



Health IT Policy Committee
Certification/Adoption Workgroup
April 21, 2011

STATEMENT BY THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association (AMA) is pleased to submit this statement on issues relevant to the usability of electronic health records (EHRs). Vendors should ensure that the systems they develop are able to meet the clinical and administrative needs of EHR users. EHR products should support the evolving payment and delivery structures expected under health care reform, physician practice workflow, clinical decision-making, and should enhance processes aimed to improve health outcomes.

At this time, the certification requirements for Stage 1 of the Medicare/Medicaid EHR meaningful use incentive program do little to address EHR usability. The current requirements only call for vendors to develop products that are capable of helping health care providers meet the criteria outlined in the CMS final rule and focus largely on the potential functions of EHRs, not usability in actual clinical practice. Vendors are not required under the Stage 1 certification requirements to address how well their systems will improve existing workflow, support and enhance care processes and clinical decision making, address patient safety, and enable appropriate methods for medical documentation and billing. Unless EHRs are developed to address user needs, widespread adoption and use of EHRs could be hampered. **While the Stage 1 certification criteria have been established, the AMA strongly recommends that standards for testing and tracking usability be incorporated in future EHR certification requirements.**

EHR Usability and Its Impact on EHR Adoption and Use

There is a direct correlation between EHR adoption and the usability of an EHR. According to the Healthcare Information and Management Systems Society (HIMSS) EHR Usability Task Force, "...usability is one of the major factors – *possibly the most important factor* – hindering widespread adoption of EMRs."¹ This premise is supported by federal research and by the vendor industry. When purchasing a certified EHR, physicians must know not only that a product can perform a function in theory, but also how efficiently and effectively the system can help them accomplish clinical and administrative tasks in reality. Physicians and other health care providers have cited EHR usability as an issue of great importance. For example, physicians have indicated that many times after they spend time entering patient information in an EHR, retrieving it for later use can be difficult. A report by Case Western Reserve University highlights challenges faced by EHR users:

Computerized records can be lengthy and cumbersome to read. Whereas having to write notes by hand encourages brevity, physicians entering notes electronically may copy large segments of information from elsewhere in the record for the sake of completeness, but this practice may make it far more difficult for a provider to obtain an overview of the patient's current condition or

¹ HIMSS EHR Usability Task Force, "Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating," June 2009.

locate a needed detail quickly. With interoperability, doctors may have access to records from patients' visits to numerous specialists and be expected to consider all relevant information concerning each patient's medical and treatment history. The challenges of reviewing a patient's entire EHR may be compounded by data display problems. Doctors may need to scroll through numerous screens in order to find the detail they seek, information may be organized awkwardly or fragmented throughout the EHR, and all data might appear in a uniform format so that it cannot be easily scanned by physicians seeking a particular fact.²

Both the Agency for Healthcare Research and Quality (AHRQ) and the National Institute of Standards and Technology (NIST) are exploring in greater depth the issue of EHR usability and adoption rates. According to the NIST, "Usability represents an important yet often overlooked factor impacting the adoption and meaningful use of electronic health record (EHR) systems. Without usable systems, doctors, medical technicians, nurses, administrative staff, consumers, and other users cannot gain the potential benefits of features and functions of EHR systems."³ However, according to a recent AHRQ report, "Current best practices and standards of design, testing, and monitoring EHR product(s), particularly for usability, are varied and not well disseminated."⁴ AHRQ also found that there are not agreed upon best practices for EHR usability standards among vendors. The report also concluded that, "Driving the EHR market toward creation of usable products requires development of a process that accurately identifies usable products, establishes and disseminates standards, and encourages innovation."⁵

Charles Friedman, PhD, the Office of the National Coordinator (ONC) Chief Scientific Officer, acknowledged during the annual HIMSS meeting in February 2011, the importance of EHR usability in fostering meaningful use of EHRs. He noted that ONC is, "exploring options for stimulating a competitive market that will improve usability and thus safety of EHR systems. Working with NIST, AHRQ, and key stakeholders, we will be actively developing necessary criteria and test procedures and will coordinate this activity with work on Stage 2 of Meaningful Use." **The AMA is pleased that ONC is working with other federal agencies like AHRQ and NIST to address EHR usability within the context of meaningful use requirements.**

EHR Usability Standards

Every major design feature of an EHR requires clinical testing and analysis, both as an independent feature and for effective integration in concert with other design features. Typically, the end user is not aware of the intricacies involved in creating a system. According to a recent NIST report, "One of the most common reasons why systems are poorly designed is that designers and developers fail to engage users in appropriate ways at appropriate times."⁶ EHR products should support physician practice workflow, clinical decision-making, and should enhance processes aimed to improve health outcomes. Due to the importance of the user's ability to maneuver within the EHR, it is necessary that EHR vendors develop processes to solicit feedback from end users and incorporate feedback into their technology as well as the upgrade and improvement processes. Therefore, we believe physician end users should be involved at all levels of the EHR design process so that usability issues can be addressed from the

² Hoffman and Podgurski, "E-Health Hazards: Provider Liability and Electronic Health Record Systems," Case Western University, Case Research Paper Series in Legal Studies, Working Paper 09-25, August 2009.

³ NIST website <http://www.nist.gov/healthcare/usability/index.cfm> referenced April 15.

⁴ AHRQ Electronic Health Record Usability Vendor Practices and Perspectives, AHRQ Publication No. 09(10)-0091-3-EF, May 2010.

⁵ Id.

⁶ Schumacher, R. "NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records," NISTIS 7741, p. 22, 2010.

beginning. The 2010 AHRQ report recommends a “user-centered design and testing process be implemented.”⁷ Incorporating the user’s needs within the design protocols will improve the usability of EHRs.

Excessive click through screens, design limitations, display menu design, overly engineered systems that attempt to mirror intuitive actions, and alert overload are factors that directly discourage the uptake of EHRs. EHR systems have also generated errors. The sources of errors include “fragmentation of data, failure to integrate all hospital systems; and human-computer interface difficulties rooted in the machine rules’ failure to reflect work organization or expected provider behavior.”⁸ There is a certain level of vulnerability involved with trusting a system that maintains hundreds, if not thousands, of medical records that could be prone to errors. Creating agreed upon EHR usability standards and encouraging best practices for testing and tracking usability issues would improve the usability of EHRs and garner more support from the end users. **The AMA supports the development of an independent body to focus on usability standards development, as suggested by the AHRQ report, and the development of best practices for EHR usability standards. We further recommend that ONC incorporate EHR usability standards into the certification process, monitor EHR usability needs, and incorporate improvements on a continual basis. We further support transparency regarding the usability testing and other measures, so that clinicians can know whether, or the extent to which, systems have been tested and proven safe and effective in clinical practice prior to purchase.**

EHR Usability and Consequences for Patient Safety

It is widely accepted that EHRs can support better clinical decisions, facilitate information exchange, and reduce duplicative efforts and costs. But studies find these same tools can also result in unintended patient safety issues. In some cases EHR design and software flaws have been found to contribute directly to errors, including some that have caused patient harm. Clinical usability issues that can contribute to unsafe conditions include use of certain colors on screens (e.g., persons with red-green color blindness might not see important distinctions), information overload due to packing too much information onto a single screen, difficult or non-intuitive navigation steps to obtain key data, use of small fonts, facilitation of “cut-and-paste” issues, alert overload leading to alert fatigue, and selecting the wrong patient when multiple patient records are open. The HIMSS EHR Usability Task Force has acknowledged these problems and has found, “Clinical systems are complex as well as information dense—it is essential for efficiency as well as patient safety that displays are easy to read, that important information stands out, and that function options are straightforward.”⁹ AHRQ similarly concluded that health IT can negatively impact patient safety if there is “a lack of integration of health IT into clinical workflow in a way that supports the cognitive work of the clinician and the workflows among organizations (e.g., between a clinic and community pharmacy), within a clinic and within a visit.”¹⁰

The AMA believes it is critical to carefully study and monitor the effects of health IT on patient safety as well as other important outcomes. Today, vendors have both formal and informal processes for identifying patient safety concerns, but we agree with AHRQ that more research and development of

⁷ AHRQ 2010.

⁸ Hoffman, S., Podgurski, A. “Finding a Cure: The Case for Regulations and Oversight of Electronic Health Record System,” *Harvard Journal of Law & Technology*, volume 22, No. 1, Fall 2008, p. 120.

⁹ HIMSS EHR Usability Task Force, “Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating,” June 2009.

¹⁰ AHRQ Incorporating Health Information Technology Into Workflow Redesign, AHRQ Publication No. 10-0098-EF, October 2010.

more effective and reliable methods to detect and track patient safety issues arising from use of EHRs is warranted. **The AMA recommends that:**

- 1) All vendors seeking EHR certification should be required to establish a formal reporting process that specifically addresses patient safety issues and reporting of potential events associated with use of these products;**
- 2) Reporting methods might include using “trigger tool” and automated reporting functions, as the most effective methods developed to date for tracking clinical safety issues;**
- 3) Consideration should be given to operationalizing these reporting processes using the protections of AHRQ-certified Patient Safety Organizations;**
- 4) ONC should track patient safety issues raised to vendors on a nationwide basis through these reporting processes; and**
- 5) The information gained from these processes should be used both within and outside the certification process to improve patient safety and the usability of EHRs.**

EHR and Coding

The usability of EHRs for helping a physician code and bill a claim for services has also been raised. EHRs have been accused of driving upcoding. While physicians are ultimately responsible for billing for the appropriate level of service based upon the medical necessity and care delivered, “EHR software vendors must provide systems whose design and functionality have the capability to guide physicians to effective care and compliant documentation, including elimination of all potentially non-compliant functionality.”¹¹ Almost all EHR vendors use templates that are designed to help speed up workflow. The use of templates, per se, does not drive upcoding, however, since coding is driven by actions the physician actually performs, which are then checked off within the template. Having a template might save time in documentation, but it does not make performing a history and physical examination faster—and the latter drive appropriate coding. Some EHRs suggest a code for billing based on information entered into templates. We are aware that the Department of Health and Human Services (HHS) and the Office of the Inspector General (OIG) have plans to audit physicians participating in the Medicare/Medicaid EHR meaningful use incentive program. OIG has detailed the following intentions in their 2011 Workplan:

We will review the extent of potentially inappropriate payments for E&M services and the consistency of E&M medical review determinations. CMS’s Medicare Claims Processing Manual, Pub. No. 100 04, ch. 12, § 30.6.1 instructs providers to “select the code for the service based upon the content of the service” and says that “documentation should support the level of service reported.” Medicare contractors have noted an increased frequency of medical records with identical documentation across services. We will also review multiple E&M services for the same providers and beneficiaries to identify electronic health records (EHR) documentation practices associated with potentially improper payments.

It is therefore critical that both management support and coding tools be clinically appropriate and compliant with established standards in CPT and E/M Documentation Guidelines. Take for instance the examination of an elderly patient with diabetes. The routine evaluation of pedal (foot) pulses is clinically appropriate. An EHR that promotes one size fits all medicine, with an eye to maximization of services, might ignore medical necessity and recommend that all elderly diabetic patients also receive an extremity arterial study, (CPT code 93922), regardless of the clinical findings on the pedal pulse exam. A good system, however, should instead recommend appropriate services, such as code 4305F—patient education

¹¹ American Association of Professional Coders, “Key Flaws with CCHIT Criteria,” Industry News, June 10th, 2009.

regarding appropriate foot care and daily inspection of the feet—for all patients in this population, and recommend further arterial studies for patients with abnormal pedal pulses or symptoms suggesting arterial occlusive disease. In compliance with the documentation guidelines above, coding recommendations should be based upon new conditions that have arisen since the last visit, and decision and documentation supports should provide meaningful lists of likely symptoms and signs that should be included in the H and P, which should minimize documentation of irrelevant services and reduce the risk of upcoding.

The AMA believes that an important part of the certification process of an EHR should include requirements that call for vendors to run test scenarios (as they do for other features) to document that their coding recommendations are accurate based on discrete data that have been entered. A vendor who cannot perform these test scenarios accurately should not be certified. It should be assumed that physicians will rely on all tools within their EHR, including coding components; therefore this portion of the EHR must also be tested and certified to conform to established standards. In addition, vendors need to be very transparent about their systems capabilities including billing and coding; physicians need to understand the limitations of these tools with regard to clinical and coding supports, and that clinical and coding decisions remain the responsibility of the physician. **The AMA therefore, recommends that the certification process include specific testing to ensure coding recommendations are consistent with coding guidelines and data entered.**

Legal Issues Associated with EHR Usability

Along with the usability challenges described above, physicians are also facing potential new liabilities with the increased use of EHRs. With EHRs, there is an unprecedented amount of patient information and data accessible to physicians. Physicians are concerned about the potential liability associated with the voluminous amount of information that is available to them through health IT. In addition, with the adoption and implementation of EHRs come contractual agreements between EHR vendors and physicians such as “hold harmless” clauses which prohibit the physicians from holding a vendor responsible for faulty systems, as well as “confidentiality” clauses that prohibit physicians from discussing such deficiencies. The AMA believes that physicians should be protected from the use of hold harmless and confidentiality agreements by EHR vendors that would shift liability to clinicians for non-user problems such as system or software failures or inadequacies. Physicians and patients alike are increasingly reliant upon EHRs in making and carrying out clinical decisions, just as they are reliant on many other clinical tools, from scalpels and IV pumps to heart-lung bypass machines. While the AMA does not hold that EHRs are medical devices, we recognize that clinical reliance confers legal and ethical responsibilities on the makers of EHRs. **Liabilities associated with the use of EHRs should be further explored by the Certification and Adoption Workgroup and solutions for minimizing legal risks should be recommended.**

Conclusion

The AMA looks forward to continuing to work collaboratively with HHS, ONC, the Certification/Adoption Workgroup, and respective stakeholders to improve the usability of EHRs for physicians and other end users. Evaluating and incorporating EHR usability standards and best practices for testing and tracking usability in future EHR certification requirements will not only improve patient care and prevent harms, it will thereby help to enhance EHR adoption and use rates.