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Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attn: EHR Reporting Program Request for Information
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RE: Document Number 2018-018297: Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Thank you for the opportunity to provide comments on the request for information (RFI) regarding the electronic health record (EHR) reporting program required by the 21st Century Cures Act. The establishment of this program has the potential to give health care providers, EHR developers, and other organizations better data to address barriers in the effective, efficient, and safe use of health information technology, and improve systems accordingly. In particular, this program could unearth key details on how clinicians utilize EHRs to meet the Office of the National Coordinator for Health Information Technology's (ONC's) goal of reducing clinician burden while improving patient safety. ONC should ensure that the reporting criteria focused on usability—which refers to the design of systems and how they are used by clinicians—also incorporate safety-related provisions.

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 electronic health records (EHRs).

The 21st Century Cures Act requires ONC to develop a reporting program that examines several different functions of EHRs, including usability and user-centered design. Findings from data and information obtained via this program, as envisioned by Congress, would be widely distributed and publicly available on ONC's website. Adherence to program criteria is also part of the conditions of certification for health information technology, meaning that adherence to the program would become a requirement for EHRs used by healthcare providers that participate in federal payment programs.

As recognized by ONC in the RFI, ineffective system usability can lead to clinician confusion and patient harm.[1] Usability challenges can result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.[2] Usability-related safety problems can emerge due to confusing interfaces to complete tasks, the need to develop workarounds, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain decision support.[3]

In one well-known case, the poor usability of an EHR contributed to a 16-year old receiving 38 times the intended dose of an antibiotic drug, resulting in a near-fatal seizure.[4] A recent study in the *Journal of the American Medical Association* described 557 safety incidents related to usability. Fourteen percent of these events caused temporary patient harm, while another 1 percent may have contributed to permanent harm, including two deaths.[5] The study used data from care delivered to adults and children.

To inform this response to the RFI, Pew obtained input from multiple human factors and health information technology experts to identify:[1]

1. Principles to inform the selection of usability-related reporting criteria—though they may have applicability to other aspects of the program;
2. Ideas for existing sources of information that could be adapted into or utilized as safety-related usability reporting criteria; and
3. Other factors that ONC should consider in developing a reporting program.

Usability principles

These principles for usability-related reporting criteria are intended to assist ONC with developing a reporting program for health care facilities and technology developers to have actionable, meaningful data on which to base EHR-related decisions and to inform future technology development and deployment. Reporting criteria developed by ONC should—to the greatest degree possible—adhere to these principles.

Usability Principle	Application to the EHR Reporting Program
Life-cycle approach	The usability of EHRs can change significantly once implemented within healthcare facilities. Initial system design, unique workflows within facilities, interactions with other technologies used within each site, and individual clinician preferences all affect system usability. EHR developers differ in how they incorporate usability- and safety-related practices during system development, and the degree to which products can be customized differs among technologies. Therefore, ONC should ensure that the EHR reporting program incorporates information from all these stages in the EHR lifecycle—from product design through implementation.
Incorporate quantitative, measurable data	Clinician perceptions on technology usability can provide key insights to inform system design and necessary modifications. These data can be obtained from end users via surveys and other methods. However, measurable, quantitative data on how these systems are used—such as the time it takes to perform functions, the frequency with which orders are incorrectly entered, or reports of errors—are also critical to guide EHR-related decisions. Data could be gathered on similar processes and functions to support comparisons across products. Given variability in how systems are implemented and used, some reporting criteria may benefit from providing ranges on which data were received. For example, on quantitative criteria, ONC could list the minimums or maximums observed in addition to the mean.
Limit burden on end-users	Clinicians should spend their time caring for patients—not data entry to meet regulatory requirements. Therefore, the reporting program should limit any additional requirements on the end user. Some information on EHR use already exists or could be collected without introducing new requirements on end-users—such as through testing already employed by health care facilities or EHR developers. That information, even where already generated, may

[1] The Pew Charitable Trusts consulted with several experts to develop these recommendations, and thanks the following individuals for their initial input: David Classen, Pascal Metrics; Raj Ratwani, MedStar Health's National Center for Human Factors in Healthcare; Hardeep Singh, Baylor College of Medicine; and Jeff Smith, the American Medical Informatics Association.

	not be aggregated or combined from different data sources to provide insights on the usability and safety of EHR systems. To the greatest degree possible, ONC should leverage the existing information being collected or that could be more easily generated by EHRs. Data may exist from: existing testing programs; artifacts on the development process created by EHR vendors; automated EHR tools; log or system files; and other similar sources that could be obtained by ONC and other organizations.
Transparent methods that prevent gamesmanship	ONC should ensure that the way reporting criteria are calculated or how data are obtained is transparent, so that health care providers and EHR developers are able to effectively use findings from the program. While the methodologies used should be transparent, ONC should also ensure that the reporting criteria are not easily gamed—where submitting organizations curate data to derive a positive assessment that may not necessarily reflect the actual usability or safety of the system. ONC should strive to identify usability and safety-related reporting criteria that mitigate the opportunity for gamesmanship. The methods by which data are submitted could also be examined or audited as needed.

Reporting criteria options to consider

The following opportunities—among others—exist for ONC to incorporate safety-related data into the usability portion of the reporting program. These options, which adhere to the above listed principles, provide examples as to currently available information sources or ideas for developing reporting criteria.

1) *Leapfrog CPOE Tool:* The Leapfrog Group maintains a tool to test the ability of computerized physician order entry (CPOE) functions of EHRs to alert clinicians to common, serious, and sometimes fatal medication ordering errors.[6] The test includes 10 categories where adverse drug events occur, such as unsafe single and daily doses, drug-allergy interactions, and contraindications based on patients' age.[7] The tool examines the implemented system within hospitals to assess the usability of factors related to medications, and provides both an overall usability score for CPOE and the 10 subcategories that represent areas where serious adverse events can occur. The Leapfrog CPOE Tool—which has been endorsed by the National Quality Forum (NQF) and has been part of Leapfrog's annual, voluntary hospital survey since 2008—is already widely used and therefore would not introduce a significant new burden on health care providers. Nearly 2000 inpatient facilities in both 2017 and 2018 completed the adult inpatient test. An ambulatory module is in development and expected to be completed in 2019.[8] While individual hospitals each complete their own test, scores at each facility using the same certified EHR may be able to be aggregated. Both the overall score from the Leapfrog test, as well as some of the specific category scores may be useful, quantitative measures to include in the EHR reporting program. Importantly, the test also includes a category to ensure that systems are not over-alerting prescribers to information that is not clinically relevant, thereby contributing to alert fatigue.

2) *Safety Surveillance Data:* In 2016, ONC published a report on data that could be used to compare different EHR functions. In the report, ONC suggests that "safety surveillance data" could be useful if made publicly available.[9] To meet that goal as part of the reporting program, ONC could use data that the agency and organizations that certify EHRs collect from surveillance activities that are already conducted.

ONC data: For example, the ONC Certified Health IT Product List (CHPL) contains those products that have been tested and certified by ONC.[10] In addition, the CHPL contains a list of certified health IT products that have elements that do not conform with the agency's EHR certification criteria.[11] The developers of these products must file a corrective action plan as to how they will resolve the discrepancy; as of early October 2018, more than 125 products have corrective action plans. This list of products with corrective action plans—especially if coupled with additional information—can inform clinicians of discrepancies with products they are using. Further, ONC could obtain data from other sources that could be examined for inclusion in this program, such as via the agency's authority to conduct direct oversight of EHRs or from non-proprietary information obtained by government.[12]

ONC-ACB data: Additionally, ONC-Accredited Certification Bodies (ACBs) also conduct surveillance activities. ONC regulations require ONC-ACBs to conduct reactive surveillance, which refers to the examination of systems when certification bodies become aware of EHRs that do not conform to federal certification criteria, including around safety-related functions such as drug-allergy interaction checks.[13] Similarly, ONC regulations enable certification bodies to conduct random surveillance of EHRs.[14] If and when conducted, the findings from ONC-ACB's reactive and random surveillance could be summarized and made available via the reporting program to provide even greater usability- and safety-related information.

3) *SAFER Guides:* ONC publishes the Safety Assurance Factors for EHR Resilience (SAFER) guides that include checklists to assess a wide range of EHR features and recommendations for functions that EHRs should possess.[15] For example, one SAFER guide on the display of laboratory test data examines whether systems provide context on the normal range of results and whether the status of orders can be tracked.[16] ONC could use the SAFER Guides as a tool to identify some high-priority functions on which to obtain information from implemented systems via the reporting program; EHRs could automate data collection on some of those functions. ONC could indicate which function—or group of functions—as identified by SAFER guides are enabled by certified EHRs. Alternatively, the reporting program could indicate whether a certain percentage of high-priority areas from the SAFER Guides are able to be completed using certified products. For example, the SAFER Guides have recommendations on how to evaluate the functional downtime of EHRs through automated means.[17] To evaluate this, a test patient medication order is displayed on a workstation every minute for 24 hours; the delay in displaying the order or number of times it is not displayed could provide information on the lag faced by clinicians when using the system.

4) *NQF Report:* In February 2016, NQF published the "Identification and Prioritization of Health IT Safety Measures" report.[18] This report identified nine key health information technology-related safety measure concepts that could be adapted into an EHR reporting program. For example, the report provides concept ideas on clinical decision support; user-centered design; system downtime; and other areas. This report, which has dozens of measure concepts, should be examined to identify areas where data exist and could be automated to provide data for the EHR reporting program.

Other critical factors

In addition to the principles and potential criteria concepts articulated, ONC should consider the following other factors to establish a successful EHR reporting program.

- *System or audit log data*: System or log files are the digital record of what happens within an electronic system—such as the buttons that pressed or the time of an entry. These data can provide interesting information to understand how systems are used, and the usability challenges encountered by clinicians. For example, NQF has endorsed a measure that uses these types of

data to understand when clinicians order a drug on the wrong patient.[19] As part of the current or future iterations of the reporting program, ONC should examine how to use system or log file data to identify usability challenges and safety risks.

- *Facility resources*: In the RFI, ONC explicitly requests information to help inform a reporting program for ambulatory and small practice settings given that these organizations may lack resources to conduct in-depth market research. In addition to those types of practices, many hospitals may also lack the resources or expertise needed for broad market analysis. For example, critical access or rural facilities may not have human factors experts to help guide usability-related decisions. Consequently, ONC should ensure that this reporting program also focuses on the needs of those types of facilities to improve usability and safety—among other critical EHR functions—across the entire industry.
- *Stakeholder engagement*: Physicians, nurses, and other clinicians interact regularly with EHRs and possess an intimate knowledge of their functionality. ONC should actively engage with these clinicians to discuss and extract specific usability-related safety information, such as input on high-risk functions or other priorities. In addition, ONC should obtain input from researchers and other experts that have industry-wide knowledge about usability and safety challenges.

Conclusion

Congress has provided ONC a prime opportunity to improve the usability—and consequently, safety—of EHRs. As ONC implements this program, the agency should ensure that the usability aspects of the program focus on the facets of EHR usability that can contribute to unintended patient harm. To achieve that goal, ONC should consider the aforementioned principles in identifying reporting criteria, and data sources that could become part of the program.

Pew can serve as an expert resource to help ONC and its contractor examine safety-related usability criteria for the program. As the program develops, Pew intends to assess data sources that can inform the reporting program and examine how to adapt existing efforts to serve as usability-related criteria.

By incorporating safety-related data into the usability reporting criteria, hospitals, clinicians, and EHR developers would have the information they need to understand how EHRs perform to inform a range of decisions—including around purchasing, customization, and future development.

Thank you for considering our comments. Should 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

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