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National Coordinator for Health Information Technology  
Office of the National Coordinator for Health Information Technology (ONC)  
U.S. Department of Health and Human Services  
330 C St SW, Floor 7  
Washington, DC 20201

April 3, 2020

Re: *2020-2025 Federal Health IT Strategic Plan*

Dear Dr. Rucker,

Thank you for the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the 2020-2025 Federal Health IT Strategic Plan (the “Strategic Plan”). We appreciate ONC’s commitment to interoperable health data exchange and its focus on price transparency as a critical aspect of its long term strategy. We agree with your statement that we must “make sure patients and caregivers have access to information they value and can use.” Real time patient access to electronic health information, including clinical, price, and payment information, will empower patients to make informed decisions about their healthcare spending and foster market competition in the healthcare industry. Ultimately, this transparency will greatly reduce the cost of healthcare and health coverage.

We agree with ONC’s conclusion that there are significant challenges in the healthcare industry, including increases in healthcare spending, access to technology, and access to care. We support ONC’s efforts to determine a number of ways that digital health systems can improve the current state of healthcare and emphasize that patient access to their health data is an essential component of the Strategic Plan. We believe that the Strategic Plan must emphasize the following objectives in the next five years:

- We suggest that ONC work with the Office of Inspector General (OIG), Centers for Medicare and Medicaid Services (CMS), the Office for Civil Rights (OCR), and other federal agencies to aggressively implement and enforce the information blocking rules under the 21st Century Cures Act, the patient right of access under the Health Insurance Portability and Accountability Act (HIPAA), price transparency, and the right of access to clinical, payment and price data under the Affordable Care Act and through CMS’ Conditions of Participation.
- We recommend that ONC emphasize the need for transparency in any agency programs that link quality measures, patient outcomes, and payment. Furthermore, value-based care organizations should be required to fully disclose their financial incentive arrangements, as they may impact provider clinical decisions and patient care.

- We encourage ONC to finalize regulations that require the adoption of open, standard application programming interfaces (APIs) for patient data that include payment and price information as well as clinical information.
- We suggest that ONC specifically adds strategies for access to price and quality information in real-time before and at the point of care so that patients can shop for the best quality of care at the lowest possible price.
- We also encourage ONC to continue supporting strategies that adopt and advance nationally endorsed standards, implementation specifications, and certification criteria through the continued collaboration across public and private sectors. We recommend that these strategies emphasize patient access to their health information in real-time, without special effort, and at no cost.

We appreciate the opportunity to provide feedback on the Strategic Plan. Our detailed comments follow below.

## **I. Opportunities in a Digital Health System**

### *Patient Empowerment*

We support ONC's goals, objectives, and strategies that encourage patient empowerment. We agree with ONC's conclusion that patients' access to their health data, including the use of APIs and the development of health apps that can provide health information and price information, is a critical component of any plan to improve health IT.

Individuals have the right to access and control their healthcare data including adjudicated claims data, such as provider remittances and beneficiary or enrollee cost-sharing data; encounters from capitated providers; and clinical data, including MRIs, films, images, laboratory results, care plans, physician notes, etc., easily available to them in a usable electronic, machine- and human-readable form.

We suggest that the Strategic Plan include leveraging the full force of government to ensure strong policies for patient access to clinical, price and payment data, but also back up these rules with strong enforcement. For too long patients have had a right of access under HIPAA that they have been unable to exercise due to non-compliance by entities and weak enforcement of these rules. We urge ONC to work with OIG, CMS, OCR and other federal agencies to aggressively implement and enforce the information blocking rules under the 21<sup>st</sup> Century Cures Act, the HIPAA right of access, price transparency, and the right of access to clinical, payment and price data through CMS Conditions of Participation.

HIPAA requires that patients are able to access health information in an electronic format if maintained electronically and readily producible in such form and format. Clinical, price, and payment information should be readily available electronically through open, standard APIs, since electronic health records (EHRs) and health plan payment systems are designed to facilitate billing and reimbursement. The HIPAA Transactions and Code Set rules specify standards and

code sets for financial and administrative transactions between healthcare providers and health plans.

The ability for patients to access this critical information will allow them to leverage innovative solutions that can aggregate and harmonize real pricing to comparatively shop for care. This transparency will allow for engagement in reporting of quality, value, and outcomes to readily be incorporated and measured like the mobile apps of Yelp, Uber, Amazon, and Priceline.

### *Movement to Value-Based Care*

While we support the use of quality measures to ensure that payments to providers are linked to patient outcomes, we believe that more transparency is needed in this area. As we discussed in our Transparency in Coverage comment letter, accountable care organizations (ACOs) and other capitated arrangements should be required to fully disclose the underlying financial incentives under a specific plan or contract, not just the consumer's anticipated liability. Opacity in value-based payment arrangements may encourage plans and issuers to simply shift costs to these sectors of the market where interoperability and data access requirements would not apply. The same concerns exist with respect to ACOs and other capitated arrangements.

Furthermore, structures that are set up for capitated payment with either a shared savings or bonus arrangements which benefits the provider may impact clinical decisions and patient care. Today, the patient has no visibility into these shared savings arrangements. For example, if a patient calls his or her provider with suspected complications post-discharge, the patient should be aware that the hospital may have a financial incentive to avoid readmission. This knowledge can help patients advocate for themselves. These payments and incentives ultimately are paid by the employer sponsored plans and by the patient in their premiums.

If a patient is part of an ACO, treatment decisions can be affected by the financial incentives and relationships between providers, plans and PBMs that drive therapies recommended, referrals provided, or prescription benefit design. Knowing the information about the financial incentives or relationships that may impact treatment decisions can lead to more fulsome conversations with providers so that patients can make decisions about their own interests. For example, in drug formulary design – brand name drugs can be cheaper than generic based on financial incentives and rebates, but may be more expensive in the new plan year when a deductible resets. Provider behaviors can provide another example of these harmful behaviors – if an integrated provider/payor or ACO and plan PBM is getting a bigger rebate on a certain medication, the doctor could experience incentives to prescribe that therapy over another. Negotiated prices for drugs by indication must be disclosed in addition to the list charge and any other rebates. This disclosure must be available to patients free of charge without conditions.

Value-based payment arrangements may hold much promise to escape the broken status quo, built upon an outdated and inefficient fee-for-service billing structure that excludes access to price and quality considerations. However, we run the risk of enabling alternative care and payment models that are mere counterfeit “value,” if the rules facilitating these arrangements simply allow for new and different types of secret deals benefiting the sellers of care – that is, healthcare providers and insurance companies.

## *Achieving Interoperability*

As we discussed in our comment to the 2019 Information Blocking Proposed Rule, we support ONC's proposals regarding the use of open, standard APIs. Increased data sharing between patients, providers, payers, and other entities will promote innovation and care coordination across the healthcare industry. This data exchange must be a priority and must include price and payment information as well as clinical information. Improvements in interoperability will allow innovative technology companies to develop solutions that allow patients to access their health information in a usable, easy to understand manner. ONC should support this goal, as it will increase competition and better inform patients about their healthcare needs. The use of open, standard APIs in other industries, such as transportation, financial services, and household goods, has allowed consumers to easily access price and quality information; the healthcare industry should be no different.

Patients must have real-time, free, machine-readable electronic access to their complete health information through open, standard APIs, without any delays or burdensome requirements – without “special effort” as intended by Congress in the Cures Act. Patients should not be required to pay for any access, exchange, or use of their electronic health information (EHI). Patients are not currently able to access the information they need to make care decisions, seek second opinions, or effectively care for family members or other loved ones. Breakdowns in patient access to health information lead to inefficiencies across the healthcare system, including duplicative testing, increased volume of services, and inflated costs. Healthcare providers, health plans and other entities artificially limit access to EHI in a variety of ways, including requiring paper consent forms, charging egregious fees for electronic access, or outright refusing to facilitate patient access to health information – despite patients' legal right to receive this information under HIPAA. These practices are widespread across the healthcare industry, and open, standard APIs are a critical element to combating these anti-competitive behaviors.

## **II. Goals, Objectives, and Strategies**

In the Strategic Plan, ONC describes four strategic goals for health IT: Promote Health and Wellness, Enhance the Delivery and Experience of Care, Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation, and Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure. ONC also provides benchmarks and measures that federal agencies can use to determine the success of each strategy.

We believe that the Strategic Plan is moving in the right direction, but it fails to center on the patient. We suggest that each of these Goals be framed in terms of the impact to the patient's ability to access high quality care and lower prices. Health IT has the opportunity to empower patients and provide tools to support patient needs, decision making, ultimately improving diagnoses, treatments, and outcomes. We recommend that the goals be revised as follows:

- Promote Patient Health and Wellness and Support Patient Decision Making and Empowerment
- Enhance the Delivery and Experience of Care for Patients and Caregivers
- Build a Secure, Data-Driven Ecosystem to Improve Transparency and Accelerate Research and Innovation
- Connect Healthcare and Health Data for Patients through an Interoperable Health IT Infrastructure

**Goal 1: Promote Health and Wellness (*Proposed Revision: Promote Patient Health and Wellness and Support Patient Decision Making and Empowerment*)**

We support ONC’s objective 1a to improve individual access to health information, as it will empower patients to be engaged with their care. We recommend that ONC state this objective more strongly. Stating that in five years we will “improve” patient access to their health information will not provide patients with the information they need when they need it. Patient access to their own clinical information today is limited, and patient access to price and payment information is almost non-existent. If ONC is truly focused on a patient-centered approach, this strategic plan should commit to ensuring patients have guaranteed, easy access to their health information. We recommend that ONC modify 1a to read as follows:

- Objective 1a: Ensure seamless, real time, free individual access to all electronic health information for all patients.

We also do not believe that ONC’s strategies go far enough. We agree that patients must be able to access all of their health information via mobile apps, patient portals, and other technologies using open, standard APIs in order to make the best health care decisions, and that health information should be portable. Patients should be able to share and receive their health information across various platforms so that they can use the tools that are most effective and meet their needs.

However, we encourage ONC to clarify that access to health information includes clinical, price, and payment information, and that information should be available to individuals without extra effort. This data is critical to improving health care outcomes and will prevent patients from being saddled with medical debt that can have catastrophic effects on their wellbeing.

Providing patients with unimpeded, real-time access via open, standard APIs to all their clinical and financial records, including physician notes and easily downloadable images, will empower them to leverage third-party apps to access, utilize, and share their health information as they choose. We encourage ONC to work with agencies to develop resources and communication plans that provide guidance on how providers and other stakeholders must comply with the information blocking rules and the rights individuals have to their data.

We recommend revising the first strategy as follows:

- Enable individuals to access *all* of their electronic health information, including price and payment information, by ensuring that they are able to view and interact with the data without special effort, in real time, via their choice of secure mobile app, patient portals, and other tools.

We also support the use of health IT to improve the quality of care and patient outcomes. In order to make informed decisions, patients need access to tools and all types of data. Specifically, we encourage the strategies that focus on leveraging all levels of data to include the notion that such information, including public health information, should be made available to the patients. Just as public health can benefit from access to patient data, so too can patients benefit from access to real time public health data, as exemplified in the recent coronavirus pandemic.

We encourage ONC to adopt its proposed goals regarding the integration of health and human services information for use by the individual. Providing information about social services that are available to the patient and enabling the individual to combine that information with clinical and financial information would be beneficial for patients in managing complex conditions and life issues.

**Goal 2: Enhance the Delivery and Experience of Care (*Proposed Revision: Enhance the Delivery and Experience of Care for Patients and Caregivers*)**

We strongly support this Goal and the notion that health IT should enable healthcare choices that are based on active consumer choice, not payer preferences. Patients should have more control in the way they receive care and their treatment choices.

We support ONC's objective 2b to foster competition, transparency, and affordability in healthcare, and the need for information on price and quality to support completion and consumer choice. We support the strategies proposed by ONC and encourage ONC to adopt strategies that enable the routine and timely availability of price information to enable consumers to shop for care and understand the impact of healthcare decisions on their lives.

We suggest that ONC specifically add strategies for access to price and quality information in real-time before and at the point of care so that patients can shop for the care that best meets their needs. The current strategy "Make care quality and price information available to individuals in an accessible, easily understandable format" is not sufficient. It must be full quality and price information for all shoppable services, including negotiated rates, and it must be in real time and machine readable format. We recommend that this strategy be revised as follows:

- Make comprehensive quality and price information (including negotiated rates) available to individuals in real time, machine-readable, format via open, standard APIs, so that patients can access such information through innovative tools.

**Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation**  
*(Proposed Revision: Build a Secure, Data-Driven Ecosystem to Improve Transparency and Accelerate Research and Innovation)*

Access, exchange, and use of data using open, standard APIs is critical to unlocking the power of new tools that leverage patient health information to improve patient care. It is important to use standards for price information that are consistent with the existing HIPAA administrative transactions, use USCDI standards, and build on any financial services standard APIs. Price and payment information already exists digitally and is shared readily within the healthcare system for purposes of facilitating billing – but it is not shared with the patient. Technology developers can easily develop useful tools for consumers, employers, and the American public to enable them to shop for care and increase accountability for industry. There are many existing standards that can be used to meet this goal, including standards for financial and administrative transactions under HIPAA. We also encourage ONC to consider standards from the financial industry for implementing this strategy.

While patients should be able to consent to data transfers to federal and state agencies, apps and other health IT solutions, we do not believe that agencies should promote programs that would enable data transfers without the patients express consent, even if the data will be used for “population health planning, analysis of quality and patient outcomes across care settings and programs, and clinical research.” We oppose any strategies that would prevent patients from having control over their data.

Furthermore, we believe that the private sector is best equipped to develop solutions and platforms that will promote innovative uses of shared data for researchers, innovators, individuals, payers, and healthcare providers. We support incentives that would reward innovators that develop data governance principles and secure, unified platforms for stakeholders to collaborate; however, we do not believe that agencies should develop these principles or platforms, as it may stifle new solutions that would better serve patients.

We also recommend that ONC add strategies that address the use of a secure infrastructure for improvement in price and quality transparency, for the benefit of patients and to ensure that where patient information is used for the benefit of research, that individuals can have access to information about how their data is being used and access to the research results. Specifically, patients should have transparency into the quality improvement and access to patient data and large data sets

To advance individual- and population-level transfer of health data, we propose that ONC add the following strategies to objective 3a:

- Support innovative uses of health data by allowing for patients to authorize apps and health IT solutions to continuously access their health data for patient use, rather than requiring consent every time new data is added to their record.

**Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure** *(Proposed Revision: Connect Healthcare and Health Data for Patients through an Interoperable Health IT Infrastructure)*

Reducing barriers to patient access will encourage trust, accountability, and confidence in the use of health IT. We support ONC's proposed strategies for advancing the development and use of health IT capabilities. We support objective 4a: "Advance the development and use of health IT capabilities. Promoting a digital economy within the healthcare industry is critical for improving patient outcomes, supporting care coordination, and reducing costs. Agencies should support developers of new and innovative business models and apps that will help patients make informed decisions about their care and that protect patient privacy.

In addition, agencies should focus on how they can reduce financial and regulatory barriers that prevent innovative developers from entering and competing in the health IT marketplace. Removing these obstacles will help reduce the anti-competitive practices within the healthcare industry that protect and unfairly benefit existing payors, providers, and EHR companies. Enforcement of the information blocking rule will allow patients and providers to share reviews and reports on health IT products and will promote trustworthiness of health IT solutions. Strong enforcement responses to violations of the information blocking rule are critical to the rule's effectiveness and to promoting interoperable data exchange. ONC should educate agencies about the rule's requirements so that they can identify practices that would be in violation of the rule and support OIG investigations of information blocking complaints. ONC should continue to support strategies that adopt and advance nationally endorsed standards, implementation specifications, and certification criteria through the continued collaboration across public and private sectors.

We also support several of the ONC's proposed strategies for establishing transparent expectations for data sharing outlined in objective 4b. As discussed above, agencies must address practices that interfere with access, exchange, and use of electronic health information that would constitute information blocking and support rigorous enforcement. We encourage ONC should urge agencies educate providers, healthcare staff, and developers about their compliance requirements to ensure that they are aware of their responsibilities when responding to patient access requests. Regulatory requirements for data sharing, including the HIPAA individual right of access and information blocking rules must be aggressively enforced to ensure that these rules have the intended impact.

We do not support the strategy related to the common agreement for nationwide exchange of health information. The common agreement will add layers of complexity, will disproportionately benefit existing health industry stakeholders, and will hamper adoption of policies that will reduce costs and improve patient access to health information. Instead, agencies should promote the adoption of open, standard APIs. We suggest that ONC replace this strategy with:

- Promote nationwide exchange of health information through the adoption of open, standard APIs. Agencies should include API requirements in all new initiatives, programs, and investments.



APIs will reduce the number of middlemen in the healthcare industry that increase costs and limit access to health information. APIs will enable individuals to have “seamless, secure, and free access to their electronic health information, which will allow them to more fully participate in the mobile app economy.”

### **III. Conclusion**

We applaud ONC for its efforts to improve interoperable data exchange and to make price information available for patients in free, machine-readable formats. These proposals will ensure that patients, providers, and employers have the information they need to make decisions about coverage, treatment, and out-of-pocket costs. We encourage ONC to reframe its goals, objectives and strategies to be designed as benefits for patients, not for the health care system and the large organizations that profit from opaque policies and practices.

Patient access to price and payment information is critical to improving health care clinical outcomes and cost reductions. Combining this information with clinical data will help patients make informed decisions about care and be partners in reducing unnecessary expenses for themselves and their employers. Public disclosure of price information will increase competition within the health care market and will allow patients to shop for services and items based on price and quality. We urge the ONC to include objectives and strategies related to price transparency and patient access in the Strategic Plan, as they will encourage innovation and allow patients to make informed decisions about the costs of their care.

Thank you for the opportunity to submit comments on the Strategic Plan.

Sincerely,



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Founder, Chairman, PatientRightsAdvocate.org  
Founder, Former CEO, ViaCord, Inc.