

- **Safety-enhanced design**

MU Objective N/A
2014 Edition EHR Certification Criterion § 170.314(g)(4) (Safety-enhanced design)

The International Organization for Standardization (ISO) defines usability as “[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.”¹ Many industry stakeholders have acknowledged that a gap exists between optimal usability and the usability offered by some current EHR technologies. However, to date, little consensus has been reached on what might help close this gap and what role, if any, the Federal government should play related to the usability of EHR technology. In June 2011, the HITPC issued a report to ONC that explored the challenges associated with EHR technology usability and user-centered design (UCD). In its report, the HITPC identified certain “desired outcomes of improved usability” including improved safety and reduced cost, clinician frustration, training time, and cognitive load for clinical and non-clinical users alike.

In November 2011, the Institute of Medicine (IOM) released a report titled “Health IT and Patient Safety: Building Safe Systems for Better Care,” in which the usability of EHR technology and quality management was often referenced. The IOM noted that “[w]hile many vendors already have some types of quality management principles and processes in place, not all vendors do and to what standard they are held is unknown.” Moreover, given this concern,

¹ ISO 9241-11

the IOM recommended that “[t]he Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.”

We fundamentally agree with the sentiment expressed by both the HITPC and the IOM. As we consider the shared goals stated by stakeholders from all sides of this discussion, we believe that a significant first step toward improving overall usability is to focus on the process of UCD. While valid and reliable usability measurements exist, including those specified in NISTIR 7804 “Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records,”² we are concerned that it would be inappropriate at this juncture for ONC to seek to measure EHR technology in this way. Recognizing that EHR technologies exist and are in use today, we have prioritized eight certification criteria³ and associated capabilities to which this proposed certification criterion would require UCD to have been applied. We chose these eight because we believe they pose the greatest risk for patient harm and, therefore, the greatest immediate opportunity for error prevention and user experience improvement. We believe this approach limits this new certification criterion’s potential burden while providing for a much needed focus on the application of UCD to medication-related certification criteria.

The methods for how an EHR technology developer could employ UCD are well defined in documents and requirements such as ISO 9241-11, ISO 13407, ISO 16982, and NISTIR 7741.

Presently, we believe it is best to enable EHR technology developers to choose their UCD

² <http://www.nist.gov/healthcare/usability>

³ § 170.314(a)(1) (CPOE); § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks); § 170.314(a)(6) (Medication list); § 170.314(a)(7) (Medication allergy list); § 170.314(a)(8) (Clinical decision support); § 170.314(a)(17) (Electronic medication administration record); § 170.314(b)(3) (Electronic prescribing); and § 170.314(b)(4) (Clinical information reconciliation).

approach and not to prescribe one or more specific UCD processes that would be required to meet this certification criterion. Thus, the use of any one of these processes to apply UCD would meet this certification criterion. Moreover, we acknowledge and expect that EHR technology developers who have already followed UCD in past development efforts for the identified certification criteria would be performing a retrospective analysis to document for the purposes of testing and certification that UCD had been applied to the specified certification criteria. However, if UCD had not been previously applied to capabilities associated with any of the certification criteria proposed, the EHR technology would ultimately need to have such UCD processes applied before it would be able to be certified.

We propose to adopt this certification criterion at § 170.314(g)(4). If we adopt this certification criterion in a final rule, we anticipate that testing⁴ to this certification criterion would entail EHR technology developers documenting that their UCD incorporates, in any form or format, all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742). We note that with respect to demonstrating compliance with this certification criterion that this information would need to be available to an ONC-ACB for review. This documentation would become a component of the publicly available testing results on which a certification is based (see section IV.D of this preamble for our proposal to make the test results used for certification publicly available).

⁴ The National Voluntary Laboratory Accreditation Program, as administered by NIST, is responsible for testing under the permanent certification program (“ONC HIT Certification Program”) (76 FR 1278).

In addition to our proposed safety-enhanced design certification criterion, we request comment on two other safety-related certification criteria under consideration for adoption by the Secretary.

Quality Systems

The IOM also recommended that we “[establish] quality management principles and processes in health IT.” Working with other Federal agencies, we **intend** to publish a quality management document that is customized for the EHR technology development lifecycle and expresses similar principles to those included in ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR 820. The document would provide specific guidance to EHR technology developers on best practices in software design processes in a way that mirrors established quality management systems, but would be customized for the development of EHR technology. We understand that some EHR technology developers already have processes like these in place, but do not believe, especially in light of the IOM recommendation, that the EHR technology industry as a whole consistently follows such processes. We expect that **this document would be published around the same time as this proposed rule and would be available for public comment.**⁵ Accordingly, we are considering including in the final rule an additional certification criterion that would require an EHR technology developer to document how their EHR technology development processes either align with, or deviate from, the quality management principles and processes that would be expressed in the document. We emphasize that this certification criterion would not require EHR technology developers to comply with all of the

⁵ The quality management document will be published on ONC’s website during the public comment period of this proposed rule and notice of its availability will be made through a notice published in the Federal Register.

document's quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology developers would need to review their current processes and document how they do or do not meet principles and processes specified in the document (and where they do not, what alternative processes they use, if any). We expect that this documentation would be submitted as part of testing and would become a component of the publicly available testing results on which a certification is based.

We are considering adopting this additional certification criterion as part of the 2014 Edition EHR certification criteria for three reasons. First, all EHR technology developers that seek certification of their EHR technology would become familiar with quality management processes. Second, the public disclosure of the quality management processes used by EHR technology developers would provide transparency to purchasers and stakeholders, which could inform and improve the development and certification of EHR technology. Last, EHR technology developers' compliance with the certification criterion would establish a foundation for the adoption of a more rigorous certification criterion for quality management processes in the future without placing a significant burden on developers. We request public comment on this additional certification criterion and the feasibility of requiring EHR technology developers to document their current processes.

Patient Safety Events

We are considering adopting a certification criterion (as mandatory or optional) that would require EHR technology to enable a user to generate a file in accordance with the data

required by the Agency for Healthcare Research and Quality (AHRQ) Common Format⁶ including the “Device or Medical/Surgical Supply, including HIT v1.1a.”⁷ The Common Formats are designed to capture information about patient safety events. In line with IOM’s recommendations, we believe that requiring this capability for certification could be an essential first step in creating the infrastructure that would support the reporting of potential adverse events involving EHR technology to patient safety organizations (PSOs). We request public comment on whether we should adopt such a certification criterion and what, if any, challenges EHR technology developers would encounter in implementing this capability.

b. Ambulatory Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the ambulatory setting.

⁶ <http://www.pso.ahrq.gov/formats/commonfmt.htm>

⁷ https://www.psoppc.org/c/document_library/get_file?p_1_id=375679&folderId=372647&name=DLFE-12734.pdf