

April 8, 2010

David Blumenthal, MD, MPP  
Chair, HIT Policy Committee  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W., Room 746  
Washington, D.C. 20201

Dear Dr. Blumenthal:

The HIT Policy Committee (Committee) has given the following broad charge to the Adoption-Certification Workgroup:

**Broad Charge to the Workgroup:** To make recommendations to the HIT Policy Committee on issues related to the adoption of certified electronic health records, that support meaningful use, including issues related to certification, health information extension centers, patient safety, and workforce training.

This letter provides recommendations on the Department of Health and Human Services' (HHS) proposed rule-making regarding the establishment of two certification programs for purposes of testing and certifying health information technology.

### **BACKGROUND AND DISCUSSION**

The American Recovery and Reinvestment Act of 2009 (ARRA) established the HIT Policy Committee as a Federal Advisory Committee. The Committee is charged with recommending to the National Coordinator a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information, consistent with the Federal Health IT Strategic Plan and that includes recommendations on other issues, including areas in which standards, implementation specifications, and certification criteria are needed.

On March 10, 2010, HHS proposed a rule regarding the establishment of two certification programs for purposes of testing and certifying health information technology. The first proposal would establish a temporary certification program whereby the National Coordinator would authorize organizations to test and certify Complete EHRs and/or EHR Modules, thereby assuring the availability of Certified EHR Technology prior to the date on which health care providers seeking the incentive payments available under the Medicare and Medicaid EHR Incentives Program may begin demonstrating meaningful use of Certified EHR Technology.

The Workgroup Recommendations are relative to the temporary certification program, and in the discussion below we outline these Recommendations and explain why we believe that these changes to the NPRM will result in more effective achievement of HHS' objectives with this temporary certification program for EHR Technology.

## **HIT POLICY COMMITTEE COMMENTS AND RECOMMENDATIONS ON TEMPORARY CERTIFICATION PROGRAM**

### **1. Certification of EHR modules working with other modules --Section II.D.1b**

#### ***Recommendation 1.0***

We recommend that certified EHR modules be required to be sold with a label indicating that HHS has not tested the module for interoperability with other modules.

Because of the complexity involved, and because of the absence of standards, we think that ONC-ATCBs should not be required to test and certify EHR modules' ability to work properly with other developers' modules. Instead, in order to avoid market confusion, we are making a labeling recommendation. Because the term "certification" is used freely in the marketplace, the labeling requirement is extremely important.

### **2. Authorization to certify for ambulatory settings--Section II.D.1b**

#### ***Recommendation 2.0***

In addition to providing authorization for testing and certifying modules and complete EHRs, we recommend that applicants should be allowed to seek more limited authorization to test and certify complete EHRs for an ambulatory setting, and applicants should be allowed to seek authorization to test and certify complete EHRs for hospital settings.

We make this recommendation because the marketplace consists of a large number of vendors that offer complete EHRs for ambulatory settings only, and because it is easier to test (and certify) for ambulatory settings. As a result, if an ONC-ATCB were to exist that offered services to these ambulatory vendors, that ONC-ATCB would perform an important service to the industry. Because most hospital vendors also provide ambulatory systems, we feel it is less important to provide this flexibility for hospital systems. It should, however, similarly be possible for an ONC-ATCB to be authorized to test and certify Complete EHRs for a hospital setting.

### **3. Authorized Testing and Certification Methods—Location**

#### ***Recommendation and Comment 3.0***

We agree with the requirement that an ONC-ATCB should have the capacity to test at its facility. For the organization requesting to have its products certified, it is expensive to test software at the ONC-ATCB's location, however. As a result, we also agree with the requirement that an ONC-ATCB should have the capacity for testing and certifying either at the physical site (location) where the software is used or, alternatively, remotely, for

Hospitals or EPs that use self-developed or open-source software. For vendors, testing and certification should continue to occur at the ONC-ATCB's facility for complete EHRs.

### ***Recommendation 3.1***

In the event that self-developed or open source software is tested at the site of a healthcare organization (including remote testing), we recommend that any resulting certification should apply to that Hospital or EP only, and should be not transferrable to other organizations. These on-site certifications should not be permitted to have a label that allows marketing of those systems as being certified.

In making this recommendation, we are repeating the recommendation that we made in August. We want to provide a level playing field for the EHR marketplace. By requiring ONC-ATCBs to provide testing and certification services at the users' sites, those organizations are receiving special treatment, when compared with a vendor. If the self-developed or open-source application is eventually commercialized, then it must be re-certified with the same process required of vendors.

This recommendation also provides an opportunity to eventually establish certification criteria that apply specifically to vendors. For example, it is possible that Stage 2 certification criteria could require vendors to make patient-safety notifications to their customers.

## **Minimum Standards**

### ***Recommendation 4.0***

We recommend that the process described in the NPRM Section II.E.4 apply to new software for the initial testing and initial certifying process only. The process should not apply to technology that has already been certified and purchased. Whenever standards are described as a "floor", then users of certified EHR technology should be free to upgrade at their option whenever they deem appropriate, without changing the certification status of their technology.

The concept of a minimum standard or "floor" should mean that subsequent revisions are automatically considered to be compliant with the regulation for existing users. Users of certified EHR technology need flexibility to upgrade to newer versions of standards in order to promptly respond to operational challenges (errors) that the subsequent versions might address. We agree with both of the approaches for authorizing an upgrade to a standard described in the NPRM, provided that these approaches are used for testing and certifying only. Users of operational certified EHR systems should be able to upgrade to newer versions as they see fit to upgrade.

## **Revocation**

***Recommendation 5.0***

We recommend that the National Coordinator have the flexibility to revoke an ONC-ATCB's status based upon his/her determination of the severity of the violations, and, as a result, we do not recommend establishing a specific number of Type-2 violations that cause automatic revocation.

We believe that revocation should not be automatic, based upon the number of violations, because there is a broad range of possible violations. Instead, the National Coordinator should have the flexibility to judge the severity of the violations along with the impact on the marketplace of a revocation.

**Certification Clarity for Stages of Meaningful Use**

***Recommendation 6.0—Section II.E.6***

We recommend that labeling be required to indicate which stage specific technology has been tested and certified, instead of using the date as described in Section II.E.6. For example, technology that is certified during 2010 should contain a label indicating that it has been certified for Stage 1 only. As another example, a future complete EHR could have a label that indicated it has been certified for both Stage 1 and Stage 2 for ambulatory settings.

With this approach, there would be clarity for a purchaser who wanted to begin Stage 1 in a later period of time. This approach would also create an opportunity for an early finalization of Stage 2 or Stage 3 certification criteria. (It will be advantageous to complete Stage 2 and/or Stage 3 certification criteria before the corresponding Meaningful Use eligibility period begins, so that developers and ONC-ATCBs can begin work earlier).

***Recommendation 6.1---Section II.e.6***

We recommend that a web site be maintained by ONC and by each ONC-ATCB that clearly identifies the names of vendors and the vendor version numbers that have received certification and which shows which Meaningful Use stage has been tested and certified.

Since there is no registration process for hospitals and EPs, and since the term "certification" is used loosely in the marketplace, clear labeling requirements and clear communications are extremely important.

Sincerely yours,

Sincerely yours,

/s/

Paul Eggerman  
Co-Chair  
Adoption Certification Workgroup

/s/

Mark Probst  
Co-Chair  
Adoption Certification Workgroup