HIMSS Electronic Health Record Association

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David Blumenthal, MD, MPP
Department of Health & Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

ATTN: HITECH Initial Set Interim Final Rule

Dear Dr. Blumenthal:

On behalf of the HIMSS Electronic Health Record (EHR) Association, representing more than 40 EHR suppliers with the vast majority of installed EHRs in the US, we applaud the effort put forth in the development of the Interim Final Rule (IFR) for standards and certification. In this letter, we provide comments on a number of key areas in the IFR.

Representatives from a number of EHR Association member companies reviewed the IFR. Our focus was on the primary tables contained in the document (Tables 1, 2A, 2B), the section related to accounting for disclosures, sections of Table 2 related to future development for Stage 2, and cost and preparation information in Tables 3, 4, 5 and 6. Our comments will be summarized briefly, followed by detailed recommendations and requests for clarification.

Summary Comments

Interoperability

As evidenced by the collaborative development and publication in 2005 of our Interoperability Roadmap, and its evolution over the past four years, the EHR Association has consistently supported a staged approach toward increasingly robust interoperability. We believe that the IFR offers a step in the right direction for interoperability, generally consistent with the EHR industry direction except in three areas:

- Introduction of an alternative to CDA/CCD, which was the result of harmonization of CDA with CCR.

- Lack of specificity for a consistent set of transport services for document exchange that covers the range of meaningful use value cases - simple direct point-point, basic sharing, nation-wide federation, e-mail and thumb drive.
- Lack of support for specific security and privacy standards needed to achieve effective interoperability.

In these three areas, the IFR does not, in our view, establish the specific technical specifications needed to deliver the necessary interoperability for Meaningful Use Stage 1, or at least to set an effective path for Meaningful Use Stage 2.

Although we appreciate the desire to keep the IFR flexible for Stage 1, it is unfortunate that the IFR did not follow the HIT Standards Committee recommendations to adopt *selected* HITSP Capabilities (e.g. CAP 118 and 119), directly relevant to the scope of Meaningful Use Stage 1 and Stage 2.

The EHR Association would be pleased to provide ONC with customer experiences that can address the IFR concerns that these HITSP implementation specifications are not sufficiently mature. This experience extends well beyond the EHR vendor community, and leverages several years of consensus building by the 600 stakeholders of HITSP, including federal agencies, prototyping and testing with NIST, product testing conducted as part of the Integrating the Healthcare Enterprise (IHE) Connect-a-thon, and, most importantly the hospitals and physicians that are currently exchanging clinical documents using this simple and effective approach to standard-based interoperability..

This progress is now becoming visible to the broad market and is the result of guidance provided by ONC over the past four years. It is the fruit of significant investments made by large and small EHR vendors and many other HIT vendors, including most of the leaders of the health IT industry. Maintaining such continuity with prior standards harmonization constructs would be consistent with the high-level framework set out in the IFR, and it would take interoperability to the strategic level needed to realize the full promise of Meaningful Use, ideally for Stage 1, but certainly for Stage 2.

Functionality

In this area, the IFR offers an approach to functionality that provides robust EHRs to hospitals and physicians. We have found that the functional criteria specified in the IFR are at an appropriately high level, given the meaningful use criteria on which they are based. Our comments are mainly targeted to improving the clarity and the specificity of the requirements to best meet the most important clinician needs:

- **Drug Interactions and Formulary Checks**
  We have a number of suggestions related to drug interaction processing and reporting, including the timing of real-time alerts, the standard to be used for formulary checking for hospitals vs. e-prescribing, and clarification around the ability to deactivate, modify and add rules. Also, reporting requirements must be clearer regarding how various types of alerts can practically be tracked.
- **Maintaining Problem Lists and Medication Lists**
  With regard to specified vocabularies, we generally recommend that the code or text not be required to display to end-users or providers, but used principally for interoperability and health

information exchange. We recommend specific changes to add clarity. For example, we suggest that "Medication Allergy List" be changed to "Active Allergy List" to ensure that both drug and non-drug allergies are included.

- **Record Demographics and Other Non-Clinical Data**
  We suggest using race and ethnicity codes based on federal standards as published by the Office of Management and Budget. The EHR Association is also recommending that the requirement to maintain growth charts for hospitals be dropped. While this may be appropriate in the ambulatory environment, hospital EHRs may not have adequate longitudinal data to accurately maintain such information.
- **Incorporate clinical lab test results into the EHR as structured data**
  We request clarification regarding the inclusion of lab test results in hospital EHRs. We suggest that this requirement apply only to lab test results related to a hospital admission; and that LOINC descriptions only be displayed and included in patient summary documents, not the codes themselves which should only be used in the electronic exchange of this information among labs and providers.
- **Report quality measures to CMS or states**
  The EHR Association is very concerned about the large number of quality measures being introduced, and strongly recommends that existing CMS measures with EHR specifications be used in Stage 1. We also suggest that standards should allow either the QRDA or PQRI XML format in Stage 1, with a single standard for Stage 2. We are concerned that the PQRI XML format does not have implementation guidance for hospitals and suggest that one be created. It is extremely important that states not be allowed to create additional quality measures, and that vendors not be required to comply with the wide variation in reporting requirements for quality, immunizations and syndromic surveillance data.
- **Implement five clinical decision support rules**
  With regard to the implementation of five clinical decision support rules, what is the meaning of "diagnostic test results", and is "condition" equivalent to "problem" or just to "diagnosis"? Are these rules to be associated with quality measures as indicated elsewhere in the meaningful use documents? If so, we suggest information be added to this criteria. We have concerns related to the variety of ways in which providers interact with CDS rules (e.g., pop-up messages or sounds) and have specific suggestions below in this regard.
- **Check insurance eligibility and submit claims electronically to public and private payers**
  Because EHRs do not provide this functionality, we strongly recommend removing criteria related to electronic eligibility checking and claims submission.
- **Provide patients with an electronic copy of their health information upon request**
  We generally support the criteria related to providing patients with an electronic copy of their health information but much more specification is required, including providing on-line access for patients to their health information within 96 hours needs clarification and whether this requires "push" to the patient, or on upon request only.
- **Exchange key clinical information among providers of care and patient-authorized entities electronically**
  We support efforts to advance the secure exchange of clinical information among providers. However, we seek further definition of "diagnostic test result" and "procedure" in the context of this criterion. Data transport is not addressed in the standards but this criterion refers to "transmit". We suggest changing the first criteria to "display" instead of "receive", and the

second criteria to ”export” instead of “transmit”. Please clarify whether a valid test for the vendor is generation of a CCD or CCR, but import and human-readable display of both document types is required.

- **Perform medication reconciliation at relevant encounters and each transition of care**
  Medication reconciliation is essential to safe patient care. In practical terms, the clinician user is responsible for the reconciliation of differences and EHR functionality does not compare differences in medication lists. We request clarification that this reconciliation could be accomplished manually by the clinician using EHR tools to compare one list to another, if the merge functionality is required for Stage 1. Please clarify that the intent is not discrete import of medications, which is beyond the appropriate scope of Stage 1. Any such functionality should be moved to Stage 2.
- **Capability to submit electronic data to immunization registries, reportable lab results and syndromic surveillance data, and actual submission where required and accepted**
  We recommend that products undergoing certification not be required to conform to the numerous state formats for these various reporting requirements. We seek further clarification of “retrieve” and how valid testing will be assessed.
- **Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities**
  With regard to the protection of electronic health information, the EHR Association fully supports the intent of the proposed regulations but we outline several specific concerns with the certification criteria and standards, including the lack of specific standards and issues with encryption requirements.

Definitions of Terms are Needed

In general, EHR Association reviewers found that there are a number of terms that, while generally understood in the medical community, need further specificity in the context of measurable criteria to determine meaningful use. For example, “specific conditions” is used broadly. We suggest a definition of “specific conditions” to mean conditions and related data as contained in the problem list.

Detailed Comments

I. Certification Criteria Table 1 (pages 2025-2028, Federal Register)

ROW 2 -- Implement drug-drug, drug-allergy, drug-formulary checks

1. The EHR Association is concerned that the criteria are vague and could be interpreted in various ways for certification testing. We would like to clarify that real-time alerts are intended to occur during the ordering process to initiate orders or revise current orders. Is the “age” reference inclusive of pediatric and geriatric?
2. The NCPDP standard is used in e-prescribing, which is a criterion for Eligible Provider (EP) certification, but not for hospitals in Stage 1. The EHR Association wishes to clarify that formulary checking in hospital certification should be based upon the hospital formularies only and not the NCPDP standard mentioned.

3. We would like to clarify that the ability to "deactivate" rules does not imply removal of specific rules or drug pairs as they exist in commercially-available clinical decision support (CDS) databases; that "modify" rules does not imply the ability of the administrator to change the rules as they exist in these commercially-available CDS databases; and that "add" new rules is not intended to imply that the administrator can create new rules in commercially-available CDS databases. We interpret "modify" to mean, for example, the requirement or not for an override or severity setting; and "add" to mean the activation of a category of CDS, such as drug-drug interactions, but not individual rules; and "deactivate" as to "turn off" specific types of rules.
4. We request clarification as to the reporting required. There are multiple types of alerts that may be unreasonable to track. The criteria also indicate tracking the number of alerts, but not responses, which may be of little value. We do not support a requirement to track responses. We suggest that report generation not be required to be automatic. We also suggest that alert tracking focuses on those alerts responded to as presented, and not alerts without response.

ROW 3 – Maintain an up-to-date problem list
We recommend that ONC should not require that the specified vocabulary be displayed as part of the problem list within the EHR, but rather to only require the specified vocabulary for interoperable exchange between EHRs.

ROW 5 – Maintain active medication list
The EHR Association suggests that the internal use of the specified vocabulary not be specified to the standard, but that the mapping to the specified vocabulary should be a requirement for the interoperable exchange between EHRs. For example, does use of the indicated standard preclude the use of RxNorm, if desired, for internal use currently? Is the intent to display the medication list with the standard nomenclature identified or just to use the standard only for interoperability? We suggest that the display not be mandated in the certification criteria, and that the vocabulary standard be required only for interoperable data exchange.

ROW 6 – Maintain active medication allergy list
We suggest that the criteria be changed to "Active Allergy List" and not "Medication Allergy List", as the list could include drug and non-drug allergies.

ROW 7 – Record demographics
We recommend that race and ethnicity codes should follow current federal standards published by the Office of Management and Budget in Table 2A as consistent with information in the IFR, page 1855 from the Federal Register document by the Office of Management and Budget in Table 2A (www.whitehouse.gov/omb/inforeg_statpolicy/#dr).

ROW 8 – Record and chart changes
The EHR Association suggests that growth charts are not meaningful or feasible for hospitals to maintain if a longitudinal trend is desired. We suggest that they should not be required certification criteria for inpatient systems.

ROW 9 – Record smoking status
We know of no defined industry standard value set for the smoking terminology required in this criterion. Are the examples indicated -- current smoker, former smoker or never smoked – the only limited responses allowed?

ROW 10 – Incorporate clinical lab test results into the EHR as structured data
1. We request clarification regarding these criteria in the hospital setting. Is this intended to be ALL results, or only results on patients admitted to the hospital? We suggest requiring only those lab test results obtained during the patient stay.
2. The EHR Association wishes to clarify whether the intent is the display of the LOINC code itself with a description, or the display of the description associated with the LOINC code in the patient summary documents. We suggest that the LOINC code should not be required in displays, but should be required only as part of interoperable exchange between EHRs.
3. We would like to clarify if the 42CFR 493.1291 point (2) regarding name and address of lab is required for in-house lab tests (laboratory tests performed in an inpatient LIS, not sent to an external reference lab)? We suggest that this not be required for in-house lab reports.
4. The EHR Association would like clarification as to whether "electronic update" has specific requirements, or is the term regarded as general to suggest a variety of responses (e.g., notation in chart that labs were reviewed)? We suggest that it not be required that a user first must review all lab tests before they are made available in the EHR, as that would severely impact workflow and availability of results.

ROW 11 – Generate lists of patients by specific conditions
We suggest removal of 'Patient's Clinical Information' as it is too vague, broad and not defined in the meaningful use requirements. We would also like clarification that "specific conditions" refers to problems and/or diagnoses.

ROW 12 – Report quality measures to CMS or states
The EHR Association suggests that standards should allow either the QRDA <u>or</u> PQRI XML format in Stage 1, with a single standard for Stage 2. We are concerned that the PQRI XML format does not have implementation guidance for hospitals and suggest that one be created. We encourage a focus on a subset of measures for certification, as there are many measures proposed without the benefit of completed testing or validation of cost and benefit.

ROW 13 – Send reminders to patients per patient preference for preventive/ follow-up care
We suggest a definition of "specific conditions" to mean conditions and related data as contained in the problem list.

ROW 14 – Implement five clinical decision support rules
1. The EHR Association seeks clarification regarding the proposed rules. What is meant by "diagnostic test results"? Is "condition" equivalent to "problem", or just to "diagnosis"? Are these rules to be associated with quality measures as indicated elsewhere in the meaningful use documents? If so, we suggest information be added to this criteria.
2. We do not believe that the alert types used as an example are inclusive of the variety of ways in which providers interact with CDS rules (e.g., pop-up messages or sounds). Is this deemed to be

more valuable than a more passive notification? Given the many ways in which providers can interact with CDS, we suggest that the word "alert" be replaced with "notification". The EHR Association suggests that use of evidence grade as a part of the rules to trigger alerts is not widely available in the marketplace. We also point out that, when available, using evidence grade in this manner could be burdensome and present a significant maintenance issue.

3. The EHR Association requests definition of the meaning of "alerts responded to by a user". Is the expectation that structured reasons for alerts and overrides will be entered by the user or that, in the case of notifications, the user will simply acknowledge the alert by clicking "OK"? This could be very difficult to track. Are ignored alerts are to be tracked? We strongly suggest removing #3, or providing specific examples of satisfactory responses, as many alerts are not conducive to tracking. As there are many kinds of alerts, forcing and tracking user acknowledgement could contribute significantly to "alert fatigue" on the part of the user, which is already reported in the literature as problematic, even prior to these proposed additional tracking requirements.

ROW 15 – Check insurance eligibility electronically from public and private payers
We suggest the removal of these criteria from the definition of a Complete EHR as these capabilities are out of scope of an EHR as defined in the industry (i.e., HL7 EHR Functional Model). As requested input, the EHR Association suggests that the CAQH CORE Phase I requirements not be included for Stage 1, noting that many payers may not be able verify eligibility electronically using these standards. Finally, a as clearinghouse services are frequently used to provide HIPAA compliant communication, criteria should not focus on the HIS modules only, but should allow for a clearinghouse service to fulfill the certification criteria.

ROW 16 – Submit claims electronically to public and private payers
We suggest the removal of this criterion from the definition of a Complete EHR as this capability is outside the scope of an EHR as defined in the industry (i.e., HL7 EHR Functional Model). As clearinghouse services are frequently in play to provide the HIPAA compliant communication, criteria should not focus on the HIS modules only, but should allow for a clearinghouse service to fulfill the certification criteria.

ROW 17 – Provide patients with an electronic copy of their health information upon request
The EHR Association requests clarification as to intent of this criterion. Is the intent to provide the patient with a complete medical record or simply a "snapshot"? How longitudinal must this record be? For example, attempting to provide larger data sets (such as ICU stay) for years of records to a single document may not be feasible. Please define "diagnostic test results". We suggest elimination of "medicine" from medicine allergy list. Please define how relevant procedures are determined for this request. We suggest that a defined subset of procedures (e.g., surgeries, catheterizations) be defined to avoid generating huge lists of "small" procedures (e.g., venipunctures). Please clarify that the medication list is limited to the current medication list.

It is essential that ONC provide a clear clinically-relevant definition of which types of procedures are to be included in the patient electronic copy and also for "exchange key clinical information" purposes.

The HL7 continuity of care (CCD) documents would better accomplish this task that the CCR, although we still think that it is important to bound the scope of the information that must be required. The continuity of care record (CCR) standard does not support information necessary for hospital-related health information (discharge information) In contrast, the CCD standard (which incorporates the clinical document architecture (CDA) standard supported by HL7), and its IHE and HITSP implementation guides is the only standard that can fully meet the intent of this item, especially for both criteria apply to EHRs for both eligible professionals and eligible hospitals, which must use the same standards specified in Table 2A, Row 1 in order to ensure that information be electronically provided and exchanged in a consistent manner. Our rationale for this conclusion is that:

1. The CCR is missing critical information related to hospitals health information (chief complaint, discharge diagnosis, etc.).
2. The CCR has never been recommended by the HIT Standards Committee as an alternative standard, although it was discussed at hearings. Finally, we note that the IFR should have displayed an asterisk by the proposed CCR given its status.
3. The additional implementation and deployment costs for an alternative to be phased out in Stage 2 needs to be accounted for. With the proposed requirement to support a second standard, additional costs are added to each EHR implementation. The desire for "simplicity" and flexibility miss the opportunity to simplify data exchange implementation in Stage 1 on the "creation" side, allowing EHRs to use either CCD or CCR. This approach introduces more burden on the "receiver" side in Stage 1, and will add **significantly** more burden and costs to receivers in Stages 2 and beyond.

Based on the clear recommendation of the HIT Standards Committee, the extensive consensus work performed by HITSP among its more than 600 stakeholders, including federal agencies, the EHR Association suggests that the standard for clinical document exchange should be CDA Release 2 with the CCD implementation guide extended by HITSP C32 with only the vocabularies defined in Table 2A. This should be at a minimum stated as the convergence target for Stage 2. There is no need to say "We also look forward to receiving recommendations from the HIT Standards Committee in this regard." (page 2031, column 2), because those recommendations have already been made.

Finally, we request clarification as to the testing necessary for product certification to support customers' ability to meet meaningful use. For example, would generation of a CCD and XDS (HITSP/TP13)/FTP/email of a document meet certification? We assume the import is implied without discrete data elements. Discharge summaries are assumed to most likely be separate documents such as an unstructured, dictated document, or could be included in expanded CCD.

ROW 18 – Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request

We request clarification as to the meaning of "procedures" in this objective. Are these procedures the procedures from this visit, or are these procedures that are scheduled for the future or during the post-discharge period?

ROW 19 – Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours from when the information is available to the eligible professional

The EHR Association requests that the word "online" in the EP criteria be replaced by the term "electronic", as the Objective says "electronic" and not "online". The use of "online" is inconsistent with the intent as stated in the document that this may be fulfilled with CD or USB and not online portal access. Please clarify the intent. We also request clarification as to whether this objective stating the 96-hour timeframe requires "push" to the patient, or is it only upon request? Also, these should be defined as 96 "business" hours. Is email considered online access? Also, since different pieces of information become available at different times (e.g., lab results aren't necessarily available at the same time or even the same day as the allergies), we suggest that the wording be changed to say "within __ hours of the time that the final set of information becomes available to the EP."

ROW 20 – Provide clinical summaries for patients for each office visit

We request a definition for "diagnostic test results". How is "encounter based note" defined? Is it longitudinal? Is the vendor required to support paper as well as electronic versions? Is the summary for "each" visit inclusive of "current problems" and "current meds," which may be from previous visits?

ROW 21 – Capability to exchange key clinical information among providers of care and patient-authorized entities electronically. Provide summary care record for each transition of care and referral.

The EHR Association requests definition of "diagnostic test result" and "procedure" in the context of this criterion. Data transport is not addressed in the standards but this criterion refers to "transmit". We suggest changing the first criteria to "display" instead of "receive", and the second criteria to "export" instead of "transmit". Please clarify whether a valid test for the vendor is generation of a CCD or CCR, but import and human-readable display of both document types is required. Also, please see our previous statements regarding CCD vs. CCR for Row 17.

R0W 22 – Perform medication reconciliation at relevant encounters and each transition of care

We suggest that Stage 1 medication reconciliation focus on the electronic tracking of the performance of medication reconciliation and not the specific merge functionality. The EHR Association notes that the clinician user is responsible for the manual reconciliation of differences and that EHR functionality does not compare differences in the lists. We request clarification that merge could be accomplished manually by the user performing such tasks as drag-and-drop from one list to another if the merge functionality is required for Stage 1. Please clarify that the intent is not discrete import of medications beyond the scope of Stage 1. The EHR Association recommends any such functionality be moved to Stage 2.

ROW 23 – Capability to submit electronic data to immunization registries and actual submission where required and accepted

We recommend that products undergoing certification not be required to conform to the numerous state formats for immunization reporting. The EHR Association assumes that "retrieve" implies the ability to "retrieve" data from EHR database. What constitutes a valid test?

ROW 24 – Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received
We recommend that products undergoing certification not be required to conform to the numerous state formats for reportable lab result reporting. Our Association assumes that "retrieve" implies the ability to "retrieve" data from EHR database. What constitutes a valid test?

ROW 25 – Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice
The EHR Association recommends that products undergoing certification not be required to conform to the numerous state formats for reporting syndromic surveillance data. We assume that "retrieve" implies the ability to "retrieve" data from an EHR database. We request clarification regarding the information that will be required to meet these criteria (e.g., lab results, diagnosis, etc.). What constitutes a valid test?

ROW 26 – Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities

Criterion (4) Encrypt and decrypt electronic health information according to user-defined preferences (e.g., backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B, ROW 1.
We suggest that this criterion be clarified as not to be intended for data at rest or physically secured. The EHR Association suggests the criteria is for data in transport, and not at rest (e.g., in the database) and would like clarification. Portable media encryption is the expectation, but we would like some clarification regarding the accomplishment of the encryption and decryption process for the media such as USB drives. Such encryption is not an EHR function.

TABLE 2B ROW 1, page 2035
Although the regulation text does not specify "AES", the specified bit values are only supported by AES. AES is not supported in older versions of Windows, which are very commonly used in business especially in healthcare (i.e., Windows XP, NT, 2000). FIPS 140-2 Annex A allows for 3DES or AES, so there should not be a mandate in the IFR that is more restrictive than FIPS 140-2. 3DES is widely available.

Criterion (5) Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B, Row 2
Table 2B, ROW 2, page 2035
We request that, if the intent is interoperability, TLS should be selected as the minimum criteria. Otherwise, there may be an unrealistic expectation that vendors must support all examples listed.

Criterion (6) Record actions (e.g., deletion) related to electronic health information in accordance with the standard specified in Table 2B, ROW 3 (i.e., audit log). Provide alerts based on user-defined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time
We suggest that "alerts" are not well defined and should be removed from the criteria.

Criterion (7) Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B, ROW 4

The EHR Association suggests clarification of "in transit" to mean network communications across organizational boundaries, not transmission of data within an internal network. Are the words "…and audit logs" a verb phrase for the data in transit integrity failure, or a noun phrase indicating a second standard of integrity protecting the audit repository itself? The EHR Association suggests removal of "and audit logs" from the criteria to make it more clear. Otherwise, how is SHA1 applied to audit information?

Table 2B, ROW 4-page, 2035

Please see comment above regarding SHA-1.

Criterion (9) Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in Table 2B, ROW 5

Table 2B ROW 5, page 2035

There is not sufficient implementation of the infrastructure necessary to support this requirement today. The criteria should be delayed until 2013 or 2015 so that providers can focus on developing the operational environment that can support identity assertions using SAML as profiled by HITSP/C19 and IHE/XUA. Note that the HIT Standards Committee has recommended against using SAML for 2011.

Criterion (10) Record disclosures made for treatment, payment and healthcare operations in accordance with the standard specified in Table 2B, ROW 6

Table 2B, ROW 6, page 2035

The EHR Association suggests that a parenthetical expression of text or object identifiers be added to the description to make it concise.

II Accounting of Disclosures

Fundamentally, there are only a few workflows where EHR technology can determine that an act will result in a recordable disclosure. We recommend that the real-time audit log focus on recording all security events without regard to whether the event will be used in an Accounting of Disclosures. Further, this security audit log should focus on identifiers and not descriptive values. Identifiers can be decoded in post-processing into descriptions (e.g., a user ID can be looked up in the user directory for the name of the user). This is especially true of the healthcare object that was accessed; including a description of the object accessed would be difficult in real-time and would make the security audit log itself a record with PHI. The security audit log contains many events that are not relevant to an Accounting of Disclosures, but it can be informative to an Accounting of Disclosures. Many security events may need to be combined to produce sufficient information to fully describe a recordable Accounting of Disclosures event. The security audit log can be post-processed into patient-specific Accounting reports.

We also ask that ONC clarify what is meant by the “description of the disclosure” so that the associated certification criterion can be implemented and tested against. Vendors and providers need such clarification as soon as possible. As with patient identification and user identification, the description should be allowed to be an object identifier that can be used in post-processing. With such an approach, real-time auditing of events is kept at a sufficient but minimal level; the record in the log is accurate yet minimal. In this spirit, we ask that ONC replace “description'” with “'description or identification”.

III. Content and Vocabulary Standards (Table 2A) pages 2033-2034 Federal Register

ROW 1
Rather than proposing CCD and CCR as alternatives, we believe that ONC’s objectives would better be accomplished with the CCD alone. CCR does not support the information necessary for hospital-related health information (discharge information), while the CDA alternative and its IHE and HITSP commonly- agreed implementation guides are the only appropriate alternative for this setting. Three important points that support this and further comments are described in our response to Row 17 on page 5 above.

UNII has not been mentioned in previous HITSP guides for medication lists. We suggest RxNorm for medication allergies. UNII is suggested for non-drug allergies in Stage 2.

ROW 2
Applicable Part D standards for hospitals should be required in Stage 2 only if e-prescribing is required for hospitals for Stage 2.

ROW 4
CAQH CORE Phase 1 may require additional certifications and does not have full market penetration. We suggest that the CAQH CORE requirement for administrative transactions be removed. For the version 5010, there are no CORE rules at present, and we do not expect any substantive changes from the ASC X12 base standard and implementation guides.

ROW 5
The EHR Association suggests that standards should allow either the QRDA <u>or</u> PQRI XML format in Stage 1, with a single standard for Stage 2. We are concerned that the PQRI XML format does not have implementation guidance for hospitals and suggest that one be created.

ROW 6
The EHR Association recommends that any public health reporting be required for HL7 2.5 for Stage 2, not as suggested for Stage 1.

ROW 7
We do not believe there is enough market penetration for GIPSE for inclusion in Stage 2, unless significant evaluation occurs before the requisite dates.

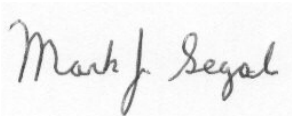
IV. Economic Impact Estimates (Tables 3, 4, 5 and 6), pages 2039-2041 Federal Register

We are not prepared to offer specific numbers for the preparation and certification of EHRs as requested. In general, the EHR Association would make the following comments relative to the cost analyses in Tables 3, 4, 5 and 6 on pages 102-106.

1. The dollar values suggested seem low. The suggested gap of 25% seems very low. We would suggest a 40-50% gap.
2. 43 (EH) or 90 (90) - Quality measures add a significant number of requirements and cannot be treated as only a single missing objective. There are many quality measures and many data elements and results to be calculated that will require significant changes throughout any EHR system.
3. The costs for development will need to be recalculated to include final development criteria. Costs must not just consider the development for certification functionality, but also the workflow redesign that must be accommodated within eligible provider and hospital systems.
4. Costs must consider interoperability implementation work.
5. Costs for hardware capable of supporting the security requirements must be considered.
6. Costs for resources for reimplementation of new functionality, including internal resources and customer resources, must be considered.

In conclusion, the member companies of the EHR Association greatly appreciate the opportunity to provide these suggestions and comments as part of the IFR process. We look forward to working with ONC staff toward final meaningful use criteria that support our mutual objectives to encourage the adoption of EHRs toward the overall improvement in healthcare quality and efficiency.

Sincerely,



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EHR Association Executive Committee

About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit http://www.himssehra.org.