Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

May 7, 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 create a temporary certification program, and the second proposal would establish a permanent certification program to replace the temporary program.

The Workgroup Recommendations, presented here, are relative to the permanent 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 permanent certification program for EHR Technology.

HIT POLICY COMMITTEE COMMENTS AND RECOMMENDATIONS ON PERMANENT CERTIFICATION PROGRAM

GENERAL COMMENT

We are pleased with ONC's structural approach to certification. By separating the certification process from the testing process, and by utilizing existing international testing, accreditation, and certification standards, ONC is improving the objectivity and transparency of the certification and testing processes.

1. Elements of Surveillance Process (Section III.D.1.C)

Recommendation 1.0-*We recommend that the surveillance process contain the following elements:*

a. *Compliance with testing criteria. Monitoring should occur to determine whether certified Complete EHRs and EHR modules that are purchased comply with the testing criteria in actual operation. As an example, while a vendor may have passed a test for an interface standard, the surveillance process should exam whether that vendor's products comply with that standard in actual operation.*

b. *Compliance with certification criteria. Monitoring should occur related to issues that do not involve software testing, but require certain behaviors by vendors or users. Examples include adherence to any labeling requirements, accuracy of representations about the certification process, and compliance with any future requirements involving patient safety reporting.*

c. *Effectiveness of Systems and Implementations. Because certification does not ensure that systems will operate effectively or safely, monitoring should occur of purchasers' opinions about the ability of operational systems to achieve meaningful use.*

Recommendation 1.1-*A labeling requirement should be established for Complete EHRs and EHR modules that provides instructions for reporting certification and testing violations or concerns.*

Because of potential confusion in the marketplace, labeling requirements are very important. A label with reporting instructions is particularly important, because many purchasers will not know how to report any complaints about the certification process. For labeling requirements, surveillance needs to be used to ensure that vendors are not misrepresenting their certification status, or the meaning of certification.

In addition, we are concerned that vendor supplied software could successfully pass required tests, but might not operate in accordance with the required standards in operation. It is important that conformance with required interoperability standards is monitored in operational systems.

2. De-Certification (Section III.D.1.C)

Recommendation 2.0-*The National Coordinator should have the authority to proactively ''de-certify'' Complete EHRs and/or EHR Modules if a pattern of unsatisfactory surveillance results emerges or if patient-safety concerns emerge. The National Coordinator's de-certification actions should be limited to egregious situations that require action to protect purchasers. For vendor-supplied systems, the National Coordinator may choose to allow existing users of a de-certified vendor's system to retain their certification status, depending on the nature of the violation.*

We believe that this authority may be necessary so that the National Coordinator has the capability to protect purchasers of Complete EHRs and/or EHR modules.

3. Differential Certification (Section III.E.8)

Recommendation 3.0-*For certification and testing for stages 2 and 3, differential testing and certification should be allowed, if all of the following three conditions are met:*

a. *An applicant has already passed a specific test in a prior stage, and*
b. *There has been no change in the criteria for that specific test in a subsequent stage, and*
c. *There has been no change in the applicant's software version*

Under these three conditions, the applicant should not be required to repeat the test. For the purposes of this recommendation, a "change in software version" is defined as a change involving addition or removal of substantial user functionality or a change involving new technology. A "change in software version" does not include error corrections (sometimes called patches), or the addition of new exchange (interface) technology which does not substantially alter the user data entry process.

In making this recommendation, we believe that it is very important that the testing criteria be the same. If a module was certified under the temporary program for Stage 1, and if the testing process for that module becomes more rigorous for Stage 2, then that module needs to be re-tested for Stage 2. We similarly think that it is very important that the software version not change.

There are several vendors with large numbers of existing customers using several older versions of their software. For these vendors, it might be burdensome to repeat any identical testing processes for each of their prior software versions when new meaningful use stages are announced. In addition to being burdensome, a requirement to comprehensively repeat all testing could delay the ability for existing users to qualify for

incentives for subsequent stages. While we are suggesting circumstances under which tests might not be repeated, we are still suggesting that all tests must occur at least once for each certified version of the software.

4. AA Ongoing Responsibilities ("Section III.F.2)

Recommendation 4.0-*In addition to the responsibilities described in the NPRM, the AA should be responsible for monitoring the speed by which an ONC-ACB processes applications for certification. Any applicant backlogs should be reported to the National Coordinator.*

5. Number of ONC-AAs and length of Approval Period (Section III.F.3)

Comment and Recommendation 5.0-*We agree that one ONC-AA should be established, and we agree with a three year term. We question, however, whether 120 days will be a sufficient amount of time for ONC to evaluate applications and select a possible successor. We recommend that ONC re-evaluate that time period, and, if appropriate, extend it, possibly to 180 days.*

6. Promoting Participation in the Permanent Certification Program (Section III.G)

Recommendation 6.0-*In addition to providing authorization for testing and certifying EHR 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 only, or to test and certify complete EHRs for hospital settings only.*

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) these products 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. Also, the ability to certify Complete EHRs for ambulatory settings might represent an important incremental step to help organizations qualify to become complete ONC-ATCBs. Because many 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.

7. Stark Exception (Section I.B.2.d)

Comment 7.0- *We agree with construing the new "authorization" process as the Secretary's method for "recognizing" certification bodies in the context of the physician self-referral EHR exception and anti-kickback safe harbor.*

It would be costly to both the government and the healthcare industry to utilize two separate certification processes.

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

Recommendation 8.0-*We recommend that certified EHR modules be required to be sold with a label indicating that the module has not been tested 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.

9. Authorized Testing and Certification Methods—Location

Recommendation and Comment 9.0-*We agree with the requirement that ONC-ACBs should be permitted to test at (a) their own facility, (b) remotely, and (c) at the site of a healthcare organization. We recommend that remote testing be designated as the primary method for testing, however, and the other locations be designated as secondary locations.*

In making this recommendation, we are changing the recommendation that we made for the temporary program. We now understand that remote testing is the least expensive methodology and is consistent with current EHR certification practices.

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10. Minimum Standards (Section II.E.4)

Recommendation 10.0-*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. 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.

11. Certification Clarity for Stages of Meaningful Use (Section II.E.6)

Recommendation 11.0-*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.

If a differential certification process is used for testing then the certification body should give permission for the label to be updated to show certification for the appropriate stage.

Recommendation 11.1-*We recommend that a web site be maintained by ONC and by each ONC-ACB 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. The web-site should also contain surveillance information.*

Because the term "certification" is used loosely in the marketplace, clear labeling requirements and clear communications are extremely important.

12. Certification of HIT Systems, in addition to EHR Systems

Comment 12.0-*We agree with providing the future flexibility to certify other HIT systems, such as PHRs. This flexibility should be used, however, to the extent that it is needed to support the stated certification objectives, which are:*

a. *Focus certification on meaningful use requirements*
b. *Leverage the certification process to improve technical progress on privacy, security, and interoperability.*

Sincerely yours,

/s/

Paul Egerman
Co-Chair
Adoption Certification Workgroup