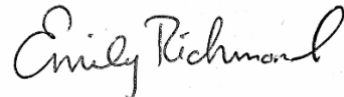**HIMSS EHR Association Executive Committee**

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.