HEALTH **INNOVATION** ALLIANCE

March 18, 2020

The Honorable Donald W. Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, D.C. 20201

Dear Dr. Rucker:

Thank you for the opportunity to comment on the draft *2020-2025 Federal Health IT Strategic Plan (Strategic Plan)*. Health Innovation Alliance (HIA) is a diverse coalition of health care providers, patient advocates, consumers, employers, technology companies and payers who support the adoption and use of health IT to improve health outcomes and to lower costs. We are focused on improving digital connectivity and unlocking data in our healthcare system. We strive for an interoperable, patient-directed health system where providers are emboldened, not burdened, by technology and entrepreneurs are able to bring new products to market at the speed of innovation.

General Comments

HIA supports the overall goals presented in the Strategic Plan, including using health IT to: (1) promote health and wellness; (2) enhance the delivery and experience of care; (3) build a secure, data-driven culture to accelerate research and innovation; and (4) connect healthcare and health data through an interoperable health IT infrastructure. The goals and strategies laid out in the Strategic Plan are laudable.

HIA urges the Office of the National Coordinator for Health Information Technology (ONC) to prioritize its focus on convening stakeholders to develop and adopt standards and systems that produce interoperability, assist stakeholders in complying with the new interoperability and information blocking rules, and working to coordinate activities across departments and agencies so that regulatory burdens on providers and software developers are reduced. These are statutory requirements on ONC. The other areas ONC has outlined in the Strategic Plan are byproducts of an interoperable system, or represent functions the private sector could do much better than a government agency. Finally, we encourage you to build on and expand your efforts to further reduce regulatory burdens on providers and software developers.

Interoperability

ONC has done a good job modifying the information blocking rules to produce a more workable system that promotes interoperability by limiting information blocking (while still allowing it in specific instances). We urge ONC to now turn its resources towards implementation as the rule is rolled out over the next two years. Stakeholders will need plenty of guidance from ONC on the rule considering its complexity, situational application and circumstances that impact when and to whom information may be shared. During this period, ONC should document and report to stakeholders and Congress any gaps or challenges that arise as a result of the regulation's implementation. Specifically, ONC should identify where any continued barriers exist, and how conflicts between the interoperability rules and existing federal and state privacy rules might impact the use and exchange of health information.

Coordination

HIA appreciates ONC's candor in identifying challenges, particularly the agency's acknowledgment that "there is almost no coordination between agencies in real-time, creating inefficiencies and inhibiting initiatives."[1] We agree. The requirements on software developers and providers flowing from the Centers for Medicare and Medicaid Services (CMS) and ONC are not well coordinated. Often, deadlines do not match up between federal agencies. This year, the ONC performance testing for CMS requirements was too late in the development cycle, and created a scramble to ensure compliance. HIA recommends that CMS and ONC have hard and fast timelines that give electronic health record (EHR) developers enough time to comply. Keep in mind a software development cycle is 18 months and then companies need almost the same amount of time to install across all customers.

Coordination should extend beyond federal and state actors to the private sector as well. ONC should work to ensure providers and software developers are partners as new care and payment models are rolled out, especially via the Center for Medicare and Medicaid Innovation (CMMI). Software developers are excellent resources for ONC to understand how workflow is set up and what software can and cannot do; what standards work, and which ones need improvement.

Burden Reduction

There is no other country in the world that regulates EHRs in the way the U.S. does. The level of micromanagement and regulatory driven processes, including requirements related to design and usability, chokes innovation while increasing compliance costs that ultimately are passed to consumers. For example, at a recent Congressional hearing, a witness from a small practice testified it cost her $100,000 in software upgrades to be eligible for a $34,000 MIPS bonus. HIA recommends phasing out CEHRT requirements altogether and instead focus on paying for outcomes. Health care and EHR development will, as a result, be focused on improving care, not just checking regulatory boxes. This should be a five-year ONC goal.

We urge ONC to give regulatory changes a pause as 2020 is a year in which there are an abnormally large number of changes for CEHRT developers and providers. In addition, and of critical importance, the coronavirus pandemic is diverting time, staff, funding and attention away from regulatory driven
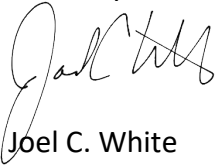
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[1] *See* page 14 of ONC's Strategic Plan at https://www.healthit.gov/sites/default/files/page/2020-01/2020-2025FederalHealthIT%20StrategicPlan_0.pdf.

changes. Pushing the pause button will allow organizations to focus on fighting the virus and delivering care to those who are infected, versus diverting attention to the next regulatory requirements.

We urge ONC, and all other relevant federal agencies, to streamline efforts related to health care – from policy development to enforcement – in order to facilitate widespread compliance and foster continued innovation from the private sector.

Attached are more specific comments on the ONC Strategic Plan. We support many of the goals outlined in the plan that will increase beneficial, widespread use of health IT while mitigating potential harms and protecting patients. These are goals shared and championed by HIA. We look forward to continuing our work together.

Sincerely,

Joel C. White
Executive Director

Specific Comments

Promote Health and Wellness

Improve individual access to health information

HIA supports a framework that allows patients to access and retrieve their health data, to know how their health data are used, and to manage, direct, and audit their data.

Advance healthy and safe practices through health IT

In the strategies described by ONC in this section of the plan, the agency notes specifically that all levels of data should be leveraged "to predict epidemics, inform and monitor public health action outcomes, improve quality of life, and address disease occurrence and preventable deaths." HIA agrees with this sentiment, and urges ONC to consider how regulations issued (particularly related to patient control of data) might impact access to large data sets for the purposes of public health or research and development. Prudent policy development and adoption of clear regulations can allow adequate patient control and privacy protections, while simultaneously supporting research using aggregated data, but these interests must be carefully balanced to avoid unintended consequences.

Integrate health and human services information

Widespread integration of diverse data that can inform and improve healthcare is a goal that HIA supports. However, as acknowledged in this section, federal agencies currently lack real-time coordination and that creates inefficiencies and impedes ONC's ability to successfully implement initiatives. This lack of coordination similarly stifles the productivity of the private sector, both in the context of public-private partnerships and purely private sector efforts that rely on clarity from ONC and federal agencies to produce meaningful innovations and useful products.

HIA strongly urges ONC to prioritize this real-time collaboration and coordination among federal agencies. Streamlining policies and regulations, and creating more consistency across the federal regulatory schema, would bolster private sector action that will advance ONC's shared goal of leveraging health IT for better health care at lower costs.

Enhance the Delivery and Experience of Care

Ensure safe and high-quality care through the use of health IT

While HIA supports all of the strategies laid out by ONC in this section of the plan, we are particularly enthusiastic about the expanded access to telehealth, remote patient monitoring, and other mobile and health IT services that can support clinical care.

Foster competition, transparency, and affordability in healthcare

HIA strongly supports technology that helps make information on the price and availability of health care goods and services available to patients. EHRs and other technologies, support, interface, and integrate

tools to help patients know the cost of their care for personalized estimates for services, procedures, and drugs. However, while the technical ability to support various tools exists, patients and providers are not easily able to use these tools, largely due to a lack of standardization. Examples of existing barriers include:

- Lack of availability of negotiated rate data for each of the health plans accepted by the provider organization in a machine-readable format;
- Lack of consistency for connected systems to have adopted content and terminology standards;
- Lack of time and resources on behalf of provider organizations themselves to complete necessary technical and workflow implementation steps and staff training which require down time; and,
- Lack of standardized data formatting and exchange, making it difficult for patients to understand what data is share (e.g., chargemaster, out of pocket cost, et cetera).

HIA urges ONC to coordinate and promote the adoption of standards-based interoperability for different sources in order to achieve real time data access to pricing information that is relevant to patients.

Similarly, HIA believes that patients require not only cost data, but information regarding quality of care and services provided. The comments above regarding standardized data collection and exchange should also be applied to quality measures that help inform patient choice.

Reduce regulatory and administrative burden on providers

Reducing regulatory and administrative burdens on providers is a critical step towards reducing the cost of and improving access to healthcare. HIA implores the U.S. Department of Health and Human Services (HHS) to better coordinate timelines and updates to the various reporting and compliance programs they have in place (e.g., Information Blocking, Transparency, Appropriate Use Criteria, Evaluation and Management code simplification, the Promoting Interoperability strategy, and Patients Over Paperwork, etc.) In order for providers comply with evolving laws and regulations, changes to these programs need to have organized, coherent and well-planned implementation timelines in order to reduce the impact on provider workflow and clinician frustration.

While ONC proposes to "monitor the impact of health IT on provider workflows" of EHRs and other health IT, ONC and HHS could play a helpful role by educating providers about federal mandates and how to best implement those mandates in the least burdensome way to minimize impact on workflows.

HIA is also a strong supporter of electronic prior authorization (ePA). As noted in the draft strategy, prior authorization requirements are extremely burdensome for providers, but also often directly impact patient care. In fact, approximately two-thirds of prescriptions that are rejected at the pharmacy counter require prior authorization and 36 percent of those will be abandoned.[2] Those abandoned prescriptions contribute to an increase in the chance for worsening conditions, decreased medication adherence, and increased hospital admissions among others, contributing to negative outcomes and increased costs. Providers also report additional burden, spending more time on prior authorizations

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[2] https://www.covermymeds.com/main/insights/scorecard/impact/

when using the traditional paper forms, phone or fax submission methods versus when using a true ePA solution.[3]

HIA and members of our Opioid Safety Alliance – an initiative comprising both HIA and non-HIA members including prescribers, dispensers, manufacturers, professional societies and patients that support the increased use of technology to fight opioid misuse, abuse and addiction – encourage the adoption of policies such as section 6002 of the *SUPPORT for Patients and Communities Act* (P.L. 115-271) that provides for the increased use of ePA for covered drugs in the Medicare Part D and MA-PD programs.

We are similarly encouraged by industry's progress in simplifying and digitizing the medical prior authorization process. While this process is certainly burdensome for providers, more alarmingly, the current prior authorization process directly impacts patient care. A 2017 survey of 1,000 physicians found that 92 percent of providers report care delays related to the prior authorization process and the same percentage report that it can have a negative impact on patient care.[4] We encourage ONC to continue to prioritize work with standards development organizations in developing processes and standards related to electronic prior authorization for medical services.

Enable efficient management of resources and a workforce confidently using health IT

HIA urges ONC and CMS to consider how burdens placed on health IT vendors directly impact usability issues. We share the goal of streamlined processes, but want to flag that the processes currently in place are not due simply to business preferences but are largely a reaction to historical regulations and requirements placed on vendors.

We are pleased that federal agencies have begun to fundamentally build the use of EHRs into quality improvement and reporting programs. However, just because an operation can be done on a computer does not mean that it can be seamlessly integrated into provider workflows. We encourage ONC to incorporate provider workflow considerations into future rulemaking to address provider burden as well as adoption reluctance. This is particularly evident when it comes to PDMP checks and the need for healthcare practitioners to check multiple disparate systems outside of the EHR workflow.

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

Advance individual- and population-level transfer of health data

HIA agrees with ONC that "access, exchange, and use of data using secure, standardized-based APIs is key to building an integrated ecosystem that can support research, clinical decision making, population health management, and individual access to quality and cost information."

Support research and analysis using health IT and data at the individual and population levels

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[3] Ibid.
[4] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf

HIA strongly agrees with ONC that there is value in data to support individual and population health. That being said, as we noted above, it is critical that ONC balance the interest in this data with other policy priorities, particularly related to privacy and consumer-driven data, as the agency continues to issue new regulations in an era of unprecedented growth and data collection.

Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Advance the development and use of health IT capabilities

HIA strongly supports a reduction in financial and regulatory barriers that impede the development and use of health IT capabilities.

Establish transparent expectations for data sharing

HIA agrees that it is imperative that information blocking is addressed and curtailed in order to promote a new era of improved access and quality of care that relies heavily on technology.

Enhance technology and communications infrastructure

As the prevalence and dependence on technology continues to grow in every sector of our lives, broadband connectivity and infrastructure development must be a core priority for the government.

Conclusion

HIA appreciates the opportunity to comment on the draft strategy and we look forward to continuing to work with the agency to reduce provider burden and improve patient care by fully leveraging technology in health care.

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