



Michael D. Maves, MD, MBA, Executive Vice President, CEO

March 15, 2010

David Blumenthal, MD  
National Coordinator  
Health Information Technology  
Office of the National Coordinator  
for Health Information Technology  
Attention: HITECH Initial Set Interim Final Rule  
Hubert H. Humphrey Building, Suite 729D  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: RIN 0991–AB58; Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology**

Dear Dr. Blumenthal:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Department of Health and Human Services' (HHS) interim final rule (IFR) on an initial set of standards, implementation specifications, and certification criteria for electronic health records (EHRs). The AMA recognizes that an initial set of EHR standards, implementation specifications, and certification criteria are required to ensure that certified EHR technology is capable of supporting the achievement of meaningful use by physicians and other eligible professionals (EPs), as specified under the Medicare and Medicaid EHR incentive programs, beginning in 2011. Not only must EHR technology be "certified" to meet the meaningful use incentive requirements, but EHRs must also adequately meet a practice's specific workflow and clinical needs. **To encourage widespread adoption and use of EHRs, complete EHRs<sup>i</sup> and EHR modules<sup>ii</sup> must be deemed capable of performing the functions required by the Centers for Medicare & Medicaid Services (CMS) so that EPs can qualify for incentives authorized under the "American Recovery and Reinvestment Act of 2009" (ARRA).** Physicians should also be able to determine whether the product they are purchasing will meet their practice workflow and administrative needs—two critical aspects that the Office for the National Coordinator's (ONC) proposed certification process should, but currently does not, address. Physicians will also require sufficient time and technical resources to successfully choose, purchase, and implement EHR systems into their practices prior to the start date of these incentive programs.

## **EHR Products Should Support Physician Workflow**

We believe that Congress' intent for requiring physicians to use a "certified" EHR product was not only to ensure the success of billions of federal health care dollars being invested in health IT use, but also to provide assurances to physicians that the EHR products they are purchasing meet the Medicare and Medicaid meaningful use incentive requirements. In addition, it is important that EHRs do not unduly create an increased risk of improper coding. To date, many EHR products meet some or all of the Certification Commission for Health Information Technology (CCHIT) certification criteria, but do not include appropriate safeguards to prevent inadvertent coding errors. The certification criteria should be revised to address this critical issue, otherwise EHR adoption rates will be significantly hampered.

Physicians should be permitted to select the technology of their choice that best meets their practice needs and workflow in order to meet the definition of meaningful user. This will afford the greatest flexibility for physicians and presents a more inclusive approach for participation while furthering the intended goal of improving patient safety and coordination of care. Attention should be placed on how the technology can be incorporated into existing workflows to improve the delivery of health care services at the point of care. For example, the technology needs of a traditional office-based physician practice could vary from those who practice remotely and/or do not practice in a traditional office-based setting (e.g., physicians who treat patients in their homes need to use mobile technology). Facilitating care coordination, improved quality of care, and greater health care efficiency will require that all physicians, including those who typically have direct or indirect contact with the patient, have access to a patient's information when and where they need it. For example, all physicians, including hospital-based physicians (e.g., anesthesiologists, pathologists) who may not be eligible for incentives under ARRA, must have full access to patient records across settings of care to ensure that all patients receive the appropriate and necessary care, at the right time, based on access to a comprehensive patient history. The usability of EHRs and other technologies will directly impact a physician's ability to deliver high quality care efficiently. EHR products should support decision-making and physician workflow, enhance processes that improve health outcomes, and reduce unnecessary costs.

In addition, physicians must be able to correctly report services delivered when using an EHR. Complete documentation and correct coding are required by CMS and other payers in order for physicians to be reimbursed for services rendered. For Evaluation and Management codes, the most commonly billed procedures, physicians use the CMS Evaluation and Management (E/M) documentation guidelines and must demonstrate the appropriate defined key elements (two or three) to be paid: 1) patient history; 2) physical exam; and 3) medical decision-making. Physicians do not always need to conduct a full history and physical. Nonetheless, due to the way some EHRs are set up, physicians have the ability to "carry forward" patient information collected during a previous history and physical and this can result in selecting a code which does not support the work done. EHR software that recommends CPT codes for the reporting of E/M services performed by the physician, should

be based on CMS' Evaluation and Management Guidelines. CPT codes for other procedure and services, should be based on CPT code guidelines and conventions. Furthermore, vendor recommended CPT codes should require physicians to select or validate the appropriate CPT code(s) for the procedure or service. Similarly, templates—when used—should require physicians to select or validate the accuracy of any data prepopulated from a previous visit into a medical record along with the appropriate code(s) and not automatically default to the standard course of care for a particular diagnosis. Physicians must be assured that the CPT code that the EHR system is recommending is based on appropriate criteria and that physicians have the opportunity to validate the recommendation. The AMA strongly supports accurate reporting of procedures and services by physicians and is very concerned some EHR systems do not provide appropriate safeguards to ensure accurate reporting and may inadvertently increase the likelihood of erroneous reporting. Physicians must be assured that services are reported and billed correctly when using an EHR. At a time when HHS and CMS have escalated efforts to address improper Medicare and Medicaid payments, it is critical that ONC makes certain that EHRs demonstrate reliable and cogent coordination of clinical and administrative processes. **We, therefore, strongly urge ONC and CMS to work with the Health IT Policy and Standards Advisory Committees and hold a hearing to address such safeguards.**

### **Calculating Numerators and Denominators**

The majority of CMS' proposed health IT measures would require the use of a numerator and denominator to meet certain objectives. The problem with this approach is that there is no simple way to calculate this data. For example, in order to meet CMS' proposed requirement that physicians send reminders on preventive/follow-up care to all patients over 50 years of age, physicians would need to keep track manually of every phone call, letter, and fax, in addition to reminders sent electronically. Even in cases where a measure is largely performed electronically, such as in the case of maintaining problem lists, a lengthy and potentially costly process involving the creation of customized automated reports may be needed in order for physicians to be assured that they have met the high threshold requirements for a measure proposed by CMS.

The IFR calls for certified EHRs to, “electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.” **However, the IFR does not require EHRs to have the ability to automatically tabulate the data required by EPs to successfully demonstrate meaningful use.** As indicated in our comment letter to CMS relating to the proposed rule on EHR incentive programs, we believe that the requirement to manually calculate numerators and denominators is too burdensome for physicians. The IFR should require EHR functionality that enables automated calculations in an easy manner (e.g., an automated report can be run on the total number of patients for whom demographics were collected and populated within the EHR during a specified period of time).

The Health IT Policy Committee's own Certification and Adoption Workgroup met on February 17, 2010, and agreed that there needs to be a reasonable way to tabulate whether measures have been met. They recommended that: 1) the certification IFR include certification criteria for a section called "Reporting Metrics," which would ensure automatic calculation of all metrics that are required to be reported; and 2) the reporting process for Stage 2 of meaningful use not require manual review of records or subjective judgments. **The AMA strongly urges ONC to adopt the recommendation made by the Certification and Adoption Workgroup which called for requiring EHR vendors to create a functionality that allows EPs to automatically calculate numerators and denominators so that they can definitively determine whether they have met the required EHR measures for incentives.**

### **Other Technical Issues**

In the IFR, there is a request for feedback on whether the HL7 QRDA (Quality Data Reporting Document Architecture) standard is mature enough to be used in the complete EHRs and EHR modules during Stage 1. We believe that there is a gap between the standard for reporting quality results (reporting out of an EHR) and the implementation of the standard. There are several issues with QRDA that makes it problematic for use. First, QRDA is a draft standard for trial use. The standard has not been fully tested for validity, reliability, or implementation capability. Second, QRDA is not a single reporting criteria; it is a reporting framework with three additional reporting frameworks, QRDA Category I, II, and III. The IFR does not define which framework will be used for reporting. Also, for each Category I, II, or III report, there needs to be an implementation guide, and the criteria/rules for reporting must be developed that outline what the reports shall and shall not contain. To date, none of the implementation guides for the measures have been developed. Moreover, the implementation guides are written in a text editor (such as Microsoft Word) and are provided in a non-computer readable format so that they can not be executed upon. Each measure has a potential for three report formats to be used; which is not a sustainable model. Moreover, the management of this standard will be costly and cumbersome, especially when the implementation guides are not written in a language that can be executed upon by a computer. We are in agreement that a quality standard should be used when the quality data sent is used for quality improvement purposes. Since the sole purpose for using a QRDA standard is for determining whether or not an EP meets the meaningful use criteria for an incentive payment, **we recommend that a single implementation guide applicable to all measures be developed by appropriate standard developing entities.**

In addition, although we support the Health Insurance Portability and Accountability Act (HIPAA) code sets required for procedures that are listed in the IFR (e.g., ICD-9-CM and CPT 4), we noticed that the Healthcare Common Procedure Coding System (HCPCS) is not listed, and should also be included. There is also a need for cross-maps to support electronic reporting. The licensing and funding of these maps should also be addressed by HHS. Other important functions need to be assessed including the ability of certified EHRs to accept

interfaced data from the dictation/transcription process. We also seek clarification on discrepancies between this rule and CMS' proposed rule on the Medicare and Medicaid EHR incentive programs. For example, this rule includes a reference to Table 2A that communicates that the CMS PQRI 2008 Registry XML specification will be the format by which quality measure information should be transmitted. This conflicts with CMS' proposed rule which indicates that EPs will not be required to transmit quality measure information in 2011 (they only have to "attest" to meaningful use of EHRs in 2011).

Patient safety is always a top priority of the AMA. We believe there must be assurances to protect patients and physicians from software failures, design defects, and any other EHR system/software inadequacies or failures that could result in possible patient harm and/or expose physicians and other users of health IT to liability. There should be a mechanism to allow for user feedback and to inform health IT users of problems and errors and resolutions to minimize risks to patient safety.

### **EHR Market and Product Selection**

We strongly recommend that HHS fully assess whether the proposed initial set of standards and implementation specifications are already in widespread use, and whether the proposed certification criteria cover core capabilities that exist in EHRs in the marketplace today. Surveying commercial EHR vendors and open source developers of complete EHRs and EHR modules that are in the marketplace today on their readiness and the actual costs to EPs for purchasing new certified EHR Technology or for modifying their current EHR to become meaningful users is a critical first step. In addition, HHS should assess whether the majority of complete EHRs and EHR modules available today are ready for testing and certification and the costs that will be incurred to prepare EHRs and EHR modules to be tested and certified.

Physicians will need substantial guidance on selecting the "right" certified EHR that is able to meet their particular practice's needs. ONC has indicated that although EHR vendors will be required to obtain certification for their products, it will be up to the EPs to determine that the EHR product(s) they purchase meet CMS' EHR incentive program requirements. We support ONC's proposal to permit physicians to use a combination of products, referred to as "EHR modules," to meet these incentive requirements. In the case of physicians who plan on combining and using multiple EHR modules, we are concerned, however, that physicians will not have adequate technical expertise available to assist them to ascertain whether or not the combination of products they have selected will enable them to perform all the requirements outlined by CMS. **We, therefore, strongly recommend that ONC: 1) provide a comprehensive list of EHR products online so that physicians can verify that the products they plan on purchasing (or have purchased) are certified; and 2) provide an easy to use online system whereby physicians can type in/select information on the EHR modules they plan on using to determine whether their selected combination enables them to meet the CMS EHR incentive program requirements. ONC should also build in a mechanism as part of the certification program to ensure that vendors of "certified EHRs" are able to maintain financial and good standing.**

As indicated in our comment letter to CMS on the proposed EHR incentive program, we strongly urge CMS/ONC to create a mechanism for the ongoing evaluation of EHR adoption and use. We believe that it is critical that CMS and ONC monitor not only the overall adoption rates, but also identify barriers and solutions for meeting individual objectives and measures (e.g., need for robust, uniform EHR standards, ability to exchange information with multiple health care partners, adjustments to address workflow, financial, or other needs). These assessments must also be factored into future CMS and ONC requirements.

### **Grandfathering in Early Adopters**

Physicians who have already invested in EHRs and use health IT, known as “early adopters,” should not be penalized for failing to meet future certification processes. **We recommend that EHRs that have been purchased and used prior to January 1, 2011, and previously certified by CCHIT, be deemed certified for the purposes of meeting the EHR incentive requirements for Stage 1 so long as the EP can attest to meeting at least five of the health IT objectives and measures specified in CMS’ proposed rule on Medicare and Medicaid EHR incentives<sup>iii</sup>.** (Please review our attached comments to CMS on the proposed Medicare and Medicaid incentive programs).

The certification process should accommodate the variety and the influx of EHR products, including: a) CCHIT-certified products; b) products that are in the formal process of being certified by CCHIT but are not yet certified; and c) other systems like “homegrown” EHRs. A variety of certified products will be needed in order to accommodate the information needs and practice workflows of different specialties.

### **Certifying Additional Products in the Future and the Need for Broadband**

It is our understanding that ONC intends to expand the EHR certification to include additional types of health IT technologies that can qualify for meeting the EHR meaningful use incentive program. One area we recommend that ONC consider concerns technologies used by physicians who treat patients in their homes, such as physicians who make house calls to the home-limited elderly, and those in rural areas who have limited or no access to broadband service at the point of care. Many health care professionals who serve vulnerable patient populations will not be able to take advantage of the EHR incentive programs because of the lack of broadband internet access. Funding is needed to construct, operate, and maintain broadband infrastructure in these underserved areas.

### **Conclusion**

It is critical that the initial set of standards, specifications, and criteria are specific enough to enable physicians to successfully meet the proposed Stage 1 meaningful use criteria yet flexible enough to allow complete EHRs and EHR modules to include other important functionalities and to evolve over time to meet future criteria. Careful consideration must be given to ensure that physicians are not financially, technologically, and operationally overwhelmed with costly, complicated EHR products or upgrades that could significantly diminish the likelihood of EHR implementations.

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ONC should create an online system that will assist EPs in ascertaining whether their EHR or EHR modules perform all of the requirements for meaningful use. ONC should also pursue an extensive education and outreach campaign to inform EPs on how they can assess whether their EHR or EHR modules meet the proposed standards, specifications, and certification criteria. The costs associated with purchasing, implementing, and maintaining EHRs is significant, especially for small physician practices. Physicians will need clear direction on which systems are fully compliant and what upgrades are needed to achieve compliance so that they can be assured that the EHR they have adopted and implemented will support their achievement of meaningful use. Finally, ONC and CMS must develop a process so that EPs are able to provide feedback to all relevant parties, including EHR vendors, measure developers, etc., where structured data fields are not available or are needed, concerns/issues with EHR specifications, report administrative complications in implementation, formatting and usability issues, and actual computer errors stemming from the programs themselves, as well as interoperability between programs.

We appreciate the opportunity to share our comments with you. Should you have questions about these comments, they may be directed to Mari Savickis at [mari.savickis@ama-assn.org](mailto:mari.savickis@ama-assn.org) or 202-789-7414.

Sincerely,



Michael Dr. Maves, MD, MBA

Attachment

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<sup>i</sup> *Complete EHR* means EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary of HHS.

<sup>ii</sup> *EHR Module* means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary of HHS.

<sup>iii</sup> See CMS' proposed rule on the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; RIN 0938-AP78.