DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the National Coordinator for Health Information Technology
Announcement of Requirements and Registration for "Easy EHR Issue Reporting"
Authority: 15 U.S.C. 3719

Subject of Challenge Competition:
Summary. Electronic Health Record (EHR) usability issues can adversely affect health care quality and patient safety. In order to effectively address such issues, clinicians, hospitals, and health IT developers need better tools to capture, analyze, and understand how and why errors occur. This challenge is a multidisciplinary call to software developers, clinicians, and innovators to create a tool that will make it easier for doctors, nurses, and other care team members to efficiently and effectively report concerns about the usability or safety of EHRs to appropriate parties, such as the hospital or practice's IT team, the EHR developer, and Patient Safety Organizations (PSOs).

Description. As of 2015, 96% of hospitals and 78% of office-based physicians have certified EHRs[1]. Clinicians and other members of the health care team routinely work in fast-paced, stressful, and challenging environments. As such, they have come to increasingly rely on EHRs to retrieve patient information, assist in making complex patient care decisions, and ultimately optimize patient safety and health care quality. Despite a growing body of evidence showing the use of advanced health IT being associated with safer care on the whole, it also poses new challenges and risks when deployed into complex clinical environments. Whether through design, development, deployment, operational, or other deficiencies, studies have also shown EHRs can contribute to adverse events and fall short of expectations for safety-related usability, in addition to frustrating end users and posing avoidable risks to patients. These issues are difficult to identify and correct unless the full array of end users' concerns are regularly captured and analyzed for trends and improvement opportunities.

When clinicians experience usability or safety issues associated with an EHR, their health IT department or EHR service/support team, internal patient safety program, health IT developer, and federally-listed PSOs can help understand and address concerns. To achieve their full potential to help make health IT better meet user needs and expectations related to patient safety, the internal programs of health care organizations, health IT developers, and PSOs need more reporting. The more easily and consistently end users can capture and share their concerns, the better the safety programs and organizations will be able to spot trends and drive improvement.

Stakeholder feedback indicates there is a need for more efficient and user-friendly mechanisms that allow EHR end users to report concerns quickly and easily, with little or no disruption to their workflow. Mechanisms widely available on the market today normally require the end user to either exit the EHR system entirely or leave the current workflow process in order to report the problem. Some EHRs may include a separate error reporting module, but others require the end user to fill out a report through a totally separate mechanism. This workflow disruption is enough of a burden on users that they avoid reporting. Indeed, the greater the workflow interruption the more likely they are to delay rather than report immediately while the experience is fresh and most accurately recalled, or to forego reporting entirely. Clinicians need better reporting mechanisms that are designed to address the end user's needs and are complementary with the workflow processes and systems they use.

Solution Requirements:
Solutions should accomplish the following:
- Facilitate the reporting of EHR usability and safety issues in an EHR platform-neutral way

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[1] https://dashboard.healthit.gov/quickstats/quickstats.php

consistent with applicable interoperability standards.
- Support reporting via [AHRQ common formats](#).
- Use relevant interoperability and technical standards to integrate a user-friendly interface with the health IT workflow clinicians and other care team members use daily, via any technology approach.
- Allow the end user to access and use the reporting tool when and where the concern arises without exiting the EHR system workflow process currently in use.
- Allow the clinician practice, hospital, or end user to choose which parties to report to, such as a provider's health IT department or EHR service/support team, a health care organization's internal safety program, the EHR developer, and PSOs.
- Minimize user and system impact:
  - For users, minimize the time and effort (as measured by, for example, number of clicks or amount of additional writing) needed to create a report through the solution. This could be achieved by, for example, use of a running cache of steps taken in the EHR or leveraging other automatically recorded system information and context (e.g., various types of audit logs) that can be used to enrich user entered data.
  - For systems, minimize the solution's performance impact on the system in use such that the end-user does not experience reduced performance to complete routine tasks.
- Provide feedback to the end user that the report was sent and/or received.
- NOTE: The safety reports' appearance and the manner in which they are generated are left to the discretion of the submitter.

Submitters are also required to undertake user testing and/or co-design with end users (preferably a mix of physicians, nurses, and other clinicians) of the tool in order to bring in direct feedback during development. Submitters may choose the level of formality or structure and must demonstrate engagement with end users in clinical practice where they regularly use at least one EHR. Pilot testing with a provider or EHR developer, a larger amount of time spent with real-world EHR users, greater formal rigor, and the number and diversity of users will result in a more positive assessment under the evaluation criteria. Evidence could include sample feedback, quotes, or pictures, and should include how it affected development of the submission. Resources like https://methods.18f.gov/discover/stakeholder-and-user-interviews/ can provide guidance.

General Solution Requirements
In order for a solution to be eligible to win this Challenge, it must meet the following requirements:
- No HHS or ONC logo: The solution must not use HHS' or ONC's logos or official seals and must not claim endorsement.
- Functionality/Accuracy: A product may be disqualified if it fails to function as expressed in the description provided by the Submitter, or if it provides inaccurate or incomplete information.
- Security: Submissions must be free of malware. Submitter agrees that ONC may conduct testing on the product to determine whether malware or other security threats may be present. ONC may disqualify the submission if, in ONC's judgment, it may damage government or others' equipment or operating environment.

Amount of the Prize:
- Total: $80,000 in prizes
- First Place: $45,000
- Second Place: $25,000
- Third Place: $10,000

Prizes will be paid by contractor.

Dates:
- Challenge launch: May 14, 2018
- Submission period ends: October 15, 2018
- Winners notified: November 6, 2018
- Winners announced: November, 2018

Basis upon Which Winner Will Be Selected:
Winners will be selected based on the following criteria:
- EHR workflow integration: Ease of accessing and utilizing the solution without exiting the EHR or having to use a separate login. This includes, for example, ease in and time needed to complete a report, time and effort required to return to prior task flow following report completion, and the ability to pull in or reproduce information from the EHR.
- Information flow: Use of or compatibility with AHRQ Common Formats. Comprehensiveness and relevance of information in generated reports (i.e., does the report include all the most relevant information but limit extraneous information). Ability to transmit data to single or multiple selected stakeholders simultaneously, at the discretion of the clinician practice, hospital, or end user.
- User experience: Usability and overall user experience, including visual appeal, simplicity, and adherence to web best practices. Also includes the impact on EHR system performance and thoroughness of user testing/co-design process.
- Technical functionality: Accomplishes the remaining specified technical functionality requirements detailed above in "Solution Requirements" not covered by the "EHR workflow integration" and "Information flow" criteria.

Eligible challenge submissions will be reviewed by a panel composed of federal employees and experts in compliance with the requirements of the America COMPETES Act and the Department of Health and Human Services judging guidelines: http://www.hhs.gov/idealab/wp-content/uploads/2014/04/HHS-COMPETITION-JUDGING-GUIDELINES.pdf. The review panel will make selections based upon the criteria outlined above.

How to Enter:
To enter this challenge, submitters can visit http://www.challenge.gov and search for "Easy EHR Issue Reporting" or directly visit the challenge homepage at https://www.cccinnovationcenter.com/challenges/easy-ehr-issue-reporting-challenge/ and follow the instructions.

Submission package must include:
- Instructions file that documents usage and installation instructions and system requirements.
- Slide deck of no more than 12 slides that describes how the solution functions, addresses the application requirements, and details consumer testing/co-design process.
- Video demo (five minute maximum) showing implementation and use of the solution; this may also address consumer testing/co-design process.

Intellectual Property (IP) Rights:
Each entrant retains title and full ownership in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the challenge, each entrant hereby irrevocably grants to ONC a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission to the extent necessary to administer the challenge, and to

publically perform and publically display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

Eligibility Rules for Participating in the Competition:
To be eligible to win a prize under this challenge, an individual or entity—
   (1) Shall have registered to participate in the competition under the rules promulgated by ONC;
   (2) Shall have complied with all the requirements under this section;
   (3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States;
   (4) May not be a Federal entity or Federal employee acting within the scope of their employment (all non-HHS federal employees must consult with their agency Ethics Official to determine whether the federal ethics rules will limit or prohibit the acceptance of a COMPETES Act prize);
   (5) Shall not be an HHS employee;
   (6) Federal grantees may not use Federal funds to develop submissions unless consistent with the purpose of their grant award; and
   (7) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

By participating in this Challenge, Participants:
   (1) Agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise;
   (2) Are financially responsible for claims by a third party;
   (3) Agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities.

Representation, Warranties and Indemnification:
By entering the Challenge, each Participant represents, warrants and covenants as follows:
   (1) Participant is the sole author, creator, and owner of the Submission;
   (2) The Submission is not the subject of any actual or threatened litigation or claim;
   (3) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party; and
   (4) The Submission, and Participants' use of the Submission, does not and will not violate any applicable laws or regulations, including, without limitation, applicable export control laws and regulations of the U.S. and other jurisdictions.

If the Submission includes any third party works (such as third party content), Participant must be able to provide, upon request, documentation of all appropriate licenses and releases for such third party works. If Participant cannot provide documentation of all required licenses and releases, ONC reserves the right, at its sole discretion, to disqualify the applicable Submission. Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party

claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from Participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of Participant hereunder. ONC reserves the right to disqualify any Submission that, in their discretion, deems to violate these Official Rules, Terms & Conditions.

ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

For Further Information Contact: Adam Wong, adam.wong@hhs.gov

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Date

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