March 4, 2010

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Blumenthal:

The HIT Standards Committee (HITSC) members identified and prioritized several recommendations on a standards and certification framework for the development and adoption of a nationwide health information technology infrastructure to permit the electronic exchange and use of health information, including areas in which standards, implementation specifications, and certification criteria are needed.

The following recommendations were developed by the Clinical Operations Workgroup of the HITSC, refined by discussion with the full Committee and adopted by the HITSC. The charge of the Clinical Operations Workgroup is to make recommendations to the HIT Standards Committee on requirements for standards, implementation specifications, and certification criteria related to EHRs and clinical operations. The Clinical Operations Workgroup was specifically charged initially to make recommendations to the HIT Standards Committee on the role of EHRs and e-prescribing, clinical summaries, laboratory and radiology report functionality, and other matters within the scope of Stage 1 meaningful use objectives and measures, including the standards for content exchange and controlled vocabularies to be used for these purposes.

HIT STANDARDS COMMITTEE RECOMMENDATIONS:

Broader Designation of Content Exchange Standards

Potential meaningful users of Electronic Health Records technology (EHRs) have strong requirements for both flexibility and detailed specificity in standards. Flexibility in the adopted standards is needed to avoid unnecessarily limiting the adoption of EHRs, for innovation to be possible, and to enable a private market to thrive in which competition may flourish. At the same time, consistency of certain implementation parameters at an extremely detailed level of specificity must be achieved by some method as a prerequisite to clinically sufficient interoperability of health information between any two or more EHRs, institutions and/or providers of care. To meet these simultaneous requirements, we recommend this Final Rule should be constrained within the scope of the Interim Final Rule (IFR) by specifying content exchange standards at the hierarchical level of Major Version Releases. Major Version Releases

of content exchange standards also are known variously as a "major standards version" (i.e., Health Level Seven International (HL7) Version 2), a "standards version" (Accredited Standards Committee (ASC) X12 Version 4010A1 or ASC X12 Version 5010), or as a "standard" (i.e., the National Council of Prescription Drug Programs (NCPDP) SCRIPT standard). Standards adopted in the IFR that do not exist within such Major Version Releases, including the American Society of Testing and Materials (ASTM) Continuity of Care Record (CCR) and the adopted vocabulary standards, would not be affected by this recommendation. Recommendations to adopt standards at the Major Version Release level should be considered in conjunction with the set of recommendations (below) to enable the simultaneous promulgation of detailed implementation specifications outside this rule because the recommended changes interrelate and both are needed.

Recommendation 1.0
§170.205(a)(1)(i) We recommend adopting HL7 Version 3 Clinical Document Architecture (CDA) as the standard for patient summary records. The HL7 Continuity of Care Document (CCD) is one type of CDA with implementation guidance for the CDA standard. We also recommend keeping the ASTM E2369 CCR standard as it is in the IFR.

Recommendation 1.1
§170.205(c)(1)(i) We recommend adopting NCPDP SCRIPT as the standard. We note no current or contemplated future conflict between this recommendation and 42 CFR 423.160(b)(2)(ii).

Recommendation 1.2
§170.205(d)(1)(i) We recommend adopting ASC X12 Version 5010 as the standard when exchanged between trading partners. This may be updated at such time as CAQH CORE operating rules that support 5010 become available and have been tested in conjunction with 5010. We recommend adopting ASC X12 Version 4010A1 and CAQH CORE Phase I Operating Rules together as alternative standards for the period before January 1, 2012, when exchanged between trading partners. We note no current or contemplated future conflict between this recommendation and 45 CFR 162.1202(b) or 45 CFR 162.1202(c).

Recommendation 1.3
§170.205(e)(1)(i) We recommend adopting World Wide Web Consortium (W3C) Extensible Markup Language (XML), and HL7 Clinical Document Architecture, as the standards.

Recommendation 1.4
§170.205(f)(1)(i) We recommend adopting HL7 Version 2 as the standard.

Recommendation 1.5
§170.205(g)(1)(i) We recommend adopting HL7 Version 2 as the standard.

Recommendation 1.6
§170.205(h)(1)(i) We recommend adopting HL7 Version 2 as the standard.

Promulgation Outside the Final Rule of Detailed Implementation Specifications For Use With Adopted Content Exchange Standards

To enable a level of interoperability sufficient to achieve goals and objectives of Stage 1 meaningful use of EHRs implementers, vendors and users of EHRs require highly detailed, comprehensive and very specific implementation guidance for the adopted standards. For health information messaging, such guidance documents dictate a specific sub-release and/or addendum of the standard to be used along with the adopted standard. They may specify as well the fixed presence or absence of otherwise optional data elements in a message; they may control the precise contents of each data element; and they may constrain the meaning of those data contents in the context of the message. It is absolutely critical that such guidance documentation should be promulgated at the same time as the Final Rule. On this the promise of any interoperability depends. Due to well-understood requirements of the process for changing adopted standards under provisions of the Administrative Procedures Act (APA) as used by the US Department of Health and Human Services (HHS), we recommend using alternative mechanisms as determined by the Secretary that may better fit the needs of consumers and industry stakeholders in this case. The Office of the National Coordinator (ONC) should consider the applicability of mechanisms used by the US Department of Commerce National Institute of Standards and Technology (NIST) in implementing provisions of the National Technology Transfer and Advancement Act (NTTAA) for this purpose, among other mechanisms that may be useful in providing implementation guidance.

Promulgating implementation guidance through some such mechanism should establish a "floor" for interoperability, that is, a minimum implementation of the adopted standard with enough specificity to establish interoperability of health information. Currently, most or all EHR vendors and institutional providers simultaneously support and use multiple different detailed implementations of each adopted standard. Most frequently for such entities the number of different implementations of HHS adopted standards is equal to the number of different trading partners with whom messages are exchanged. We believe the establishment of a minimum "floor" implementation guide, published by mechanisms outside this Final Rule, would greatly broaden the adoption of EHRs and the achievement of practical interoperability of health information. The HITSC found that different electronic clinical documents best serve different purposes in the use of EHR technology, therefore ONC should consider the possibility of providing guidance on these specific uses through the implementation guidance process.

At the same time, broad adoption and effective use of controlled vocabularies depends on the easy availability of a starting point comprising a list of terms and/or concepts to be used in each initial implementation of EHR technology. We recommend that ONC should follow recommendations made by HITSC and the National Library of Medicine (NLM) from time to time to make available both value sets that must be used for particular purposes such as quality reporting as well as convenience subsets of controlled vocabularies that ease the adoption, clinician training, and initial use of these technologies. All controlled vocabularies required for Stage 1 quality reporting should be adopted in the Final Rule. Alternative display names, that

articulate the adopted codes in clinician-friendly descriptive text, similarly have been proven to improve adoption of EHR technology and should be made available. Also, cross-maps between adopted vocabularies are needed by EHR implementers and should be made available through federal programs. Specifically, we recommend cross-maps should be made available from SNOMED CT to ICD9 and ICD10 for the billing use case, and that cross-maps from the proprietary medication terminologies adopted in the IFR to RxNorm should be made available to enable transitions from Stage 1 to Stage 2 medication vocabularies.

Recommendation 2.0
§170.205(a) through §170.205(h). We recommend ONC should remove from the Final Rule all detailed implementation guidance for content exchange standards including "dot release" standards versions as well as other guidance. We recommend ONC should ensure the availability of detailed implementation specifications for adopted standards through processes outside the scope of the Final Rule. We recommend ONC should consider the potential applicability of processes previously used by NIST under NTTAA, and by HITSP in relation to EO13410, among other processes that may achieve this end outside the Rule.

Recommendation 2.1
§170.205(a) through§170.205(h) We recommend ONC should ensure an alternative promulgation of the following detailed implementation specifications as applicable to the adopted standards. The intent of this recommendation is for this implementation guidance to serve as a specific floor or minimum for interoperability using the adopted standards, not to the exclusion of any other implementation specifications or updates.

Recommendation 2.1.1
§170.205(a)(1)(i) HITSP C32 version 2.5

Recommendation 2.1.2
§170.205(b)(1) 42 CFR 423.160(b)(5)

Recommendation 2.1.3
§170.205(c)(1)(i) 42 CFR 423.160(b)(2)(ii) and NCPDP SCRIPT 10.6

Recommendation 2.1.4
§170.205(d)(1) 45 CFR 162.1202(c), and CAQH CORE Phase I Operating Rules for the period before 1 January 2012.

Recommendation 2.1.5
§170.205(e)(1) CMS Physician Quality Reporting Initiative (PQRI) 2008 Registry XML Specification

Recommendation 2.1.6
§170.205(f)(1)(i)
Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, Implementation Guide Update, March 2005, Centers for Disease Control and Prevention
-- And --
HL7 U.S. REALM - INTEROPERABILITY SPECIFICATION: LAB RESULT MESSAGE TO EHR, ORU^R01, HL7 Version 2.5.1, July, 2007
-- And—
consider adding the following implementation guide if it is published in final form in advance of the Final Rule date: HL7 2.5.1 Laboratory Result Reporting to Public Health (Release 1).

Recommendation 2.1.7
§170.205(g)(1)
Public Health Information Network HL7 Version 2.5 MESSAGE STRUCTURE SPECIFICATION for NATIONAL CONDITION REPORTING, Final Version 1.0, August 18, 2007, Centers for Disease Control and Prevention
-- And –
Message Structure Specification v 1.0 Errata and Clarifications, 05/23/2008, Centers for Disease Control and Prevention.

Recommendation 2.1.8
§170.205(h)(1)(i)
Version 2.2 - Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the HL7 Standard Protocol (Published 6/2006), Centers for Disease Control and Prevention.

Recommendation 2.2
§170.205(a) through) (h) We recommend following the recommendations of the HITSC and the National Library of Medicine in making available specific value sets comprising the whole list of terms and concepts in all adopted standard controlled vocabularies required for each measure of Meaningful Use of EHRs defined by CMS.

Recommendation 2.3
§170.205(a) through) (h) We recommend following the recommendations of the HITSC and the National Library of Medicine in making available implementation guidance and tools for implementation assistance for the adopted vocabulary standards.

Recommendation 2.3.1
Subsets of each adopted standard controlled vocabulary, both as subsets of each entire vocabulary for all purposes and as subsets only with relevance for each medical specialty, should be made available as a convenience for implementers of EHRs who may become meaningful users.

Recommendation 2.3.2
Clinician-friendly alternative display names that have been shown to enable real- life adoption of EHR technology should be made available as a convenience for EHR vendors and implementers of EHRs who may become meaningful users.

Recommendation 2.3.3
Cross-maps between adopted vocabularies should be made available, specifically the cross-maps:

- *from SNOMED CT to ICD9 and ICD10;*
- *from SNOMED CT to CPT4 and HCPCS;*
- *bidirectionally between SNOMED CT and LOINC for vital signs and other purposes in meaningful use;*
- *from the adopted proprietary medication terminologies to RxNorm;*
- *other cross-maps recommended by HITSC and the National Library of Medicine.*

These should be made available as a convenience for EHR vendors and implementers of EHRs who may become meaningful users.

Recommendation 2.3.4
All controlled vocabularies needed for quality reporting in Stage 1 of the CMS meaningful use incentives program should be adopted standards in this Final Rule.

Clarification of Interoperability Requirements

It was deemed unclear as to which standards are intended to be required to be used internally within each provider's office, institution or closed system and which standards are intended to be required only for purposes of ensuring interoperability between such entities and consistency of information flows outside the borders of meaningful users. The HIT Standards Committee believes standards adopted in the IFR apply only to the interoperability of health information exchanged outside the perimeter of closed systems.

Recommendation 3.0
We request clarification in the Final Rule as to what is required for information capture and use inside the EHR versus what is required for interoperability of information exchanged outside the perimeter of closed systems.

Vocabulary for Vital Signs

Despite the importance of Vital Signs for Stage 1 of meaningful use and beyond, we note that no controlled vocabulary is adopted in the IFR. We believe controlled vocabulary standards for Vital Signs are needed now, and that a lack of adopted standards will lead to confusion and higher costs over time. Both SNOMED CT and LOINC currently are used for this purpose in the US, and both vocabularies may be deemed more appropriate than the other for some reasons, some purposes, and/or in certain situations. We understand, as with other clinical data, that multiple ways of capturing the same concept in vital signs can make more work for the developers of quality measures; at the same time, we see current usage and benefits of both SNOMED CT and LOINC for Vital Signs and we believe both vocabularies should be adopted for this purpose.

Recommendation 4.0
We recommend the adoption in this Final Rule of the following controlled vocabularies for Vital Signs: SNOMED CT and LOINC.

CAQH CORE Phase 1 Operating Rules

We applaud the inclusion of CAQH CORE Phase 1 Operating Rules in the IFR; we believe they provide much-needed implementation specifications and associated business rules for the applicable HIPAA Administrative Simplification transactions most widely used today. These are the ASC X12 Version 4010A1 standards. However, we note that CAQH CORE Phase 1 Operating Rules apply exclusively to transactions defined in this standard. At the same time, current HIPAA Administrative Simplification regulations allow today the use of transactions based on ASC X12 Version 5010 between willing trading partners, and mandate the use of these updated transactions on and after January 1, 2012. We believe this Final Rule should be restated to clarify that CAQH CORE Phase 1 Operating Rules may only be used with transactions that are based on the ASC X12 4010A1 standard, until new rules are available and tested successfully in conjunction with the ASC X12 5010 standard.

Recommendation 5.0
§170.205(d)(1)(ii) We recommend rephrasing this section as follows:
"(ii) The operating rules specified in Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) when transactions based on ASC X12 Version 4010A1 are exchanged between trading partners (incorporated by reference in § 170.299)."

Recommendation 5.1
At such time as CAQH CORE operating rules are available that support ASC X12 version 5010, we suggest ONC should update this section to account for their use between willing trading partners.

We appreciate the opportunity to provide these comments and look forward to discussing next steps for the Committee.

Sincerely yours,
/Jamie Ferguson/
Jamie Ferguson
Chair, Clinical Operations Workgroup

Sincerely yours,
/John Halamka/
John Halamka
Co-Chair, Clinical Operations Workgroup