March 18, 2020

Dr. Donald Rucker
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

RE: 2020-2025 Federal Health IT Strategic Plan

Dear National Coordinator Rucker,

Thank you for soliciting comments on the 2020-2025 Federal Health IT Strategic Plan, which contains principles for advancing policies for the effective use of technology and supporting data exchange within the federal government. The federal government, through the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS), recently took significant strides to advance interoperability in health care, and increase patients' and caregivers' access to important health data. However, the federal government can take additional steps to improve: 1) data access and exchange, and 2) the safety of health information technology products. This plan, if accompanied by meaningful and effective policy changes, can help support these important goals.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, and facilitating the development of new medical products. Pew's health information technology (health IT) initiative focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records (EHRs).

Previous iterations of this strategic plan have focused on digitizing medical records and working towards widespread use of all forms of health IT.[1] The new version of the plan builds upon the successful adoption of EHRs and recently finalized regulations implementing health IT provisions from the 21st Century Cures Act (Cures), passed by Congress in 2016, to set the vision for health technology across federal agencies for the next five years. Many of the goals identified in the plan can promote data exchange to advance care coordination, improve patient safety, and lay the groundwork for nationwide interoperability. Now that EHRs are widely adopted and with the recent finalization of interoperability rules, the federal government should focus on better improving the exchange of health data and improving patient safety.

Use of new digital tools, patient matching essential to realizing the vision on data exchange

Currently, many providers face challenges extracting and exchanging data from EHRs, finding relevant information in the records they review, and matching patients across sites of care. These difficulties lead to patients and clinicians having an incomplete picture of individuals' medical history, which can contribute to medication errors and costly duplicative testing.[2]

Resolving these problems require better tools to help patients and clinicians extract data from records, enable informed decisions, and support the ability of providers to link records across sites of care. One such tool is application programming interfaces (APIs)—software that allow systems to request and deliver information to other systems—have been offered as a solution to addressing these challenges. Another solution is more data to help with patient matching, which refers to the ability to link patients' records across different sites of care.

Federal policies in the next five years offer opportunities to advance these solutions. For example, the Trusted Exchange Framework and Common Agreement (TEFCA, which creates a series of requirements to enable the exchange of information across health care organizations nationwide), CMS payment rules, and other regulations can advance interoperability.

APIs support patient, provider data access, but gaps remain

In the plan, ONC highlights the importance of enabling easier extraction and use of health data from EHRs via APIs. The federal government has already taken strides to advance the use of APIs in health care, as ONC and CMS recently finalized regulations to enable the use of these tools to equip patients and clinicians with data to inform medical decision-making and the coordination of care.

Once implemented, the regulations will help patients get their records—including new information not typically made available, such as clinical notes—both from their providers and health plans through APIs. ONC has required use of the industry agreed-upon Fast Healthcare Interoperability Resources (FHIR) standard for APIs, which helps harmonize how data are represented to enable different systems to communicate more effectively.

In the plan, ONC proposes to "promote greater portability of health information through APIs and other interoperable health IT that permits individuals to readily send and receive their data across various platforms." To achieve that goal, ONC should address the remaining gaps that prevent patients from getting their complete records and providers from being able to exchange information to coordinate care of shared patients. Specifically:

- *More data elements needed*: Patients require access to their relevant medical information to effectively engage in health promotion and disease self-management. Despite ONC adding more data elements to the set of information to which patients have access, such as clinical notes, important data are still missing, including images, which are frequently stored outside of the

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EHR. ONC should increasingly strive to make all data elements in health records available to patients in a usable format. That requires data to be standardized so that patients can, for example, use any application of their choice to obtain their health data on personal devices.

- *Provider-provider exchange:* Today, APIs are mainly used for patient access and clinical decision support tools, which are applications that use EHR data to help guide clinician decisions, such as which medication to prescribe. However, APIs also offer promise in the exchange of records among providers. Currently, when one patient is cared for by multiple providers, clinicians exchange full clinical documents that may contain unnecessary information in treating that individual.

   Through FHIR-based APIs, health care providers could send individual—or modular—pieces of data to one another. For example, providers could send just patients' medication lists or only their most recent care plans, instead of a broader document containing more data, some of which might be unnecessary or sensitive such that individual patients may not wish to share it. Allowing providers to move away from sharing long documents to only the necessary information can reduce burden, improve care coordination, and protect patient privacy. ONC should explore ways to advance provider-to-provider exchange of data via APIs, such as through scaling existing pilots. The agency should also implement APIs in TEFCA to ensure that clinicians will be able to exchange modular data, in addition to whole documents.

- *Write access*: ONC's regulations only require that EHRs have APIs that enable other systems to read—or extract—information. However, some applications—such as decision support tools—may also be able to provide additional benefits to clinicians by entering, or writing, data into EHRs.

   As FHIR further develops and API adoption increases, ONC should advance the use of these write capabilities for the bidirectional exchange of information out of and into EHRs by third-party applications. For example, patients could use this capability to upload care plans, such as advanced care directives or birth plans. In the finalized rule, ONC added data provenance, which refers to where the information originated from and the associated time stamp, to the data exchanged via APIs. Increased use of provenance data can pave the way for write access by ensuring that providers know from where information was obtained. ONC should also work with other federal agencies to maintain robust cybersecurity practices—and, if applicable, introduce new policies—to safeguard that the addition of write capabilities does not introduce security risks.

The federal government has recently taken critical steps to better equip patients and clinicians with data and has outlined additional priorities for APIs in this strategic plan. Going forward, the federal government should further leverage TEFCA and future rulemaking to advance the use and capabilities of APIs.

Solutions exist to improve patient matching, support care coordination

Patients seek medical attention in a variety of settings—including in primary care offices, emergency departments, and specialty facilities. To exchange medical data across these different sites of care, health organizations must be confident that they are communicating about the same person. Patient matching refers to the ability to accurately link information about an individual among the multiple doctors' offices or hospitals where that person seeks care. Presently, up to half of the information exchanges made by health care organizations may fail to accurately match records for the same patient.[3]

In the plan, ONC rightly highlights that the federal government needs to "establish identity solutions that improve patient matching across data systems."

The federal government can achieve that goal by encouraging health technology developers to add and standardize data elements for patient matching.

- *Adding more data elements*: The current matching process relies largely on demographic data, such as names and dates of birth, but it does not sufficiently account for similarities among patients and data entry errors. The federal government should advance the use of other regularly collected demographic data elements for patient matching. ONC currently requires EHRs to make some demographic data—such as name, birth date, and sex—available. However, health records contain other information routinely collected that are not typically used or made available to match records.

  In the recently finalized rule, ONC adds email address, previous address, and other information as data elements to make available via APIs so that they can be used for matching. These additional items have the potential to improve match rates. For example, research published in 2017 showed that email addresses are already captured in more than half of patient records.[4] The documentation of email is likely higher today given the adoption of patient-facing tools, like portals, that often require this information to register. ONC could improve match rates by identifying other readily available data elements to require for use in matching, and encouraging their use.

- *Standardizing data elements*: Currently, data elements may not be standardized across health IT systems. Research has shown that standardizing specific data elements can improve match rates. In particular, ONC should encourage the use of the U.S. Postal Service (USPS) format for address; the USPS standard, for example, indicates appropriate street suffixes. Pew-funded research at Indiana University revealed that use of the USPS format for address can improve the accuracy of matching records by approximately 3 percent.[5] An organization with a match rate of 85 percent, for example, could see its unlinked records reduced by 20 percent with standardization address alone. The research further revealed that standardizing last name in conjunction with address could improve match rates from approximately 81 to 91 percent, which would reduce the number of unmatched records by half.

ONC can advance these policies through TEFCA. As TEFCA will govern nationwide data exchange, it can require the use of the USPS standard to ensure that patients' data can reliably follow them across different sites of care around the country. TEFCA can also require data useful for matching—like email—be sent when the record is transferred. Similarly, USPS could make its address format more accessible to health care by enabling the use of its web tool that converts addresses into the agency's standard. The tool, available via an API, is already available to the shipping industry at no cost.

Policies to enhance usability can improve workflows, safety

The ONC plan highlights another challenge with EHRs: subpar system usability. Usability refers to how EHRs are designed, implemented, and used by clinicians. Usability-related safety problems can emerge due to confusing interfaces, the need to develop workarounds to complete tasks, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs have in health care. Pew research, conducted in collaboration with MedStar Health's National Center for Human Factors, examined 9,000 safety events in three hospitals, and found that EHR usability contributed to approximately one-third of those errors.[6]

There are two concrete steps HHS and private sector oversight organizations can take to improve EHR usability at key points in the lifecycle of these technologies.

- *Transparency on vendor usability:* Through Cures, Congress tasked ONC with developing a reporting program to gather and release data on several different aspects of EHR functionality, including usability. This EHR Reporting Program can deliver better information to identify industry-wide gaps, encourage an enhanced focus on safety by product developers, and give clinicians greater insight on the functions of the digital systems that they use.

  Earlier this month, Pew and MedStar released a series of recommendations on how ONC could incorporate safety into this program. For example, ONC could collect more data on the test cases used to evaluate system usability, such as the number of test participants and the rigor of the scenarios.[7]

- *Adoption of best practices by hospitals:* Hospitals can play a key role in health IT safety through appropriate implementation of new systems and monitoring use. While best practices exist to improve health IT safety, they are often not adopted by hospitals. For example, ONC developed recommendations for how hospitals can assess the safety of their systems.[8] Though these checklists, called the Safety Assurance Factors for EHR Resilience (SAFER) Guides, are freely available, their use by hospitals is low.[9]

  CMS has previously examined ways the agency could address EHR safety challenges. Adding EHR safety elements to CMS' Promoting Interoperability program, on which CMS has requested information, would encourage health care provider adoption of strategies to reduce patient harm.

The Joint Commission, which accredits approximately 80 percent of hospitals for participation in Medicare, could also drive adherence to best practices though its accreditation process. The Joint Commission should commit to assessing the incorporation of health IT-related criteria into its accreditation program, and convene stakeholders—such as hospitals, clinicians, usability experts, and technology vendors—to evaluate different approaches.

The strategic plan gives ONC and CMS the opportunity to take a leadership role in monitoring the safety of EHRs and encouraging implementation of best practices to reduce patient harm. In addition, both ONC and CMS can work with and encourage private sector groups, like the Joint Commission, to advance adoption of health IT safety best practices.

Conclusion

The broad adoption of health IT and bipartisan passage of Cures launched a new era for advancing health data exchange and patient safety. The recently finalized rules from HHS implement key policies that the federal government can build upon over the next five years.

In executing this plan, the federal government should:
- Continue standardization of data elements to ensure patients and providers can easily access and exchange information;
- Explore new use cases and functionality for APIs, including provider-to-provider exchange and write access;
- Add and standardize more data elements to improve patient matching;
- Enhance transparency on vendor usability through the EHR Reporting Program; and,
- Urge hospitals to adopt best practices that can reduce patient harm associated with EHR use.

Thank you for the opportunity to provide comments on the 2020-2025 Federal Health IT Strategic Plan. Should you have any questions or if we can be of assistance, please contact me at 202-540-6333 or bmoscovitch@pewtrusts.org.

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The Pew Charitable Trusts

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