June 7, 2012

Farzad Mostashari, MD, ScM

National Coordinator for Health Information Technology

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Washington, DC 20201

Dear Dr. Mostashari:

The HIT Policy Committee’s (Committee) Information Exchange Workgroup and Certification and Adoption Workgroup were asked to provide comment on the Office of the National Coordinator’s Standards and Certification Criteria Notice of Proposed Rulemaking for Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition.

The Workgroups’ findings were presented to the Committee on May 30, 2012. The Committee deliberated on the findings and approved the consolidated comments below for transmittal to the National Coordinator.

**Safety Enhanced Design Certification Criteria**

* Require EHR technology developers to document (with evidence) that user centered design principles were employed throughout product development.

**Quality Management Principles**

* Require use of quality criteria for software development, which would be captured in the documentation EHR technology developers provide during certification. For quality criteria, it should not be limited to one or two pre-determined methods. Rather, publication of what the developer is actually doing in terms of quality principles being applied to the development of the EHR technology.

**Patient Safety Events**

* There should be a means for reporting patient safety events to Patient Safety Organizations (PSOs) with EHR technology. However, the committee acknowledged that this recommendation is contingent on the existence of a common format (standard) for achieving this that is both mature and widely adopted. Some acknowledgement of the AHRQ Common Format as a potential mature standard, but there is little evidence of provider implementation or adoption currently. ONC should assess the maturity of the Common Format for use in 2014.

**Clinical Decision Support Certification Criteria**

* The use of intervention vs. rule is a good decision.
* Infobutton is premature and not really a decision support standard. Rather, it could be used for providing appropriate education materials.
* Add procedures to patient context. Discussion: Immunization information should be available for decision support. It could be included as a medication or as a procedure.
* EHR technology should provide the capability to capture/record user actions in response to a decision-support intervention. This is to help assess whether an intervention had made a positive, negative, or neutral impact.

**Certification and Certification Criteria for Other Health Care Settings**

* Encourage the use of the same standards in all settings to facilitate health information exchange (the exchange of the summary care record).
* Encourage developers of EHR Technology for other healthcare settings to have their software certified (complete or modular, as appropriate). This is particularly valuable for the “exchange” standards.

**Accounting of Disclosures Certification Criteria**

* Do not alter the current certification criteria. Do not change from optional to mandatory or make more “rigorous.” Any change is premature since there is no final rule for accounting of disclosures.

**Disability Status**

* Capture for Stage 3 based on our assessment of currently available standards. There was discussion about standards development that might be completed in time for inclusion in Stage 2.
* Use of the term “functional level” is more appropriate than “disability status”.
* It is important to capture in terms of tracking disparities and providing appropriate care.
* Could be record via registration, patient-reported survey/questionnaire, clinician assessment, or problem list. Recording via demographics is not the best option.
* Could be included in a summary of care record, but concerned that there is no appropriate standard.

**Sexual Orientation and Gender**

* Capture for Stage 3 (consistent with previous Committee discussion); Note lack of standards

**Data Portability**

* This is a great goal, but no appropriate standard available. It would have to be limited to a snapshot of each patient (CCDA-type document) versus a “wholesale swap/changeout of information”

**EHR Technology Price Transparency**

* There are many pricing models for EHR technology which may include more or less of the full cost to implement and operate the technology. Providing a “list price” for a certified Complete EHR or certified EHR Module could be as confusing as it might be helpful and should not be required.

**Information Exchange – Public Health**

* Support policy of a single standard for public health transactions (uniformly use HL7 2.5.1 rather than permitting the 2.3.1/2.5.1 choice offered in Stage 1), however, recommend grandfathering those EPs and EHs who: 1) implemented 2.3.1 to achieve Stage 1 objective; 2) went beyond the single test and maintained submission to public health during the Stage 1 period; 3) are reporting to a public health department that is accepting 2.3.1 messages, and 4) are utilizing the same EHR technology that was used for their Stage 1 attestation.
* “Successful ongoing submission” needs a specific definition.

Sincerely yours,

/s/

Paul Tang

Vice Chair, HIT Policy Committee