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January 28, 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; Mail Stop 7033A
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 Dr. Rucker:

ECRI Institute appreciates the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Strategy)*. We strongly support ONC's emphasis on reducing the regulatory and administrative burden relating to the use of health IT and EHRs and its focus on usability and reduction of clinician burden. In particular, we support the three overarching goals:

1. Reduce the effort and time required to record health information in EHRs for clinicians;
2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
3. Improve the functionality and intuitiveness (ease of use) of EHRs.

In furtherance of these goals, ECRI Institute offers its expertise and resources in support of this work and in its implementation moving forward. Our comments primarily focus on Clinical Documentation and Health IT Usability and the User Experience. We emphasize our strong support for data standards, open application programming interfaces (APIs) and increasing the usability of functions associated with EHRs and other reporting methods, such as prescription drug monitoring programs (PDMPs). Such technology advancements have the ability to both enable safer patient care and to lessen burdensome clinician interactions. We continue to aim our work through this lens.

ECRI Institute is a 50-year-old independent, nonprofit, 501(c)(3) applied research organization with a deep commitment to improving patient safety and quality. Our more than 5,000 members and clients include hospitals, health systems, ambulatory care, aging services providers, public and private payers, voluntary sector organizations, associations, U.S. federal

and state government agencies and ministries of health worldwide. ECRI's work in patient safety, medical product testing and evaluation, accident investigation, and dissemination of alerts and recommendations improves patient care and prevents patient harm. Among other roles, the U.S. government has designated ECRI Institute as a federally listed Patient Safety Organization (PSO) and, with Penn Medicine, as an Evidence-based Practice Center (EPC) to conduct research reviews for the federal government's Effective Health Care (EHC) Program. Our integrity builds on our evidence-based research, strict conflict-of-interest policies, and transparent reporting of findings. Neither ECRI Institute nor its employees accept gifts or grants from the pharmaceutical or medical device industries and our publications and informational products carry no outside advertising.

We also highlight, relative to the ONC's draft *Strategy*, the *Partnership for Health IT Patient Safety* (*Partnership*). In 2014, ECRI Institute convened the *Partnership* as a multi-stakeholder collaborative that identifies and examines safety concerns, develops health IT safe practices, and provides tools for stakeholders to implement these practices. The *Partnership* comprises healthcare providers, health IT developers/vendors, academic researchers, patient safety organizations, medical malpractice insurers, professional societies, patient groups and others. Its workgroups draw on the expertise and deliberations of participants, analyses of data submitted to ECRI Institute PSO, and evidence-based literature reviews. Reports generated from this effort are pertinent to ONC's draft *Strategy* and its implementation and are publicly available at no cost.[1]

In this letter, we provide focused comments to help ONC and its colleagues at the Centers for Medicare and Medicaid Service (CMS) refine and implement this important proposed strategy to reduce clinician burdens with use of health IT, to increase health IT usability, and to use technology to promote safer patient care. We enthusiastically support the 21st Century Cures legislation requirement for this report and the way that ONC and CMS have done the needed work. Reduced clinician burden and increased usability can translate into safer care, more effective EHRs, and advances in other health IT. We agree with the four focus areas and applaud ONC's identification of issues, strategies, and recommendations.

**Comments**

Clinical Documentation

It is likely that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences (NASEM 2015).[2] Accurate and timely clinical documentation is closely related to the critically important areas of diagnostic error and patient safety. Reducing the regulatory burden associated with documentation through improvements in reuse of information, standard data elements and fields for collection of information have all been the focus of ECRI Institute's multi-stakeholder *Partnership* work, whose work aligns with ONC first two Clinical Documentation Strategies: *Strategy 1: Reduce regulatory burden around documentation requirements for patient visits; and Strategy 2: Continue to partner with clinical*

[1] https://www.ecri.org/HITPartnership/Pages/Safe-Practices.aspx
[2] http://www.nationalacademies.org/hmd/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx

*stakeholders to encourage adoption of best practices related to documentation requirements.*

One example of this alignment is the *Partnership's* work on copy and paste. The resulting safe practice recommendations encouraged the appropriate reuse of information and recognized the hazards of clinician burden due to excessively long and "bloated" notes. The four multi-stakeholder safe practice recommendations were later evaluated and supported by NIST (NISTIR 8166). Thereafter, NIST provided "specific recommendations for user interface design to ensure safety-related usability for the 'copy and paste' function".[3] We agree strongly with the importance of enhanced clinical documentation, to reduce clinician burden and enhance patient safety. This work, and that in the draft *Strategy*, suggests that revised federal documentation policies could play an important role in reducing drivers for copy and paste and encouraging use of best practices. This collaboration also illustrates how the private sector and the federal government can work in a complementary fashion on health IT safety issues.

With respect to *Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes*, we highlight recent work on closing the multiple loops of test orders and results communications by ECRI Institute's *Partnership*.[4] Here, the work highlighted the various ways technology can facilitate this clinical process without adding additional complications or increasing burdens.

Health IT Usability and the User Experience

Our research strongly supports ONC's recommendations. Having the necessary information in a useful format at the appropriate time in the workflow was the emphasis of the *Partnership*'s 2018 workgroups—*Safe Practices for Drug Allergy Interactions Using Clinical Decision Support and Health IT* and *Safer Opioid Prescribing Through Measures and CDS*. This recent work aligns well with recommendations for *Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools*. Each of these four recommendations, *Recommendation 1: Better align EHR system design with real-world clinical workflow; Recommendation 2: Improve clinical decision support usability; Recommendation 3: Improve clinical documentation functionality;* and *Recommendation 4: Improve presentation of clinical data within EHRs* are areas of focus in these soon to be published *Partnership* safe practices. In addition to these new areas of examination, the *Partnership* work on clinical documentation mentioned in the first focus area is also relevant to this second focus area. In addition, the *Partnership's* report *Safe Practice Recommendations for Developing, Implementing, and Integrating a Health IT Safety Program*[5] highlights the importance of usability in EHR development and implementation, including better presentation and display of information within the EHR.

[3] https://www.nist.gov/publications/examining-copy-and-paste-function-use-electronic-health-records and https://nvlpubs.nist.gov/nistpubs/ir/2017/NIST.IR.8166.pdf.
[4] https://assets.ecri.org/PDF/HIT-Partnership/Closing-the-Loop-Safe-Practice-Recommendations.pdf, https://assets.ecri.org/PDF/HIT-Partnership/Closing-the-Loop-Toolkit.pdf, https://assets.ecri.org/PDF/HIT-Partnership/Closing-the-Loop-Evidence-Report.pdf
[5] https://assets.ecri.org/PDF/HIT-Partnership/HIT-Safety-Toolkit-2018.pdf

With respect to *Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden*, we agree strongly with the need to standardize medication and order entry content and, based on work by the *Partnership*, also support *Recommendation #3*, on standardizing display content (see also our comments on Strategy 1). In addition, we highlight the importance of harmonized clinical practice guidelines in enabling harmonization of clinical content. In this regard, we highlight the ECRI Guidelines Trust™, a publicly available web-based repository of objective, evidence-based clinical practice guideline content.[6] This repository builds on ECRI's long experience as the sole prime contractor for the National Guideline Clearinghouse.

EHR Reporting

We agree with the identified strategies and recommendations. We especially highlight *Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs* and its *Recommendation 1: Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting;* and *Recommendation 2: Adopt additional data standards to makes 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.* High quality data is essential for safe patient care, especially when such data is used in and derives from interoperable systems. Use of data standards that make extraction of data, integration of data, and data analysis easier decreases administrative burdens and has the potential to improve patient safety. With respect to data integration, we highlight the importance of accurate patient identification for extensive, effective and safe integration.[7]

Public Health Reporting

We agree with *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* and especially the first part of its *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 . . .".*

Recent work on opioid prescribing by ECRI Institute in collaboration with the EHR Association (publication expected in January 2019), focused on measurement and clinical decision support, highlighting the need for better integration of Prescription Drug Monitoring Program (PDMP) data into EHRs. This work also emphasizes the need for harmonization and enhancement of state PDMP laws and policies to enable such integration and use. ECRI Institute has also released a "Data Snapshot: How Health Information Technology Can Facilitate Safer Opioid Prescribing" that addresses the role of CDS in opioid prescribing and how it can be enhanced. [8]

[6] https://guidelines.ecri.org/
[7] https://assets.ecri.org/PDF/HIT-Partnership/Patient-Identification-Toolkit.pdf, https://assets.ecri.org/PDF/HIT-Partnership/Patient-Identification-Toolkit.pdf
[8] https://assets.ecri.org/PDF/HIT-Partnership/Patient-Safety-Update/PartnershipUpdate1018.pdf and https://www.ecri.org/components/HRCAlerts/Pages/HRCAlerts101817_Iceberg.aspx

Having a clearer picture of all prescriptions readily available without having to exit one activity and sign into another would reduce clinician burden and could improve patient safety. Consistent standards within those state PDMP databases, consistency in the ability to electronically prescribe controlled substances, and improvements in interoperability could likewise reduce burden, enhance safe prescribing, and enhance the data available for measurement and clinical decision support are all useful.

**Conclusions**

ECRI Institute encourages ONC to draw widely and deeply on the inputs that it receives on this draft *Strategy*. We urge a continued recognition that there is much that the federal government can do by revising its own regulatory and programmatic requirements and that there are also many opportunities for the federal government to work collaboratively with the private sector to identify and mitigate clinician burdens and usability challenges.

We look forward to continued collaboration with ONC. For questions, please do not hesitate to contact me at rsolomon@ecri.org. ECRI Institute welcomes further discussion on this topic. Our website is www.ecri.org.

Sincerely,

Ronni P. Solomon, JD
Executive Vice President and Chief Policy and External Affairs Officer