



Charles N. Kahn III
President

March 9, 2010

VIA ELECTRONIC SUBMISSION

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: HITECH Initial Set Interim Final Rule
200 Independence Avenue, SW
Suite 729-D
Washington, DC 20201

**RE: Initial Set of Standards, Implementation Specifications, and
Certification Criteria for Electronic Health Record Technology; 75
Federal Register 2,014 (Jan. 13, 2010)**

Dear Dr. Blumenthal:

The Federation of American Hospitals (“FAH”) is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, including inpatient rehabilitation, long-term acute care, cancer and psychiatric hospitals.

The FAH has long-supported the adoption of interoperable health information technology (“HIT”) as a means of improving the quality, safety and efficiency of health care delivered to patients in the United States. The standards and certification criteria adopted in this rule will undoubtedly be a critical first step in ensuring that clinicians can exchange and access critical health information to best serve the needs of America’s patients. The FAH supports the need to establish standards to promote interoperability as it relates to the exchange of information among users of certified EHR technology, but we do not believe those requirements should govern exchange of data within the “four walls” of a hospital.

On behalf of our member hospitals, thank you for the opportunity to comment on the interim final rule specifying the initial set of standards, implementation specifications and certification criteria for electronic health record (“EHR”) technology (“Interim Final Rule”). (75 *Fed.Reg.* 2,014 (Jan. 13, 2010).)

CERTIFICATION CRITERIA

The FAH was pleased to see that the Office of the National Coordinator (“ONC”) for Health Information Technology has been closely coordinating with the Centers for Medicare & Medicaid Services (“CMS”) regarding the proposed meaningful use Stage 1 objectives. Not surprisingly, then, the certification criteria contained in the interim final rule very closely track the proposed meaningful use criteria proposed by CMS. However, the FAH has a number of concerns with the proposed Stage 1 meaningful use criteria and their related measures. We have made CMS aware of these concerns and have attached for your information a copy of the comments submitted to CMS. (See Attachment.)

With respect to the Interim Final Rule, the FAH assumes that the ONC plans to match any changes made to the meaningful use criteria by CMS by making corresponding changes to the interim final rule. In this regard, we urge the ONC to pay particular attention to comments submitted by EHR vendors regarding their capacity to meet the initial set of certification criteria—and other elements of the interim final rule—given the acquisition of certified EHR technology is the first step that eligible professionals (EPs) and eligible hospitals must take in order to ultimately qualify for Medicare and Medicaid EHR incentive payments (generally by demonstrating meaningful use of such technology). We worry that the ONC and/or CMS will not have reasonable expectations with respect to what EHR vendors are able to do in the near term. We, therefore, are concerned that certified EHR technology might not become available in a timely fashion.

With respect to certification criteria, we would ask that ONC ensure that certified EHR technology is able to generate the data that EPs and eligible hospitals will need to establish meaningful use requirements. For example, if the measure for a meaningful use criterion involves calculations using a numerator and a denominator, every attempt should be made to ensure that any certified EHR technology is capable of making such calculations. Otherwise, the value of EHR technology will be substantially reduced and EPs and eligible hospitals left to generate necessary data by labor-intensive and costly non-electronic means.

MODULE CERTIFICATION

In the Interim Final Rule, the ONC notes that it believes it will be common in the near future for certified EHR technology to be assembled from several replaceable and swappable EHR modules and thus, defines “Certified EHR Technology” as a complete EHR or a combination of EHR modules, each of which: 1) meets the requirements included in the definition of a Qualified EHR; and 2) has been tested and certified in

accordance with the certification program established by the ONC as having met all applicable certification criteria adopted by the Secretary.

While the FAH appreciates that the ONC has provided for the use of EHR modules as well as a complete EHR, we disagree regarding the need for certain administrative systems (such as those now being used to check insurance eligibility electronically or to submit claims to public and private payers electronically) to be certified. These non-clinical components should not need to be separately certified, especially since the ONC itself warns that such certification would not guarantee that EHR Modules “can properly perform in their expected operational environment.” In short, we believe that provision should be made to permit hospitals to construct “Certified EHR Technology” from a combination of certified and non-certified “modules,” with certification not required for those components that relate to administrative transactions. In our view, such a policy would strike a reasonable balance and help facilitate the timely availability of certified EHR technology.

Further, in many cases, hospitals will need to implement a variety of certified technology products in combination with software applications to meet the meaningful use criteria, including reporting on clinical quality measures. It is unrealistic to expect every component of a hospital’s HIT system to be certified. Ancillary components, such as databases, should be excluded from the certification process. Ultimately, the burden is on the provider to ensure that software applications interface with certified technology products to meet the requirements of meaningful use using the standards specified in this Interim Final Rule.

CONTENT EXCHANGE STANDARDS

The Interim Final Rule adopts standards in four categories, including Content Exchange Standards. More specifically, for the Patient Summary Record, the Interim Final Rule specifies that the adopted standard for Stage 1 is the Health Level Seven Clinical Document Architecture Release 2 Continuity of Care Document (CCD) Level 2 or the ASTM Continuity of Care Record (CCR). As the candidate standard for Stage 2 for the Patient Summary Record, the Interim Final Rule notes that alternatives are expected to be narrowed based on HIT Standards Committee recommendations. The FAH believes that the proposed standard for Stage 1 and the proposed approach for arriving at a standard for Stage 2 serve as excellent examples of how the ONC is providing flexibility initially and then relying on input from stakeholders, through the HIT Policy Committee and HIT Standards Committee, to arrive at an appropriate longer-term standard. We commend the ONC for taking this approach.

The Interim Final Rule adopts another content standard for Quality Reporting, the CMS Physician Quality Reporting Initiative (PQRI) 2008 Registry XML Specification. However, hospitals are not familiar with PQRI and have been reporting performance data to CMS under a separate program. The FAH is, therefore, concerned that the PQRI-related specification might not be appropriate in a hospital context. We were disappointed that the Interim Final Rule did not acknowledge this concern and/or provide

assurance that this was not expected to be a problem for hospitals. We note, too, that this proposed standard is not a voluntary consensus standard, which increases our concerns further.

PRIVACY AND SECURITY STANDARDS

The Interim Final Rule also adopts privacy and security standards, including one whose purpose is to “Record Treatment, Payment, and Health Care Operations Disclosures.” For this standard, the Interim Final Rule specifies that the date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded. The Interim Final Rule goes on to acknowledge that what should be included in a disclosure description is not being specified. In this regard, the ONC invites comments regarding the technical feasibility of recording the purpose or reason for a disclosure, to whom the disclosure was made (*i.e.*, the recipient), and any other elements that may be beneficial for a patient to know about with respect to their health information.

The FAH urges the ONC to eliminate the disclosure recording element from the privacy and security certification criteria. Before even reaching the narrow issue of what data is technically feasible to record, a threshold concern is that covered entities have been subject to the HIPAA accounting for disclosures rule for several years and already have systems in place to meet those requirements. Moreover, there will be additional policy development in the area as a result of other provision of the HITECH Act. In our view, it is not imperative that certified EHR technology be able to serve this function. If it remains a certification criterion, we are concerned this policy could easily be a precursor to CMS requiring this functionality as part of the meaningful use incentive payment programs.

Additionally, the FAH is very concerned about the potentially burdensome nature of disclosure recording, especially as it relates to capturing the purpose or reason for a disclosure. Among other things, we are concerned that certified EHR technology will provide inadequate support to hospital staff in capturing all the required information, especially information about purpose or reason, in an efficient manner. Further, we suspect that the number of disclosures required for treatment, payment and health care operations is large, and expecting hospital personnel to enter information regarding purpose or reason for each such disclosure could prove overwhelming.

We also fear that disclosure recording activities could prove quite costly and administratively burdensome. Finally, because the ONC acknowledges that it is not specifying what information should be included in a description of each disclosure, it might be better to defer requirements relating to “purpose or reason” until the capabilities of available—or soon to be available—EHR technologies are better ascertained and until further work is done to identify approaches that would minimize the related administrative burden on EPs and eligible hospitals.

IMPLEMENTATION SPECIFICATIONS

The Interim Final Rule adopts relatively few implementation specifications. One notable exception is adoption of the PQRI Measure Specifications Manual for Claims and Registry (for the standard CMS PQRI 2008 Registry XML Specification). As noted earlier, the FAH is uncomfortable with the proposed quality reporting standard because it is based on a program that has not been used by hospitals, and thus we are equally uncomfortable with the idea of adopting a related implementation specification. At the very least, we ask that the ONC ensure that the proposed quality reporting standard and related implementation specification will not cause problems for hospitals and discuss this matter in the forthcoming final rule. Alternatively, if on further review the ONC determines that such problems are possible, then we ask that the final rule be modified accordingly.

CERTIFICATION PROCESS

When the Interim Final Rule was published, the ONC announced that it also planned to issue a notice of proposed rulemaking (“NPRM”) to establish the policies for the certification of HIT and the process a certification body will need to follow to become an authorized certification body. This Proposed Rule was slated to be published “early in 2010” but has been delayed to a release date near the end of the IFR’s comment deadline. Just recently, on March 2nd, 2010, the ONC released the display version of the Proposed Rule on Certification Programs for HIT. The NPRM notes it is likely that the temporary certification entities will not exist until May or June 2010. It will then take time for the newly-designated bodies to complete the certification of HIT products. The FAH is very concerned that this delay and related implementation challenges will delay EP and eligible hospital access to certified EHR technology, without which EHR incentive payments will be inaccessible to providers.

The ONC itself assumes that it would generally take 6 to 18 months for commercial vendors and open source developers of complete EHRs and EHR modules to prepare for testing and certification. If this estimate is accurate, it suggests that there is considerable risk that certified EHR technology would not be available for acquisition, let alone meaningful use, in time for EPs and eligible hospitals to qualify for EHR incentives in 2011 (FY 2011 in case of hospitals and CY 2011 in the case of EPs). Obviously, this means that the finalization of certification ground rules and the recognition of EHR certification bodies must be a very high priority.

In addition, we believe it also means that the ONC and CMS should collaborate to adopt some kind of “grandfathering” policy under which certain EHR technology would be considered “certified” for purposes of qualifying for EHR incentive payments. For example, EHR technology previously certified by the Certification Commission for Health Information Technology could be considered acceptable for some period of time. This might, for example, require ONC and CMS to agree that the functionalities of such EHR technology, when properly used by EPs and eligible hospitals, would satisfy

applicable meaningful use requirements, at least for the first year or two of the incentive program.

There undoubtedly are other ways in which a “grandfathering” policy might be structured. In any case, absent such a policy, we fear there would be significant delays in making certified EHR technology available to EPs and eligible hospitals. Without such technology, its meaningful use would obviously be impossible and EPs and eligible hospitals would be denied access to incentive payments promised by the Stimulus bill. We do not believe that this is the outcome contemplated by the Congress or the Administration.

We hope the preceding comments are helpful. If you have any questions regarding our comments or need additional information, please contact me or Samantha Burch of my staff at 202-624-1500.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia", with a horizontal line underneath it.

Attachment: FAH Comments on EHR Incentive Program Proposed Rule