January 28, 2019

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

Re: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear National Coordinator Rucker:

Thank you for the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology's (ONC's) draft strategy to reduce the burden on clinicians in the use of electronic health records (EHRs). In the report, ONC underscores two key challenges with the use of EHRs that can increase provider burden: poor system usability—which refers to how EHRs are designed, implemented, and used—and ineffective exchange of health data. These same challenges can also introduce patient safety problems and hinder the coordination of care. ONC, through several policies under development, can take steps to address these challenges.

The Pew Charitable Trusts is a non-profit research and policy organization with a number of initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products, and reducing costs. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safety of EHRs.

Section 4001 of the 21st Century Cures (Cures) Act, passed in 2016, requires ONC to develop a strategy that reduces clinician burden when using health information technology. In implementing this Cures Act requirement, ONC underscores the importance of making EHRs more user-friendly while improving the ability to extract and share data.

Usability challenges can arise from the implementation, customization, layout, use, and maintenance of the EHR system. These same factors can also contribute to medical errors—such as patients receiving the wrong dose of a drug. In the draft burden reduction strategy, ONC identifies several practices that can improve the usability of EHRs; many of these same efforts could also enhance the safe use of this technology. Forthcoming regulations from ONC on EHRs used in the care of children and the development of a new reporting program offer opportunities to enhance usability—which would simultaneously reduce burden and improve safety.

In addition, ONC's draft strategy highlights how application programming interfaces (APIs)— which are software tools that enable data extraction from EHRs—can enhance the sharing of

patient information. Forthcoming ONC regulations should ensure that EHRs make data available via APIs in an effective and efficient way—which would reduce burdens on clinicians while also equipping health care providers and patients with more usable information to inform medical decisions.

Improving usability to increase safety and reduce burden

In the report, ONC emphasizes that the usability of EHRs can introduce burdens on clinicians, such as confusing layouts that hinder the effective ordering of medical treatments or system designs that require physicians to respond to frequent alerts. While ONC focuses in the report on burden, these same factors can contribute to patient harm. For example, clinicians may ignore alerts that occur too frequently, which may result in a medical error.[1] Recent data from a study led by MedStar Health's National Center for Human Factors in Healthcare (MedStar) in conjunction with Pew further reinforced the connection between usability and safety. Ineffective usability contributed to approximately a third of 9,000 medication safety events reviewed from three health care systems.[2]

To address challenges with usability, ONC recommends several principles, such as considering workflows in health care facilities and engaging with end users—e.g. physicians and nurses—throughout the development and implementation of systems. These principles were also highlighted in an August 2018 report from Pew, MedStar and the American Medical Association (AMA) following a series of convenings with EHR, usability, and patient safety experts.[3] For example, when implementing and customizing EHRs, user-centered design (UCD) processes enable organizations to obtain feedback from end-users to better understand their needs and inform the design and implementation of systems. This feedback can help developers and facilities understand how clinicians use EHRs and when workarounds are initiated to address design deficiencies.

A second example of how good safety practices can reduce burden involves testing EHRs throughout their lifecycle. Using rigorous test cases can unearth issues that frustrate clinicians, while also detecting those that contribute to patient safety problems. Pew, MedStar, and AMA released a series of test cases in the August 2018 report.

ONC should address these usability and safety challenges

Two provisions in the Cures Act afford ONC the opportunity to improve reduce clinician burden and improve safety via enhanced usability: the development of a reporting program on EHR functions and the establishment of new voluntary criteria for technology used in the care of children.

First, the Cures Act directs ONC to develop a reporting program to collect data on a variety of EHR-related functions, including system usability. Given the intersection of usability and medical errors, ONC should ensure that some of these usability-related criteria focus on safety. In previous comments to ONC, organizations representing clinicians, hospitals, health information technology professionals, and other key stakeholders emphasized the importance of embedding safety into the usability-related criteria.[4]

Several existing programs can inform how to collect data on usability and safety. For example, the Leapfrog Group—a non-profit organization that advances patient safety on behalf of large companies—developed a tool to test the usability and safety of EHRs' drug ordering system; the tool was used by nearly 2000 inpatient facilities in 2017 and 2018.

Second, the Cures Act directs ONC to issue regulations that establish a voluntary certification program for EHRs used in the care of children. EHRs designed for use in adult populations may overlook differences in the care of children—such as growth patterns—and introduce the opportunity for error. For example, children often receive medication doses based on their weight. Poor usability can make it challenging for physicians to prescribe the correct weight-based dose of a drug, and potentially lead to children receiving the wrong amount of a medication. In implementing this provision from Cures, ONC should focus on the safety and usability of EHRs, including by incorporating some of its own recommendations from the burden reductions report—such as by requiring input from end-users such as pediatricians.

Effective use of APIs can further reduce burden, enhance care quality

As part of the burdens reduction report, ONC also recommends several strategies to improve the way health information technology systems can extract, receive, and interpret patient data. The inability to effectively exchange information results in clinicians and patients not having the data they need to inform medical decisions, which leads to unnecessary tests and introduces safety problems—among other factors that can hamper the quality of care. Poor interoperability also results in clinicians often having an abundance of information without an ability to easily identify the most critical data needed in the provision of care, requiring health care providers to comb through pages of documentation to find the relevant aspects of patients' medical histories.

In the report, ONC highlights an approach to address this challenge: the use of APIs. APIs—particularly those that leverage the Fast Healthcare Interoperability Resources (FHIR) standard—enable health technologies to extract only the information needed. For example, FHIR-based APIs can enable clinicians to access patients' medication lists without having to also receive every blood pressure reading or laboratory result in individuals' records. As a result, these APIs can reduce clinician burden when using EHRs, but only if the interfaces are effectively implemented.[5]

Forthcoming API regulations represent opportunity to improve care

ONC has an opportunity to ensure that APIs used to extract data from EHRs can effectively advance information exchange to both reduce clinician burden and improve patient care. Another Cures Act provision directs ONC to develop regulations for EHRs to include APIs that allow access to and extraction of "all data elements" in patients' records "without special effort." This provision—often referred to as "open APIs"—has the potential to improve the use of health data, such as by ensuring that patients can download their entire medical records, allowing health care facilities to exchange information more seamlessly, and enabling clinicians to use new decision support tools that rely on patient data contained in EHRs.

As ONC implements this open API provision from Cures, the agency should take several steps to ensure that these interfaces enable the effective exchange of information.

First, these APIs should support the exchange of more data from EHRs than currently enabled. As part of ONC's most recent criteria for EHRs, the agency requires that APIs used for patient access to information provide the Common Clinical Data Set (CCDS). While the CCDS contains some information, such as medication lists, it lacks other needed data—including clinical notes. As a result, ONC should expand the data available via open APIs beyond the CCDS.

Second, ONC should ensure that these APIs support access to individual data elements without requiring clinicians to receive the entire patient record. Use of the FHIR standard can enable this type of access. Recent data from ONC has shown that more than four out of five hospitals and approximately two-thirds of clinicians report using EHRs that have implemented some version of the FHIR standard.[6]

Third, ONC should ensure that data are exchanged even when not documented in a widely used terminology, such the Logical Observation Identifiers Names and Codes or Systematized Nomenclature of Medicine–Clinical Terms standards. Similarly, any information that is coded in a standard or otherwise formatted so that it can be processed by a computer should remain in that structure and not converted to a less-usable configuration, such as a PDF.

If incorporated in forthcoming API regulations, these—among other provisions related to APIs— could help ONC meet its goal of reducing clinician burden while enhancing the information available to patients and medical professionals to improve the quality and coordination of care.

Conclusion

Thank you for providing us the opportunity to comment on ONC's draft strategy to reduce clinician burden. The principles outlined in ONC's report have the potential to address challenges faced by clinicians in using EHRs, while also advancing patient safety and the coordination of care. To implement those principles, ONC should leverage its forthcoming policies, including by incorporating safety into the usability aspects of the EHR reporting program and prioritizing safety in new certification requirements for EHRs used in pediatric care. In parallel, ONC should ensure that its forthcoming regulations on APIs enable the effective and efficient exchange of data to both alleviate clinician challenges with EHR use and enhance care coordination.

Thank you for considering our comments. If you have any questions or need additional information, please contact me at bmoscovitch@pewtrusts.org or 202-540-6333.

Sincerely,

Ben Moscovitch
Project Director, Health Information Technology
The Pew Charitable Trusts

[1] The Pew Charitable Trusts, "How to Make Electronic Health Records Easier to Use—and Safer for Patients," (April 2018), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/how-to-make-electronic-health-records-easier-to-use-and-safer-for-patients.

[2] Raj M Ratwani, et al, "Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings," (Nov 2018), Health Affairs.

[3] The Pew Charitable Trusts, the American Medical Association, and the National Center for Human Factors in Healthcare, MedStar Health, "Ways to Improve Electronic Health Record Safety," (August 2018), https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety.

[4] Ben Moscovitch, "Medical Groups Urge Federal Government to Strengthen Health IT Usability, Safety," (December 2018), https://www.pewtrusts.org/en/research-and-analysis/articles/2018/12/11/medical-groups-urge-federal-government-to-strengthen-health-it-usability-safety.

[5] The Pew Charitable Trusts, "Electronic Tools Can Strengthen Health Care Data Access, Sharing," (September 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/09/electronic-tools-can-strengthen-health-care-data-access-sharing.

[6] Steven Posnack, Wes Barker, "Heat Wave: The U.S. Is Poised to Catch FHIR in 2019," October 2018), https://www.healthit.gov/buzz-blog/interoperability/heat-wave-the-u-s-is-poised-to-catch-fhir-in-2019.