TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

May 7, 2012

Kathleen Sebelius
Secretary, Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2014 Edition EHR Standards and Certification Criteria and Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW.
Washington, DC 20201

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

Dear Secretary Sebelius,

The Texas Medical Association ("TMA") is a private, voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medical specialization.

On behalf of our more than 45,000 member physicians, the Texas Medical Association (TMA) appreciates this opportunity to review and offer comments on the above referenced proposed revisions to the EHR Certification Program. The following comment is offered.

Overarching Comments

Comment: TMA is concerned that CMS and ONC have not provided sufficient time for vendors and physician/hospitals to incorporate Stage 2 requirement into EHRs safely.

Rationale: Assuming that a final rule is issued in the fall of 2012, our experience is that vendors need about 18 months to put the requirements into their systems and to get them certified. Physicians and hospitals then need time to fit these into their budget cycles and obtain vendor support for upgrades. At least a year must be allowed after vendor release for this process. This totals over two years from the time of issuance of the final rule, which makes January 2015 the earliest that Stage 2 could be required for ambulatory EHRs.

Comment: Certified EHRs should be required to integrate the "Blue Button" so that there is a single standardized way for physicians to provide information to their patients and a single concept that can be communicated to patients.

Rationale: The Veteran's Affairs (VA) has effectively integrated the Blue Button into their EHR, Vista. The Blue Button essentially is a way for patients to download their data from their personal health record. It gives patients access to their relevant health information, and allows patients to share their information with those they trust.

Comment: Physicians need a single place to report EHR vendor problems that negatively impact patient safety without fear of vendor retaliation.

Rationale: Patients can be harmed due to EHR problems. When physicians find these problems, they often have no way of knowing if it is something within their EHR specifically, or common to other users of that product. By having a reporting and tracking mechanism that is designated as the sole place to report such issues, industry can quickly be made aware of and respond to such issues. This mechanism also holds EHR vendors responsible for quickly addressing issues that need immediate attention. We know of a proposal for such a reporting system that was made to AHRQ in 2006, but insufficient action has been taken towards creating a reporting system and the risks increase daily. While ONC proposes some initial steps towards capturing safety events on page 13843, TMA feels that these are inadequate and that the process of reporting events to multiple PSOs risks losing the ability to aggregate data nationally.

Specific Comments

Page 13834
ONC proposes "to require that test results used for certification of EHR technology be available to the public…."

Comment: TMA agrees with this criterion. Some of our members have experienced situations where vendor have passed certification but their product does not seem to work as certified. Having the certification information would help physicians and hospitals understand how this situation could exist.

NEW CERTIFICATION CRITERIA

Page 13838
MU Objective: Record electronic notes in patient records.
2014 Edition EHR Certification Criterion: § 170.314(a)(9) (Electronic notes)

Comment: TMA agrees with this criterion.

Page 13838
MU Objective: Imaging results and information are accessible through Certified EHR Technology.

2014 Edition EHR Certification Criterion: § 170.314(a)(12) (Imaging)

> **Comment:** TMA agrees with this criterion for inpatient EHRs linked to inpatient radiology systems in the same hospital. For ambulatory EHRs, image and report interfaces are not yet standardized to where all radiology system vendors are using the same interface so that physicians do not require a separate interface for each system.

Page 13838
MU Objective: Record patient family health history as structured data.
2014 Edition EHR Certification Criterion: § 170.314(a)(13) (Family health history)

> **Comment:** TMA agrees with this criterion, but there doubts that there are sufficiently robust standards to require this for inpatient or ambulatory EHRs at this time. We are not aware of widespread adoption of the HL7 Pedigree Standard and are concerned that there is not enough time for EHR vendors to put this into place before Stage 2 requirements need to be met. The Surgeon General's tool is interesting but has not been widely adopted.

Page 13838
MU Objective: Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion: § 170.314(d)(4) (Amendments)

> **Comment:** In general, TMA agrees with this criterion but recommends that ONC should have robust standards for how patient information is appended to EHRs before allowing vendors to create multiple versions of this workflow.

Page 13842
2014 Edition EHR Certification Criterion: § 170.314(g)(4) (Safety-enhanced design)

> **Comment:** TMA strongly agrees that this additional criterion should be added.
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> > **Rationale:** TMA believes that lack of adherence to established guidelines, principles and best practices for the safe development of health IT software is a significant avoidable risk to safe patient care. Therefore, TMA strongly agrees with requiring EHR vendors to follow well-established processes and guidelines for User-Centered Design (UCD). Comparative third-party evaluations of UCD could be valuable to physicians when selecting EHRs if bias could be avoided or managed, which may be difficult. It would be more valuable to ensure vendors embed established UCD processes into their product development life cycle through ONC requirements as proposed. Third-party UCD evaluations might be a better fit if done through the already established EHR certification process. ONC provided a Sharp-C grant to the University of Texas School of Biomedical Informatics in Houston to assess and test usability of EHRs. This program was not mandated for EHR vendors, however, and most choose not to participate.

Page 13839
§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

Comment: The "patient accessible log" referred to needs to have more specificity regarding the definition of auditable events. For example, "user identification" could be interpreted by EHR vendors as the user's mnemonic (mmurr01). However, if Meaningful Use dictates user identification include the users first and last name, the EHR's automated log will not allow the EP to meet the requirement. This would force the EP to use additional time and resources to customize the EHR product's automated report which is an additional burden.

Rationale: This unintended burden could be avoided if the required elements of automated reports are adequately specified for the EHR vendors so that the reports do not have to be customized at the physician's expense.

Page 13841
2014 Edition EHR Certification Criterion: § 170.314(g)(1) (Automated numerator recording)

Comment: TMA agrees with this criterion.

Page 13841
2014 Edition EHR Certification Criterion: § 170.314(e)(1)
Standard § 170.207(m) Use of ICD-10

Comment: TMA strongly recommends that for encounter diagnoses and procedures ICD-9 should be permitted. ICD-10 should not be required as it may be further delayed or skipped altogether. SNOMED should be considered as an alternative, with background translation into the appropriate ICD coding.

Page 13845
MU Objective: Provide structured electronic laboratory results to eligible professionals.
2014 Edition EHR Certification Criterion: § 170.314(b)(6) (Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers)
Standards and Implementation Specifications: § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

Comment: TMA agrees with this criterion.

REVISED CERTIFICATION CRITERIA

Page 13846
MU Objective: Implement drug-drug and drug-allergy interaction checks.
2014 Edition EHR Certification Criterion: § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks)

Comment: TMA agrees with this criterion. However, TMA is concerned that EHR vendors may interpret this section to prohibit physicians in small practices from tailoring alerts to fit their practice. Alert fatigue is a well-known problem. If the criteria "eliminate the ability for EHR technology to permit users to adjust drug-allergy interaction checks"

we are concerned that the net effect will be a decrease in safety through alert fatigue rather than an increase.

Page 13846
MU Objective: Record the following demographics: preferred language; gender; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.
2014 Edition EHR Certification Criterion: § 170.314(a)(3) (Demographics)
Standards: § 170.207(f)(OMB standards); § 170.207(j) (ISO 639–1:2002); and § 170.207(k) (ICD–10–CM)

Comment: TMA agrees with this criterion. However, TMA cautions ONC to consider the impact on workflow of recording "preliminary cause of death" as a physician is frequently not present at the time of death. There is no patient benefit from capturing this information (the patient is dead) and so the cost-benefit of collecting this information is questionable at best.

Page 13846
MU Objective: Maintain an up-to-date problem list of current and active diagnoses.
2014 Edition EHR Certification Criterion: § 170.314(a)(5) (Problem list)
Standards: § 170.207(a)(3) (SNOMED CT® International Release January 2012)

Comment: Paper-based problem lists are notoriously difficult to keep up-to-date because they require manual intervention by clinicians. As a result, TMA believes that the trustworthiness and value of paper problem lists for patient care is low.

Rationale: Electronic problem lists promise to add value to patient care if the manual intervention can be eliminated. EHRs today typically allow clinicians to manually enter the problems as they can on paper, but may also provide automation by capturing problems through ICD-9 codes and automatically adding them to the Problem List (where they can then be manually modified if necessary). Some EHRs provide other functionalities that further improve the usability of electronic problem lists. Some EHRs currently do not use SNOMED codes for their problem lists today as this proposed rule will require.

In order to promote trustworthy and valuable electronic problem lists, EHR products should be specifically required to map ICD-10 codes to SNOMED CT codes. The work flow for physicians using EHRs today commonly involves the physician entering diagnosis codes during charge entry. If the physician chooses, the EHR product should be required to automatically enter those diagnoses into the electronic problem list so that physicians do not have to manually re-enter the same problem into a second part of the EHR. Accordingly, if an EHR uses ICD-10 codes for charge entry, the EHR should automatically map the codes to the appropriate SNOMED CT code or assist the physician with selecting the best code. Physicians could then modify the automated list and add or delete problems. EHR vendors can decide which codes to present to physicians so long as they do not require physicians to manually enter the same diagnoses two different times.

It is doubtful whether vendors and users can comply in Stage 2 with a requirement to have SNOMED as the sole standard for recording problems in a problem list. Also, TMA questions the logic of ONC requiring the use of SNOMED for problems (which we prefer) at exactly the same time that CMS is requiring the use of ICD-10.

Page 13847
MU Objective: Use clinical decision support to improve performance on high-priority health conditions.
2014 Edition EHR Certification Criterion: § 170.314(a)(8) (Clinical decision support)
Standard: § 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (''Infobutton'') Standard, International Normative Edition 2010)

Comment: TMA agrees with this criterion. However, ONC should permit vendors to offer the Infobutton as an optional addition for EHRs for those physicians who do not need it in their practice (e.g., a pediatrician who is not eligible for Meaningful Use). Physicians may have other ways to meet this objective if they are not part of the Meaningful Use program and should not be saddled with a technology that they do not want to use.

Page 13848
MU Objective: Use clinically relevant information from Certified EHR Technology to identify patient specific education resources and provide those resources to the patient.
2014 Edition EHR Certification Criterion: § 170.314(a)(16) (Patient-specific education resources)
Standard: § 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010)

Comment: TMA agrees with this criterion with the same cautions as above.

Page 13848
MU Objective: The EP, EH, or CAH who transitions their patient …. Should provide summary care record for each transition of care or referral
2014 Edition EHR Certification Criterion: § 170.314(b)(1) and (2) Incorporate summary of care record and create and transmit summary of care record

Comment: TMA agrees with this criterion, but cautions ONC that a proliferation of methodologies across vendors for incorporation of summary care records into EHRs is inherently dangerous. TMA physicians have seen multiple methods of incorporation and some have inherent safety risks (e.g., creating a situation where a patient is both allergic and not allergic to a medicine). Standards for incorporation of summary of care records should be adopted and required.

TMA is also concerned about ONC's referral to a "care plan" in the summary of care record. There is no standard for this at this time that we are aware of, and this is likely to cause significant confusion in patient care as each vendor interprets this requirement differently.

Finally, TMA recommends that ONC carefully define of "transition of care". This could be interpreted to mean movement from one location of a hospital to another or even the transition from one attending physician to another.

Page 13849
MU Objective: The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.
2014 Edition EHR Certification Criterion: § 170.314(b)(4) (Clinical information reconciliation)

Comment: TMA agrees with this criterion. Using EHR technology to perform demographic matching and verification between data sources when those sources are being merged would reduce the risk of patient harm that can arise when data from another patient is inadvertently merged into a patient's record.

Page 13849
MU Objective Incorporate clinical laboratory test results into Certified EHR Technology as structured data.
2014 Edition EHR Certification Criterion: § 170.314(b)(5) (Incorporate laboratory tests and values/results)
Standards and Implementation Specifications: § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

Comment: From the EP perspective, it should be "doable" for EHRs to capture the number of results that are expected for each type of test ordered. For example, when EP orders "Lytes II", the EHR product should be configured in such a way that this individual order is linked to five discrete results: Na, K, Cl, CO2, Glucose. The EHR should include a configurable attribute for each lab order that links the number of expected results to each order. One Lytes II order would be linked to 5 expected results. This built-in attribute will enable a report to create a 1:1 ratio of "#orders **:** #results" even if panel orders are entered. An EHR product would ideally include this as a standard report.

Page 13850
MU Objective: N/A
2014 Edition EHR Certification Criteria: § 170.314(c)(1) (Clinical quality measures— capture and export) § 170.314(c)(2) (Clinical quality measures— incorporate and calculate) § 170.314(c)(3) (Clinical quality measures— reporting)
Standard: § 170.204(c) (NQF Quality Data Model)

Comment: TMA strongly agrees with this criterion. Something to avoid would be an EHR product that requires all of the CQM data elements to be captured, thus creating an overly cumbersome documentation template. TMA, therefore, believes that this criterion should be clarified to state that the EHR must be able to capture all of these elements, but that the user will be able to determine which ones will be incorporated into their documentation templates.

Page 13858
MU Objective: Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.
2014 Edition EHR Certification Criterion: § 170.314(a)(4) (Vital signs, body mass index, and growth charts)

Comment: TMA believes that the criterion to plot and display growth charts should be required, not optional, and should be specified in more detail.

Rationale: While it may be true that "some EPs, EHs, and CAHs would not (or would never) use such a capability due to scope of practice or other reasons," there are still compelling reasons to make this criterion required.

First, each of the 17 MU Core Objectives that physicians are required to meet should have a corresponding 2014 EHR Certification Criteria to ensure certified base EHRs have the necessary capability. One of the 2014 required MU core objectives is to plot and display growth charts. Since this is a requirement, then the base EHR should, likewise, be required to support that functionality. This situation is different than objectives that are on a menu set or to CQM measures from which physicians may select. As this NPRM states on page 13865, EHRs will not be required to demonstrate an ability to capture data for all of these CQM measures, but instead will be required demonstrate the ability to capture data only for § 170.314(c)(1) and (2). The rule goes on to explain that it expects EHR developers to develop EHRs that incorporate functionality to support additional CQMs that would be needed by the providers to which they are marketing their EHRs. As the rule discusses, there is a potential for this strategy to leave a void in the market for EHR technology to support certain CQMs. Even if such a void existed for a particular CQM, though, physicians could still achieve MU by selecting different CQMs that their EHR does support. On the other hand, if there is a void in the market for functionality that is needed to demonstrate a required MU objective, the physician will be penalized if their certified base EHR does not provide this capability. To avoid this situation, either this MU objective should be placed in the menu set as an optional objective, or this functionality must be a requirement for base EHRs to provide.

Second, nearly a third of outpatient primary care EP visits are children under 18 years of age, all of whom should have growth parameters plotted and displayed as a part of assessing growth and development. Base EHRs should, therefore, be required to provide capabilities to adequately manage such a large percentage of primary care visits. It would seem inconsistent to have MU objectives that apply to smaller patient populations have corresponding capabilities that are required, such as the ability to transmit data to a registry for cancer patients.

Third, it is unfortunate that while some EHR vendors have declared an ability to display growth charts, their charts do not meet the specifications for standard growth charts established by the CDC. The CDC released a revised version of

growth charts in 2000, called the 2000 CDC Growth Charts, which are based on statistical and graphical measures. A CDC standard growth charts display the 5th, 10th, 25th, 50th, 75th, 90th and 95th percentiles (seven lines). These are required for the purpose of assessing growth and development. If an EHR displays a growth chart with only 5 lines (10th and 90th percentile limits), it will not adequately assist with the clinical assessment of healthy growth and development. To avoid this potential problem, the proposed rule should specify that growth charts must meet the specifications provided by the CDC.

Page 13871
We are interested in whether commenters believe that the 2014 Edition EHR certification criterion for ''accounting of disclosures'' should be revised to be a mandatory certification criterion.

Comment: TMA believes that this criterion should be mandatory, not optional, and revised to include capabilities that would more fully support an EP's, EH's, and CAH's ability to comply with the current HIPAA Privacy Rule accounting for disclosure requirements

Page 13872
Data Portability

1. Is EHR technology capable of electronically providing a sufficient amount of a patient's health history using summary of care records formatted according to the Consolidated CDA for the scenario described above?

Comment: TMA believes that all of the data needs to be accessible to preserve the legal Medical Record (see below). It would be very helpful to require EHR products to, at least, require the summary of care records to be portable between vendor products.

Rationale: EHR products should be able to convert discrete summary-of-care data from one EHR to another. For example, summary of care data that is included in the important "clinical lists" of one EHR product (the allergy list, medication list, problem list and diagnoses list) should be able to be converted onto the corresponding clinical lists of another EHR. EHR vendors should be required to be able to convert lab data and reports from one EHR to the corresponding lab result and report sections of other EHRs.

Comment: CMS and ONC should consider that when physicians are forced to transition to another EHR, the data migration is very expensive and is cost prohibitive for small practices.

For example, a physician in Texas was recently forced to change EHRs because a major vendor was sunsetting the product this physician had purchased only 9 months before. The new product that the vendor recommended (a different version of their offerings) cost twice as much as the product initially purchased. Because of the price difference, the physician shopped around and decided to switch to another company. The cost for the physician to migrate only 9 months of patient data was $12,000. One possible solution to this problem would be to require vendors to tag key data element that would typically be

moved in an EHR transition with standardized XML. Vendors would also need to be able to receive and process data feeds with this standardized XML, storing it in their native tables. This process is used for the CCD/CCR but on a limited scale. This process would also assist with transfers of Meaningful Use data to HIEs that are not part of the current CCD/CCR, such as smoking cessation.

2. Is all of the data in a provider's EHR #1 necessary to migrate over to EHR #2 in the event the provider wants to switch? We recognize that medical record retention laws affect the provider's overall approach in terms of a full archived data set, but our question seeks to determine whether the loss of some data would be tolerable and if so, which data?

   Comment: Yes. TMA cannot think of any patient data or EHR logs that would not need to be retained and retrievable in order to both comply with state law and provide quality patient care. Some older EHR logs may not need to be retained, such as access logs longer than 10 years old (this time period depends on state and federal law as well as contracts with insurance companies), but it would be easier to retain all log data rather than trying to set retention times for each type of log.

   > **Rationale:** A different way to think about this issue is from the perspective of the legal medical record. Physicians are required to retain the legal medical record for a period of time as required by federal and state laws. If a medical record is requested for legal purposes, the EHR must be able to produce the legal medical record. This same legal medical record is what physicians must be able to retrieve even if they change EHR products. Although this record would ideally be incorporated into the new EHR, this is not currently a functionality EHRs provide and concern exists over whether EHR vendors would view it as a feasible capability by 2014. However, the legal medical record as produced by the EHR product must be able to be stored in an electronic format that the physician would be able to retrieve and exchange even if they do not use that EHR product anymore.

3. Considering the standards we have adopted and propose for adoption in this rule, we request comment on what additional standards and guidance would be necessary to meet these market needs for data portability, including the portability of administrative data such as Medicare and Medicaid eligibility and claims. Additionally, we are interested in commenters' thoughts related to an incremental approach where a specific set of patient data could be used as a foundation to improve data portability for the situation described above as well as other situations.

   Comment: TMA believes that HHS should require EHR vendors to provide "clinical continuity plans" to reduce patient safety risks that are inherent to EHR downtime or disasters when patient data becomes inaccessible.

   > **Rationale:** Most businesses are familiar with the concept of "business continuity planning" which is the development of processes and procedures that enable the business to maintain operations during technical downtimes or disasters. EHRs, likewise, should enable clinical continuity through processes and procedures that allow physicians to access a summary care record for any of their patients even when the EHR is inaccessible such as during planned or unplanned downtimes,

internet outages and disasters. For example, if the ambulatory EHR automatically stored a summary care record every night onto a stand-alone computer in the physician's office, then when an unplanned downtime occurs in the middle of a work day, the physician will at least have access to summary care record for patients they are actively seeing. An alternative method to mitigate clinical risk would be to have the summary care record stored every night on a server separate from the EHR that the physician can access online even if their EHR is inaccessible. This strategy reduces risk but relies on the Internet being available, unlike the first strategy which could utilize a stand-alone PC.

Page 13872
EHR Technology Price Transparency

Comment: TMA believes that EHR vendors should provide price transparency when providing information to a buyer of EHR products. TMA recognizes that there are many variables that go into pricing including size of practice, needs of practice, specialty needs, etc… which may make providing pricing information difficult on the ONC-ACB site. ONC should require that when physicians make inquiries of EHRs, the vendor must disclose all that is required to get started and for add on modules that are available. Training price should be included. Many EHR vendors charge almost as much for training as they do the EHR product. If a physician is informed of this price difference after signing a contract, there is potential for a practice to reduce the training to a minimal due to cost limitations. The success of EHR implementation many times pivots on the staff and physician training. Therefore, knowledge of training costs is vital.

Thank you for the opportunity to comment on the proposed rule. Should you have any additional questions or need any further information, please do not hesitate to contact us, Shannon Moore, 512-370-1411, or Jeff Gdula, 512-370-1344, Texas Medical Association.

Sincerely,

Joseph H. Schneider, MD, MBA
Chair, *ad hoc* Committee on Health Information Technology