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Farzad Mostashari, MD, ScM
National Coordinator
Health Information Technology
Office of the National Coordinator
for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0991-AB82; Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record (EHR) Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

Dear Dr. Mostashari:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule on the 2014 Edition of EHR standards, implementation specifications, and certification criteria, as well as the revisions to the permanent certification program. The AMA is pleased to provide our recommendations for revising the proposed rule so that the 2014 Edition and revised permanent certification program support the availability of EHRs that are best able to meet the needs of physicians as they strive to successfully participate in the EHR meaningful use (MU) incentive program and provide high quality patient care.

The AMA recognizes the value and challenges of an EHR certification process that parallels with the Medicare and Medicaid EHR incentive programs. The AMA is pleased that ONC proposes the concept of a "Base EHR" and is focusing more attention on patient safety issues. **However, we continue to harbor significant concerns over EHR usability issues and the lack of robust health information exchanges—challenges that must be addressed so that physicians are able to use EHRs to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies.** Below we provide a more detailed review of our concerns and the areas where we concur with the proposed rule.

Health Information Exchanges

A fundamental concern with the MU incentive program is that the program requires physician use of technological standards that are not well-tested and require increased health data exchange, which remains a challenge today due to the lack of health information exchanges.

The AMA supports the use of health IT in a manner that best supports medical practice efficiencies and enables physicians to provide better care to their patients. Just like other consumers of information technology, physicians embrace technology when it allows them to be more efficient and productive when providing services. Physicians are eager to access information where and when they need it. This is evidenced by increased physician use of computer tablets and personal digital assistants (PDAs). One of the most compelling reasons for physicians to use EHRs and other health IT tools is their ability to exchange data with other health care providers in order to improve the continuity and quality of patient care.

While the AMA recognizes that there are increasing efforts to further data exchanges throughout the country and that setting standards will help promote health information exchange efforts, the reality is that the vast majority of physicians today are not in a position to exchange data, because the underlying infrastructure for exchanging data is spotty at best. Unfortunately, requiring EHR certification standards to facilitate information exchange to support the MU objectives and measures is not enough to overcome the current data exchange challenges. **We urge ONC to focus its resources on ensuring the development and availability of secure, meaningful health information exchanges throughout the country.**

Patient Safety

As discussed in the proposed rule, the Institute of Medicine (IOM) has studied patient safety issues involving use of health IT at the request of ONC. In the IOM's 2011 report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, concerns were raised about patient safety and health IT use.[1]

> Usability represents an exceptionally important issue overall, and undoubtedly affects safety. However, it would be challenging to mandate usability. While some efforts are beginning to develop usability standards and tools…more publicly available data about and testing regarding usability would be helpful in this area. EHRs should increasingly use standards and conformance testing to ensure that data from EHRs meet certain standards and would be readable by other systems to enable interoperability is practical. Besides providing feedback to vendors about their products, users also have important responsibilities for safety during the preimplementation phase. Users need to make the often difficult and nuanced decision of choosing a product to purchase…. If a product does not meet the needs of the organization and does not appropriately interface with other IT products of the organization, safety problems can arise. Similarly, organizations need to be ready to adopt a new product in order for the transition to be successful.[2]

The IOM Committee tasked by ONC with reviewing the potential patient safety risks associated with health IT use indicated that "some case reports suggest that poorly designed health IT can create new

[1] http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.asp.
[2] Id.

hazards in the already complex delivery of care."[3] The report further detailed features necessary for improving the design and development of EHR technology.

The AMA appreciates that ONC has recognized the importance of the findings by the IOM, as well as concerns raised during a hearing and subsequent letter from the Health IT Policy Committee to ONC on the usability and patient safety issues associated with EHR use. ONC's requirement that health IT vendors apply "user-centered design" (UCD) to certain areas of EHRs in order to focus more attention on concerns involving EHR use and patient safety is a step in the right direction. We provide more detailed comments on ONC's UCD proposal under the "General Usability Concerns" section of this comment letter.

It is also important to keep in mind that most research on health IT systems and patient safety has been limited to the hospital setting and there has been limited research on the impact of EHR use on patient safety in the ambulatory setting. More research is needed in the ambulatory setting to determine and monitor the effects of EHR use on patient safety, an issue, among others, that the AMA addressed in our March 1, 2012 letter to ONC and the Agency for Healthcare Research and Quality (AHRQ).[4] The AMA agrees with the IOM's recommendation that "current government programs, such as EHR product certification, can also be a path towards more effective usability and safer use of health IT products."[5] **The AMA looks forward to continuing to work collaboratively with the ONC, AHRQ, and vendors as well as other respective stakeholders to increase our understanding of safety risks associated with health IT use in the ambulatory setting, and use this knowledge to improve the safe design, implementation, and use of health IT systems.**

General Usability Concerns

As ONC's proposed rule notes, the International Organization for Standardization (ISO) has defined usability to mean "[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." There is a direct correlation between EHR adoption and the usability of an EHR. Physicians cite EHR usability as a key factor in their decision to purchase an EHR system. 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."

> Many problems with health IT relate to usability, implementation, and how software fits with clinical workflow…. Many health information systems used today provide poor support for the cognitive tasks and workflow of clinicians. This can lead to clinicians spending time unnecessarily identifying the most relevant data for clinical decision making, potentially selecting the wrong data, and missing important information that may increase patient safety risks. If the design of the software disrupts an efficient workflow or presents a cumbersome user interface, the potential for harm rises. Software design and its affect on workflow, as well as an effective user interface, are key determinants of usability.[6]

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[3] Id.
[4] http://www.ama-assn.org/resources/doc/washington/health-information-technology-patient-safety-letter-01march2012.pdf.
[5] http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx.
[6] Id.

EHRs should facilitate care coordination, practice efficiencies, and enhance processes that improve health outcomes. The usability of EHR products should also support decision-making, not circumvent the need for critical thinking. Both the AHRQ and the National Institute of Standards and Technology (NIST) have studied the issue of EHR usability and adoption rates. The May 2010, AHRQ report, *Electronic Health Record Usability Vendor Practices and Perspectives*, indicated that "[d]riving 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."[7]

The MU incentive program offers physicians an unprecedented opportunity to invest in and use EHRs. To date, ONC has certified over 1,700 EHR products. ONC's web site lists these certified products, but does not provide any information on their usability. While Regional Extension Centers (RECs) have been tasked with helping primary care physicians select an appropriate EHR product for their practices, we believe more information on certified EHR products needs to be made available so that physicians in any specialty can use this information to determine which EHR product(s) best meet their practice and specialty needs.

The AMA is also very concerned with the viability of the 1,700 certified products and the likelihood that not all of these products will be around for the long-term, which is a reality that the industry is already experiencing. Usability standards being included in the certification criteria will be critical for ensuring that physicians invest their resources in EHR products that work for them. In order to address usability concerns, **the AMA recommends that the Department of Health and Human Services (HHS): 1) collect data based on an EHR user (physician) satisfaction survey that can be included in the attestation phase of the MU program; 2) collect and disseminate survey results on usability experiences based on practice size, specialty type, and geographic location, and incorporate this feedback into future certification processes; 3) include usability and patient safety criteria into the certification process as discussed in the IOM report; and 4) promote innovation in EHR design that not only addresses patient safety and usability, but can be more seamlessly integrated into smaller practices that do not have the luxury of resources to completely redesign the way they work to accommodate the EHR.**

UCD

The AMA is pleased with ONC's proposal to prioritize eight areas (computerized provider order entry (CPOE), drug-drug and drug allergy checks, medication list, medication allergy list, clinical decision support, electronic medication administrative record, e-prescribing, and clinical information reconciliation) in the EHR certification process. This focus on UCD will help to shed more light on EHR usability and patient safety issues. According to NIST, "an established UCD process ensures that EHRs are efficient, effective, and satisfying to the user." **While requiring EHR vendors to apply UCD to these priority areas is a step in the right direction, we believe it falls short of what is needed to ensure patient safety is adequately addressed and that physicians are purchasing systems that perform in a manner that increases practice efficiencies and meets their particular practice workflow and care needs.**

EHRs have not traditionally focused on UCD, as evidenced by the findings in the aforementioned May 2010, AHRQ report on usability EHR vendor practices. It is our understanding that the UCD process will be left to the discretion of EHR vendors to implement. ONC indicates in the proposed

[7] http://healthit.ahrq.gov.

rule that, "valid and reliable usability measurements [already] exist, including those specified in NISTIR 7804 Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records." It is important to note that the NISTIR 7804 document further states:

> The purpose of this proposed usability protocol is to encourage user-centered development processes focused on safety by facilitating the design of EHR interfaces with good usability. The authors of this document seek to make EHRs safer by providing methods to measure and validate user performance prior to deployment. Moreover, the authors hope to encourage system developers to apply human factors best practices and incorporate user-centered design processes into the development and deployment of EHR systems. Such practices and processes have a proven record in industries such as aviation, military systems, transportation, and nuclear power.[8]

The NISTIR 7804 document outlines an EHR Usability Protocol or "EUP," a three-step process, which analyzes the overall EHR application's design, a review of the application by a team of clinical safety and usability experts, and validation testing to measure performance to ensure patient safety issues are not occurring. According to NIST, "It is our expectation that the potential for use errors can be identified and mitigated by using the EUP."[9] It is unclear to us why ONC has not elected to mandate that EHR vendors adhere to this complete process. In addition, we recommend that ONC publish the research findings of their Cognitive Strategic Health IT Advanced Research Project (SHARPC) grantee, University of Texas Health Science Center at Houston, on multiple vendor systems, which may have identified over 1,000 usability problems. **The AMA strongly urges ONC to: 1) apply the principles in the NISTIR 7804 to the entire EHR certification process; 2) seek industry feedback—including physician feedback—on what constitutes an appropriate level of risk as it relates to patient safety; 3) ensure that the ONC Authorized Testing and Certification Bodies (ATCBs) have the expertise to address UCD issues; 4) publish the results of each vendor's performance on the eight required areas of focus for the UCD; 5) name the "Customized Common Industry Format"[10] template for EHR testing as developed by NIST to be required for use by all EHR vendors that seek certification, and publish each vendor's results; and 6) immediately publish the research findings of the University of Texas Health Science Center at Houston under the SHARPC contract on vendor usability problems.**

Base EHR

The AMA supports ONC's proposed concept of a "Base EHR," whereby physicians who qualify for an exclusion(s) for certain objectives/measures under the MU incentive program, or who plan on "deferring" compliance with particular objectives/measures, would have increased flexibility to meet the MU measures with the use of certain types of EHRs. The "Base EHR" would include the "fundamental capabilities all providers would need to have" in addition to other technology needed to meet the clinical quality measures they intend to meet. **ONC should require EHR vendors in their marketing activities and materials to make it very clear what measures their EHR is capable of meeting AND not meeting since physicians who defer meeting particular measures may**

[8] http://www.nist.gov.
[9] http://www.nist.gov.
[10] (NISTIR 7742) Customized Common Industry Format Template for Electronic Health Record Usability Testing, Published: November 16, 2010, http://www.nist.gov.

ultimately need a certified EHR with the functionality to help them meet deferred objectives/measures at a later point.

Measure Calculation

The AMA is pleased that ONC has recognized the need to include certification criteria that require a certified EHR to automatically calculate the percentage-based measures. According to the proposed rule, a certified product would have to have the capability to: 1) automatically record numerators (complete and module EHRs); and 2) automatically calculate for each non-percentage based MU measure the numerator and denominator, and create a report including the numerator, denominator, and resulting percentage associated with each applicable MU measure (complete EHRs only). **While "automated measure calculation" suggests a simple process is required for physicians to calculate their data for meeting MU measures, the AMA strongly recommends that ONC explicitly require that EHRs enable the automatic creation of reports that indicate both percentage-based measures and non-percentage based measures.**

We also support ONC's proposal that calls for any EHRs presented for certification which contain functionalities that are not percentage-based to be capable of recording that a user had certain EHR technology capabilities enabled during the EHR reporting period in order to help a physician demonstrate MU. ONC is also proposing that these new requirements become effective for the 2014 Edition. **The AMA strongly recommends: 1) requiring the automated measure calculation reporting functions to be effective as soon as possible; and 2) that EHR vendors be required to provide free updates to physicians who are using systems certified under the current certification edition.**

ICD-9 and ICD-10

On April 9, 2012, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule that would delay, from October 1, 2013 to October 1, 2014, the compliance date for use of the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10). **Pursuant to CMS' proposal to delay the compliance date for ICD-10 to the last quarter of 2014, which falls within the first year of the second edition of the MU Certification (also known as the 2014 Edition), the AMA strongly urges ONC to adopt both ICD-9 and ICD-10 for encounter diagnoses and procedures for hospital EHRs and for diagnoses in the outpatient setting.**

Also, some proposed recommendations from the Health IT Standards Committee's Vocabulary and Clinical Operations Taskforce recommend only including SNOMED CT for encounter diagnosis and procedures. **The AMA strongly urges ONC to include a wider range of options including ICD and Current Procedural Terminology (CPT), in addition to SNOMED, otherwise this will force all users to adopt a vocabulary that is neither tested for its usability nor implemented as widely as other vocabularies like ICD and CPT. This approach will also give users the flexibility to record clinical data at the most appropriate level rather than forcing it to be very specific or be very general depending on their use case. Another major issue is that there are not many systems which are SNOMED CT compatible and transition to those systems will be very costly and resource intensive.** It is also important to note that the Clinical Operations Task Force is working on recommendations with the focus on quality measures even though these measures only constitute a component of a much larger initiative.

In the proposed rule, ONC references that certified EHRs in the hospital setting are expected to support ICD–10–PCS, and that certified EHRs in the outpatient setting are expected to comply with the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT–4). We agree and request that ONC make it clear in the final rule that CPT remains the Health Insurance Portability and Accountability Act (HIPAA) named code set for outpatient procedures.

Medication Lists

Having an up to date medication list is extremely important to physicians. The AMA believes that functionality requirements EHRs would need to meet including displaying medications, their source, and the last modification date, ability to merge or remove medications, and present a final set of merged medications for a physician to view and validate before confirming are important and necessary. We agree with ONC that "EHR technology's role is to be assistive and not to determine without human judgment which data elements should be reconciled."

Drug Formulary Checks

A case study reported in the January 2012, *Journal of the American Board of Family Medicine* indicated that the formulary and benefits information is complex and always changing which makes them difficult to rely on for drug selection.[11] Faced with this unreliability, many physicians reported that they have to rely on patients or pharmacists to notify them regarding medication costs or other health plan considerations in order to select an alternative medication.[12] **Given challenges still experienced with drug formulary checks, we urge ONC to ensure that physicians are able to obtain drug-formulary information that is accurate, in real-time, and includes the necessary details for the prescriber's review.**

Capturing Race, Ethnicity, and Preferred Language

The AMA supports ONC's proposal to include a method for EHRs to capture that a patient declined to specify race, ethnicity, and/or preferred language given that we have heard from physicians that some of their patients are not comfortable disclosing certain information or refuse to share this information with certain health care providers.

Amendments

The proposed rule requests comments on whether EHR technology should be required to be capable of appending patient supplied information in free text and scanned format. We recommend that certified EHRs be able to accommodate both formats. However, any modification to scanned text should be distinguishable from the original scanned text to support data integrity.

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[11] Jesse C. Crosson, PhD, Anthony J. Schueth, MS, Nicole Isaacson, PhD, MSS, and Douglas S. Bell, MD, PhD *Early Adopters of Electronic Prescribing Struggle to Make Meaningful Use of Formulary Checks and Medication History Documentation.* Journal of the American Board of Family Medicine. Available at: http://www.jabfm.org/content/25/1/24.full.pdf+html.
[12] Id.

Protecting Patient Information on End-User Devices

We also support ONC's proposal to have the certification standards focus more on promoting EHR technology design that secures electronic health information on end-user devices, thereby allowing greater security protections for information that is stored on or accessed by a device (e.g., mobile device used to access an EHR) given the number of security breaches being reported. **The AMA strongly urges ONC to work with CMS and the Office for Civil Rights (OCR) to develop a user friendly sample tool kit for physician practices that includes sample checklists, as well as other tools that physicians can implement in their practices to help them to safeguard patient data from security breaches.**

Program Integrity

> [S]omething has gone awry to create an environment that leaves well-intended physicians victimized when government audits reveal their software systems have allowed—even facilitated—submission of non-compliant and potentially fraudulent E/M services."[13]

The AMA supports ONC's proposal to require EHRs to record auditable events and create audit reports to better detect breaches. The AMA believes that the use of time-saving features, such as cloning, templates, macros, "cut and paste" or "pull forward technology," auto-population and identical language in EHRs, by themselves, are not an indication of inaccurate documentation or incorrect coding. While physicians are ultimately responsible for documenting and billing for the appropriate level of service based upon the medical necessity and care delivered, as the American Association of Professional Coders indicates, and we agree, "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."[14]

The AMA believes that an important part of the certification process of an EHR should include requirements that call for EHR vendors to run test scenarios to document that their coding recommendations are accurate based on discrete data that have been entered. An EHR 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.

Almost all EHR vendors use templates that are designed to help speed up practice workflow. The use of templates, per se, does not drive upcoding; however, 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 HHS and the Office of the Inspector General (OIG) have

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[13] S. Levinson, D. Grider, R. Linker, S. Thurston. The Perfect Storm. Medical Economics, April 2009.
[14] American Association of Professional Coders, "Key Flaws with CCHIT Criteria," Industry News, June 10th, 2009.

plans to audit physicians participating in the Medicare and Medicaid EHR MU incentive programs. OIG has detailed the following intentions in their 2012 Workplan:

> We will assess the extent to which CMS made potentially inappropriate payments for E/M services and the consistency of E/M medical review determinations. 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. Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service based upon the content of the service and have documentation to support the level of service reported.[15]

As we have detailed in our comments to the Health IT Certification and Adoption Workgroup,[16] it is critical that both management support and coding tools be clinically appropriate and compliant with established standards in CPT and E/M Documentation Guidelines. Coding recommendations should be based upon new conditions that have arisen since a patient's last visit, and decision and documentation supports should provide meaningful lists of likely symptoms and signs that should be included in the history and physical, which should minimize documentation of irrelevant services and reduce the risk of upcoding. We also believe more attention must be placed on cut-and-paste/pull forward functionality so that it does not facilitate a situation whereby a physician is not documenting their work appropriately. This issue surrounding cut and paste functionality involves both a need for better education and is an example of an EHR usability issue. The IOM raised this issue in their report referenced earlier, and, it is clear that Medicare is paying close attention to this issue. Medicare GBA, a contractor, posted the following notice on its web site:

> When documentation is worded exactly like previous entries, the documentation is referred to as cloned documentation. Whether the cloned documentation is handwritten, the result of pre-printed template, or use of Electronic Health Records, cloning of documentation will be considered misrepresentation of the medical necessity requirement for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made. It would not be expected that every patient had the same exact problem, symptoms, and required the exact same treatment. Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information for each unique patient. Documentation exactly the same from patient to patient is considered cloned and often occurs when services have a specific set of limited or select criteria. Cloned documentation lacks the patient specific information necessary to support services rendered to each individual patient.[17]

The AMA recommends that: 1) the certification process include, among the other certification criteria and usability standards, specific testing to ensure coding recommendations are consistent with coding guidelines and data entered; and 2) ONC work with the OIG, CMS, and the ATCBs to ensure that certified EHRs do not facilitate upcoding and are structured in such a manner to best support a physician's ability to document their work, and that this structure be built into the certification process.

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[15] http://oig.hhs.gov/reports-and-publications/archives/workplan/2012/wp01-mcare_a+b.pdf.
[16] http://www.ama-assn.org/resources/doc/hit/ama-ehr-usability-statement.pdf.
[17] http://www.palmettogba.com/palmetto/providers.nsf.

CPT Clinician and Consumer Friendly Descriptors

The proposed certification rule names CPT as the standard for the following three MU objectives and measures, among other standards a physician: 1) must provide patients with the ability to view online, download, and transmit their health information within four business days of the information being available to the eligible professional (EP); 2) who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care, should provide a summary of care record for each transition of care or referral; and 3) must provide clinical summaries for patients for each office visit. While the proposed rule does not specify CPT to be used just for the outpatient procedures, we presume this to be ONC's intention and request that the final rule provide such clarity. **The AMA supports ONC naming CPT as among the standards used for these objectives and measures in the final certification rule.**

In addition to the CPT descriptors used for representing procedures in the outpatient setting, CPT also develops and maintains consumer friendly and clinician descriptors which can support several of the MU objectives. An example of a CPT consumer-friendly descriptor, which could be used for providing patients with access to their information as well as providing them with reminders for preventive follow-up care, is CPT code 30130 which represents "Excision inferior turbinate, partial or complete, any method" which had been translated to "Removal of nasal air passage" for the purposes of providing a plain English description for consumer use. An example of a clinician descriptor, which can be used for clinical summaries and transitions of care documentation, is CPT code 30130, "Excision inferior turbinate, partial or complete, any method" would be translated to read as "Partial Excision of Inferior Turbinate" and "Complete Excision of Inferior Turbinate." Vendors are already extremely familiar with the CPT and incorporating these new descriptors would be welcomed by vendors and would not result in significant changes to existing systems as they are already using CPT for representing procedures. Furthermore, most products on the market today do not include a functionality for using SNOMED. In addition, these additional CPT descriptors will be available as part of the CPT code set to all CPT licensees at no additional costs. **Therefore, the AMA strongly recommends that ONC recognize the use of CPT clinician-and consumer-friendly descriptors, along with the CPT code set, to support the use of the MU objectives/measures referenced above in addition to SNOMED.**

EHR Certification Criteria for Clinical Quality Measures (CQM)

Creation, incorporation, and transmission of summary of care records

The AMA agrees that data elements for summaries of care records should be created and incorporated into EHR Certification Criteria for CQM. The proposed data elements capture information about the patient and their care necessary to ensure care is not fragmented, duplicative, or delayed. However, there is no guarantee in the present health care system environment that care will be continuous and seamless, unless EHRs are integrated and fully interoperable to support the ability to pull down patient information when needed. Therefore, the ability to meet certification requirements around summaries of care records will be limited to those providers who are in systems capable of sending and receiving secure, interoperable transmissions.

Alternative data capture certification options considered

The AMA agrees that use of the Quality Data Model (QDM) is a good first step in aligning CQM and EHRs to a defined set of data elements. EHRs should align their data systems to use the

QDM in its current state. Efforts should also be made to align the QDM with the other standards used with CQMs and EHRs. **To help facilitate this harmonization, we recommend that an expert panel, comprised of vendors and providers, be convened to further review the QDM to determine if the model should be taken forward as a recognized standard.**

In addition, regardless if the QDM is the standard approach for how quality measures are made ready for electronic capture, an inventory listing all of the data elements required for quality measure reporting should be developed and published by CMS. This inventory of data elements would be valuable information for implementers, including vendors and end users. Moreover, this work should be aligned with the agency's quality measurement work related to the Medicare Physician Quality Reporting System (PQRS) EHR reporting option.

It is also important to note that certification of individual data elements is burdensome and exhaustive. If determined as the viable long term solution, the QDM should provide a framework for certification of other clinical quality related data elements. This framework must be flexible and adaptive to keep pace with the rapidly changing health information technology enterprise.

Explicit certification criteria

In the proposed rule on the Stage 2 CQMs, CMS proposes that EHR Technology, certified by the ONC, will be required to report CQMs. Reporting methods may include attestation, reporting under the PQRS EHR reporting option, the group reporting options for EPs, the aggregate portal-based reporting methods, and the finalized reporting method for eligible hospitals and critical access hospitals (CAHs). In addition, for attestation and the aggregate portal-based reporting methods for EPs, eligible hospitals and CAHs, Certified EHR Technology must be certified to "incorporate and calculate"for each individual CQM that an EP, eligible hospital or CAH submits. EPs, eligible hospitals, and CAHs must only submit CQMs that their Certified EHR Technology is explicitly certified to calculate in order to meet the MU requirement for reporting CQMs.

The AMA is concerned that this certification requirement places the onus on EPs to determine which combination of CQMs and CQM domains a particular EHR Technology is certified to capture. The MU program is quickly expanding, making it too difficult, burdensome, and expensive for EPs to determine independently what product is "certified" and for what measures. Therefore, **CMS should ensure that EPs are not penalized if it is later determined that a vendor has not met the certification requirement, especially if the EP is making a good faith effort to report CQMs under the MU program. If an existing EHR is determined to be non-certified, this means an EP would be required to purchase additional certified modules, and their use would require onerous modifications to an EP's workflow. This burden and expense should not fall on the EPs, and we urge CMS to ensure this does not occur. The AMA also urges CMS to provide an exemption for EPs from the CQM requirements until measures have been tested and vendors have shown they have met the certification requirements for the specific EHR Technology being utilized by an EP.**

In addition, the AMA believes CQM exceptions provide actionable information for patient care and are important to quality measurement. Therefore, we encourage CMS to include the reporting of measure exceptions and mechanisms to do so, in addition to overall performance rates of CQMs, in the Stage 2 CQM certification criteria requirements.

The AMA continues to explore an approach to quality measure exceptions that will ensure exceptions are collected as part of the clinical workflow and can be queried for automated quality reporting. In March 2012, the AMA-convened Physician Consortium for Performance Improvement (PCPI) held a day-long multi-stakeholder meeting to evaluate options for specifying, documenting, and reporting quality measure exceptions within EHRs. CMS and ONC participated in these discussions, along with other major stakeholders, including the National Quality Forum, EHR vendors, performance measure methodologists, and specialty society representatives. Participants in these discussions plan to formalize recommendations regarding the electronic capture of CQM exclusions later this year. In the meantime, exceptions will continue to have a place in quality measures developed by measure developers.

2014 Readiness of EHR systems

In evaluating the use of the QDM, ONC must also assess the readiness of EHR systems to capture the necessary elements of the proposed CQM requirements for Stage 2. **The AMA recommends ONC work with the vendor community to accurately assess whether EHR systems are "2014-EHR-ready," before requiring providers to adopt and implement new health information technology systems and modules for Stage 2.** Much innovation is ongoing and necessary in the EHR vendor community in order to adequately respond to the technological demands of accurately and meaningfully capturing electronic clinical data to help improve patient care.

In addition, the AMA believes a standard that allows all CQM data to be named should be developed. Specifically, if a standard is not yet available that has been fully tested, we do not believe it should be a requirement of Stage 2.

Calculation and testing of CQMs

We agree and support that Certified EHR Technology should be capable of accurately calculating each CQM that it offers to users. The AMA recommends that test data sets be created for each measure and include the clinical coding for the measure. These data sets must also be accompanied by an answer key. Use of test data sets will ensure uniform measure calculation regardless of practice site or EHR technology. Testing of CQMs, using a data set, must demonstrate absolute feasibility before they are finalized for the 2014 program. Lack of this type of testing for Stage 1 CQMs caused significant difficulties for EPs trying to successful attest.

Finally, the reporting file used to test CQMs should include the ability to report results for all of the various measure criterion including numerators, denominators, exclusions, and exceptions. Exception rates should be reported with performance rates; if raw data is submitted to CMS for measure calculation, then the data that support the exceptions should also be reported when transmitting patient data. The XML file format should also be a valid standard that has been tested for accuracy and completeness.

Contractual Concerns

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

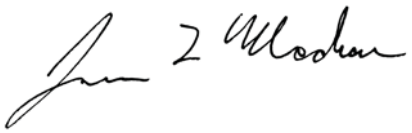
hold harmless and confidentiality agreements by EHR vendors that would shift liability to clinicians for non-user problems such as system or software failures or inadequacies and safety issues. The IOM also raised this concern in their report:

> Another impediment to gathering safety data is contractual barriers (e.g., nondisclosure, confidentiality clauses) that can prevent users from sharing information about health IT–related adverse events. These barriers limit users' abilities to share knowledge of risk-prone user interfaces, for instance through screenshots and descriptions of potentially unsafe processes. In addition, some vendors include language in their sales contracts and escape responsibility for errors or defects in their software (i.e., "hold harmless clauses"). The committee believes these types of **contractual restrictions limit transparency, which significantly contributes to the gaps in knowledge of health IT–related patient safety risks.** These barriers to generating evidence pose unacceptable risks to safety.[18]

The IOM report also called on ONC to develop model contract language to ensure physicians are able to report safety concerns related to EHR use. And, they recommended that the RECs could be used to help educate physicians about what to look for in an EHR contract before signing it to ensure provisions that preclude them from reporting patient safety issues are not included. These are two recommendations we support. **We also refer you to our March 1, 2012 letter to ONC that details our recommendations on the voluntary, confidential reporting of patient safety events through Patient Safety Organizations (PSOs), and the need to further examine vendor contracts that include certain types of hold harmless and nondisclosure clauses, which pose challenges for physicians.[19]**

To ensure widespread adoption and implementation of EHR technology by physicians, the EHR standards and certification criteria should enable physicians to successfully participate in the MU program and use EHRs in a way that improves quality of care delivery, enhances patient safety, and supports practice efficiencies. We appreciate the opportunity to share our comments with you. Should you have questions or require additional clarification about these comments, they may be directed to Mari Savickis, Assistant Director, Division of Federal Affairs, at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,



James L. Madara, MD

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[18] http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx.

[19] http://www.ama-assn.org/resources/doc/washington/health-information-technology-patient-safety-letter-01march2012.pdf.