January 9, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
330 C ST SW
Mary Switzer Building
Washington, D.C. 20201

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

Submitted electronically to:
https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs

Dear Doctor Rucker:

The Sequoia Project is pleased to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the request for comments on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Strategy).* We appreciate ONC's demonstrated commitment to consider thoughtfully the comments that it receives from its stakeholders in response to such requests.

The Sequoia Project is a non-profit, 501(c)(3) public private collaborative that advances interoperability for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth Exchange health information network and Carequality now operate under their own corporations, but coordinate with Sequoia and their perspectives inform these comments that we are submitting to ONC.

The Sequoia Project currently supports the RSNA Image Share Validation Program and the Patient Unified Lookup System for Emergencies (PULSE). Our comments on the draft Strategy are based on our organization's significant experience supporting large-scale, nationwide health data sharing initiatives, including assessments of interoperability and security capability of exchange participants. Through these efforts, we serve as an experienced, transparent and neutral convener of public and private-sector stakeholders to address and resolve practical challenges to interoperability, including in-depth development and implementation of trust frameworks and associated agreements. This work extends to several crosscutting projects, including patient matching, improving the quality of clinical

documents exchanged, information blocking, and other matters prioritized by these stakeholders, such as health IT disaster response.

Our deep experience implementing national-level health IT interoperability, including our track record of supporting and operationalizing federal government and private sector interoperability initiatives, such as the eHealth Exchange, Carequality and PULSE, provide a unique perspective on interoperability-related provisions of the draft Strategy.

In this letter, we provide priority high-level comments intended to help ONC and its collaborators in the Centers for Medicare and Medicaid Service (CMS) refine and implement their highly valuable strategy to reduce burdens associated with use of health IT and electronic health records (EHRs). We share an overall aim to improve the health and health care of patients and our nation through more seamless patient and provider access to patients' health information.

Overview

We fully support the congressional intent from the 21st Century Cures legislation for this report and the manner in which ONC and CMS carried out this assignment. This draft Strategy fits well with other recent HHS efforts to reduce burden. Reducing regulatory and administrative clinician burden associated with use of EHRs and other health IT is indeed a high national priority and we agree that there are significant opportunities to do so as identified in the Strategy. Reduced clinician burden can help enable more effective interoperability and its ensuing benefits for patients and our nation; lower clinician burdens will in turn result from well-designed, usability-focused interoperability initiatives. We agree with the four areas of focus for burden reduction and appreciate the clear identification of issues, strategies and specific recommendations.

Specific Recommendations and Comments

Clinical Documentation

Relevant to this focus area and its *Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements, Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices*, Carequality has been working with the CommonWell Health Alliance to develop implementation guidance[1] aimed at generating clinical summaries (for transitions of care and other purposes) that are less subject to "bloat" and can provide more focused, higher value information to clinicians for their use and potential incorporation into EHRs. This project was motivated by four challenges related to clinical documentation quality and usability - unacceptably large C-CDA documents, an absence of clinical notes in exchanged documents, support for encounter summary documents, and the need for document version management.

Beyond enhancements to implementation guidance for electronic clinical documents, we strongly urge that ONC and CMS regulations, and implementation of existing and new

[1] https://s3.amazonaws.com/ceq-project/wp-content/uploads/2018/10/03211340/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf

standards, permit clinicians to be "smarter" about the information included in clinical summaries, such as those created with the CDA standard. CMS took important steps in this direction in its Stage 3 EHR Incentive Program Final Rule (80 CFR 62852 through 62861) and its recent CY2019 physician fee schedule final rule, including clarification that clinicians can constrain the information included in the summary care record to support transitions of care and can also use the most appropriate C-CDA document template.

Regarding *Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes* and especially its *Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization,* we note that increased use of image exchange can reduce the need for duplicate imaging and associated order review processes, such as consultation with appropriate use criteria (AUCs).

Health IT Usability and the User Experience

The work discussed in the prior section on clinical documentation improvement is also extremely relevant to this second focus area and its *Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools, Recommendation 1: Better align EHR system design with real-world clinical workflow, Recommendation 3: Improve clinical documentation functionality,* and *Recommendation 4: Improve presentation of clinical data within EHRs.*

We also emphasize the need for EHR functionality to integrate received electronic data into the EHR with a high level of usability and clinician-focused reconciliation functions, including the ability to label problem-related information as an *observation* rather than a definitive *diagnosis,* which will enable clinicians a higher degree of comfort with such integration. We also highlight the importance of including and using *provenance* information as part of clinical data exchanged across systems and therefore also agree with inclusion of this data element in the proposed U.S. Core Data for Interoperability (USCDI).

We also emphasize the importance of development and implementation by EHR vendors and providers of robust capabilities to query external systems for patient data. Such queries, and integration of obtained data into the EHR, will enable EHRs to maintain reliable and credible longitudinal views on patients. eHealth Exchange, Carequality, and standards-based image sharing all support such data queries.

With respect to *Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden, Recommendation 1: Standardize medication information within health IT,* we underscore the importance of consistent reporting of medication data using RxNorm codes and observe that many prescription drug monitoring programs (PDMPs) do not provide medication data using RxNorm, hindering interoperability and usability.

EHR Reporting

We strongly support ONC and CMS implementation of *Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians* and its associated recommendations.

We also strongly support *Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.* With respect to *Recommendation 2: Adopt additional data standards to make access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals,* we agree with the importance of standards and believe that critical needed standards and implementation guides already exist or are in near-term development.

At the same time, available standards are not always used in a standard fashion and sometimes are not used at all. For example, many clinical labs do not report lab results using LOINC codes or do not do so is a standardized fashion. Consistent use of LOINC can reduce the extent of duplicate lab tests. Both eHealth Exchange and Carequality invest significantly in efforts to achieve standardized use of standards through their implementation documents. We also support the promise of the USCDI and its associated processes for careful stepwise expansion, and the potential for using the USCDI beyond the forthcoming Trusted Exchange Framework and Common Agreement (TEFCA).

For *Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden* and *Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives,* we note that health information exchange can be a viable model to access data needed for quality reporting. For example, instead of manually entering extensive information into a CMS web site after every dialysis procedure as required, some dialysis centers automatically push clinical performance measures data to CMS' CrownWeb[2] system via the eHealth Exchange. We understand that CMS is in the early stages of redesigning and rebuilding the legacy CrownWeb system. Instead of continuing to accept End-Stage Renal Disease (ESRD) quality data from dialysis centers via direct interfaces and needing to rebuild the web data entry user interface, CMS should consider requiring dialysis providers to submit ESRD quality data via the eHealth Exchange using the End-Stage Renal Disease C-CDA implementation guide[3] designed by the dialysis industry.

Public Health Reporting

We strongly support *Strategy 1: Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow*. We have some suggestions regarding its

[2] http://mycrownweb.org/help/about-crownweb/
[3] http://sequoiaproject.org/wp-content/uploads/2016/09/End-Stage-Renal-Disease-Implementation-Guide-Package.zip

Recommendation 1: Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs using existing standards. We believe that the value of PDMPs and vendor and public sector cross-PDMP connections would be enhanced if:

- State rules regarding the use of this data could be harmonized and normalized:
    - States vary on whether only physicians can retrieve and use the data versus also allowing social workers, nurse practitioners, physician assistants, nurses, unit clerks, etc. to do so;
    - States vary on whether data can only be used during prescribing as opposed to allowing use of PDMP data during diagnosis/assessment; and
    - States vary regarding if/when PDMP data can be propagated and further disclosed.

- All PDMPs were connected to the U.S. Department of Justice RxCheck Interstate Hub.

- Drugs were shared using RxNorm codes versus free-text which EHRs struggle to ingest.

- Toxicology lab results and risk scores (codified with LOINC/SNOMED) were also shared, since both values are stored in most state PDMP repositories.

Finally, we emphasize that eHealth Exchange can provide a viable platform to facilitate EHR integration with PDMPs via connectivity between eHealth Exchange and the RxCheck Hub.

Conclusions

We thank ONC for providing the opportunity to comment on this draft Strategy. The Sequoia Project is eager to assist ONC and CMS in advancing our national interoperability agenda.

Most respectfully,

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cc: Jon White, MD
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