

April 24, 2014

Steve Posnack
Director
Federal Policy Division, Office of Policy and Planning
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

RE: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements

Submitted via: http://www.regulations.gov.

Dear Mr. Posnack:

The American Health Information Management Association (AHIMA) is pleased to submit the following comments on the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria: Interoperability Updates and Regulatory Improvements. AHIMA represents more than 71,000 health information management and health informatics professionals in the United States and around the world. AHIMA is committed to promoting and advocating for high quality research, best practices and effective standards in health information and to actively contributing to the development and advancement of health information professionals worldwide. AHIMA's enduring goal is quality healthcare through quality information.

AHIMA thanks the Office of the National Coordinator for Health Information Technology (ONC) for issuing this request for comments and applauds the effort to address this critical and complex topic. In the following remarks, we offer comments on selected sections of the proposal.

§ 170.315(a)(4) (Drug-drug, drug-allergy interaction checks)

Comment Request

We therefore seek comment on whether we should consider adopting a certification criterion as part of a future edition of certification criteria that would require EHR technology to be able to track health professionals' responses to the DDI/DAI checks that are performed and whether such a capability should track if and when the health professional viewed, accepted, declined, ignored, overrode, or otherwise commented on the product of a DDI/DAI check.

AHIMA Comment

AHIMA supports capturing the health professional's response to the DDI/DAI. The response to the checks may then be tracked by the healthcare organization to support patient safety and outcomes. The organization will be able to determine if the DDI/DAI have been set to the appropriate adjustment as needed. This may also be used to review adverse outcomes and mitigate further untoward events. Finally, this supports the business record of the organization.

§ 170.315(a)(11) (Electronic notes)

Comment Request

- Whether this functionality should extend to all patient electronic notes stored in the EHR or
 just to a specific patient's electronic notes or specific types of patient notes;
- Whether we should require this functionality in the 2015 Edition or wait to include it in a potential 2017 Edition "electronic notes" certification criterion; and Show citation box
- Health care provider opinions on whether the availability of such functionality (either searching across a specific patient's electronic notes stored in the EHR or all patients' electronic notes stored in an EHR) is so widespread that it would be unnecessary to require it as a condition of certification. We note that the "electronic notes" objective and measure for MU Stage 2 requires that notes be text searchable, but does not require searching across electronic notes.
- Whether additional metadata should be required as part of electronic notes (such as the HL7 R2 header) to assist in both searching of notes, but also to make exporting electronic notes for patient data portability easier.

AHIMA Comment

While we support the functionality to search across notes, we believe that this is not likely to be helpful unless and until functionality is added to help manage the misuse of copy and paste of electronic notes. Notes which are repeatedly and carelessly copied and pasted from previous entries are often indecipherable and unwieldy and have little value; more important, they are often inaccurate and unsafe. We expect that searching across these poorly written notes would only add to both provider and patient frustration. While recognizing that misuse of copy and paste is a behavioral, education, and organizational policy issue, we also believe that facilitating adherence to organizational policy and reinforcing desirable documentation habits can be supported in EHR system design. We therefore strongly recommend adding functionality that would allow easier management of these notes so that the ability to search across notes will truly be beneficial. Search function should extend to all patient notes and we agree with the above recommendation that it should be added as a condition of certification. Additional metadata are essential for supporting search and portability of patient data and should be required as part of electronic notes.

§ 170.315(b)(1) (Transitions of care)

Comment Request

- We seek comment on the proposed standardized data to improve patient matching, including whether other data or constraints on proposed data should be modified to better support patient matching practices and work flow.
- Similarly, we request comment on how to best handle or anticipate changes to the way in which data may be represented in other rapidly evolving standards approaches. For instance, we are aware that V2 and V3 HL7 standards use an identical format for date of birth, but the more recent Fast Health Interoperable Resources (FHIR) standards framework uses a different format.
- In addition, we seek comment on approaches to address other recommendations from the HITSC. For example, data quality is an important aspect of patient matching success. We seek comment on methods that leverage the certification program, ways to test and measure data quality, and approaches to sharing best practices for improving data quality.
- Finally, we seek comment on additional findings from the 2013 Patient Matching Initiative that
 include studying non-traditional attributes to understand the potential for
 matching improvement, developing open source algorithms for testing purposes or use by EHR
 technology developers, the development of a formalized structure for establishing best practices,
 advancing consumer engagement with and access to their demographic data and attributes for
 correction or approval, and developing and/or disseminating options and training materials that
 improve data quality.

AHIMA Comment

Existing standards are largely targeted at vendor and source system data format and position, not content accuracy, completeness, or relevance to industry changes. Examples of such standards and their inadequacies include:

- The Patient Identification (PID) segments in the Health Level Seven (HL7) message not being consistently populated
- The use of components in the PID segment is not consistently implemented
- Vendors and providers typically do not upgrade to newer versions of the HL7 standards that incorporate better support of patient identification integrity

Various healthcare industry initiatives such as, Integrating the Healthcare Enterprise (IHE) have long embraced the need for protocols that address patient identification, including Patient Identifier Cross Referencing Integration (PIX), Patient Data Query (PDQ) and Patient Administration Management (PAM) integration profiles. However, these protocols and standards are not routinely adopted or consistently implemented by vendors, enterprises or HIOs. Organizations rely instead on data being captured in compliance with older HL7 standards. AHIMA recommends following the PIX, PDQ and PAM profiles.

We refer to the following AHIMA resources with regard to this comment:

- "Managing the Integrity of Patient Identity in Health Information Exchange (Updated)"
 Journal of AHIMA 85, no.5 (May 2014): 60-65.
- "Data Quality Management Model (Updated)." *Journal of AHIMA* 83, no.7 (July 2012): 62-67.
 - http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_049664.hcsp?d DocName=bok1 049664
- AHIMA. "Enabling Consumer and Patient Engagement with Health Information." *Journal of AHIMA* 88, no.2 (February 2014): 56-59.
 http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050578.hcsp?d DocName=bok1_050578
- AHIMA. Dimick, Chris. "Governance Apples and Oranges: Differences Exist Between Information Governance, Data Governance, and IT Governance." *Journal of AHIMA* 84, no.11 (November–December 2013): 60-62.
- AHIMA website Information Governance http://www.ahima.org/topics/infogovernance
- 1) For patient matching data quality AHIMA recommends:
 - *Previous names* should be captured in a separate field. 50% of real duplicates have a discrepancy in Last Name and/or First Name, so previous names are important.
 - Name should be stored in four separate fields: Last Name, First Name, Middle Name, Suffix
 in the source system's database. In order to accommodate better matching accuracy and to
 differentiate between common names for male and minor patients (specifically children's
 hospitals) the Mother's Maiden Name should be a required data element.
- 2) AHIMA recommends that the *V2 and V3 HL7 standards and Fast Health Interoperable Resources* (*FHIR*) standards should be harmonized.
- 3) It is more difficult to match records that are missing key fields than it is to compensate for typographical or misaligned information. AHIMA recommends that data quality be measured by the percentage of (non-bogus or default) values present in each of the key required demographic fields.
- 4) AHIMA recommends that more attention should be placed on developing an accurate testing procedure to certify the accuracy of the patient matching reports so healthcare organizations can be made aware of what types of duplicate records they are missing. Each matching algorithm should be rated on how many real duplicates along with how many false duplicates (false alarms) they report and, finally how many real duplicates they miss (false negatives). If this approach is not feasible because of vendor push-back, then each hospital should be required to perform an independent audit with a certified advanced matching algorithm to validate the accuracy of the healthcare organizations' MPI on an annual basis.

Clinical Quality Measures – Electronically Processing eMeasures

Comment Request

- We solicit comment on industry support for unified, modularized CDS and CQM standards for the 2017 Edition.
- We also solicit comment on what we should require EHR technology to be able to demonstrate for certification (e.g., to require that EHR technology be able to electronically process any eCQM formatted in a unified, modularized CQM standard such as a new HQMF standard). To inform our future rulemaking, we also solicit comment on:
 - Recommended testing and certification processes for the electronic processing of eCQMs;
 - A way in which to classify measures so as to select a subset of measures that would be easier and simpler to be electronically processed by EHR technology in testing and certification;
 - The ability/readiness of EHR technology to store and incorporate an eCQM in HQMF R2;
 - The ability/readiness of EHR technology to map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information).

AHIMA Comment

Both the unification of CDS and CQM and the creation of modules that can be independently updated without changing the entire standard should make it easier to not only ensure that the underlying data in CDS would be there to support new CQM's but provide flexibility to make changes targeting a specific module in a more timely manner.

AHIMA believes that the readiness of EHR technology to handle eCQMs and/or updates to new versions of the standards such as HQMR R2 is varied and feels that until EHR certification includes the actual capability of creating, processing and submitting eCQMs directly from the EHR, we won't be able to determine the readiness of the technology to support quality measures and whether the data received is consistent across systems and can support the measures.

Clinical Quality Measures – Functions and Standards for CQM Certification

Comment Request

To inform our 2017 Edition rulemaking, we solicit comment on what requirements for supplemental data and reporting should be included as part of CQM certification criteria. Quality reporting programs such as those required by states and CMS programs other than the EHR Incentive Programs may require additional supplemental data and capabilities beyond what ONC currently requires for certification. For example, the HIMSS EHR Association (EHRA) issued a letter to CMS in November 2013, citing variances between ONC's certification requirements and a supplemental implementation guide CMS issued, "Hospital Quality Reporting (HQR) Quality Reporting Document Architecture Category I Release 2 Supplementary Implementation Guide." 70 According to EHRA, these variances include, but are not limited to:

- The need to create QRDA—I reports on a per encounter basis rather than per patient, as had been required for certification;
- The EHR certification number must be assigned to each QRDA submission, an entirely new data element that would need to be added to databases and user interfaces in many cases;
- The new requirement to include the NPI/TIN for "associated providers" when the official Data Element Catalog referenced as a standard by ONC indicated that the NPI would only be required for EPs—again, a new data element with multiple implications for software development and provider usage.

AHIMA Comment

EHR certification should attempt to incorporate commonly used supplemental data elements to the extent possible but recognize that the universe of data elements that may be used at the state or national level may not be able to be included. Certainly any data elements used in CMS programs that are intended to allow eMeasures to be used for reporting need to be included, otherwise providers would not be able to meet those program requirements with their EHR data elements.

§ 170.315(c)(1) (Clinical quality measures – capture and export)

Comment Request

We solicit public comment on the following in consideration of our upcoming 2017 Edition rulemaking. In the 2014 Edition Final Rule, we required that for certification to 170.314(c)(1) EHR technology be able to export a CQM data file formatted in accordance with the QRDA Category I standard. We solicit public comment on the potential usefulness of broadening the export requirement to also include reference to a QRDA Category II formatted data file, which would address the bulk reporting of quality data that includes the patient level data as outlined in the QRDA Category I report.

AHIMA Comment

AHIMA is not sure that it is important to add QRDA Category II format to the certification requirements would be at this point in time. Category I reports should provide all the raw data necessary to calculate the eMeasures. Adding flags and including multiple patients into one file, which is basically what Category II would allow may be more of a stretch right now for implementers. AHIMA would rather see the focus on ensuring that the right data is being collected and classified and that we can get it out of the EHR at the patient level before adding another format for vendors to handle.

§ 170.315(d)(3) (Audit reports)

Comment Request

Should we establish a minimum/baseline set of actions that EHR technology must always be capable of being audited. For instance, we could see the potential for "copy," "print," and "query" capabilities to not be included in certain EHR technologies.

Thus, we could set a baseline that within section 7.6's actions, EHR technology must always support "additions, deletions, and changes."

AHIMA Comment

AHIMA supports establishing a minimum/baseline set of actions that EHR technology must always be capable of auditing. We agree that EHR technology must always support the following actions "additions, deletions, and changes." In addition, "print", "transmit", "copy" are functions that must be captured. Printing and transmitting are critical when researching security incidents and potential breaches under HIPAA. In order to fully investigate and mitigate concerns, an audit trail of who, what, where and when the information was printed or transmitted must be supported. In addition, the multiple reports on records that have been copied within the EHR have caused many patient outcome and billing concerns. The ability to track the copied information will help to track and mitigate patient safety concerns. AHIMA references the following materials with regard to this comment:

- AHIMA Position Paper: Appropriate Use of the Copy and Paste Functionality in Electronic Health Records http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050621.pdf
- CMS and Its Contractors Have Adopted Few Program Integrity Practices to Address Vulnerabilities in EHRs. DHHS Office of the Inspector General. OEI-01-11-005751. January 2014. http://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf
- Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications. Bowman, Sue, MJ, RHIA, CCS, FAHIMA. Perspectives in Health Information Management. Fall 2013. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797550/
- AHIMA Testimony to the HIT Policy Committee on Clinical Documentation. Dougherty, Michelle. February 13, 2013.
 http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050290.pdf
- Are Electronic Medical Records Trustworthy? Observations on Copying, Pasting and Duplication.
 Hammond, Kenric W., MD; Helbig, Susan T., MA, RHIA; Benson, Craig C., MS; and Brathwaite-Sketoe, Beverly M., BS. AMIA 2003 Symposium Proceedings.
 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1480345/

Comment Request

(3) Are there other actions that we should consider specifying in an updated standard for the 2017 Edition that the current standard does not sufficiently address, such as the act of "transmission"? We do not favor this approach because implementing it in regulation would cause us to add to the existing standard. Thus, we seek feedback on whether the standard is sufficiently up-to-date and appropriately specifies all of the actions necessary for EHR audit logs to capture.

AHIMA Comment

AHIMA believes that data provenance is a critical issue. AHIMA believes that when data are sent and/or received, information describing who, what, when, and how data must be captured along with where the data originated. These functions are critical as evidenced by the newest S&I Framework initiatives on Data Provenance.

Comment Request

(4) Finally, we seek comment on whether there are any alternative standards to ASTM E2147 that we should consider in light of the aforementioned concerns and ambiguities.

AHIMA Comment

AHIMA recommends the consideration of HL7/ISO 10781 Electronic Health Record Functional Model (EHR-FM), specifically the Record Infrastructure section.

§ 170.315(e)(1) (View, download, and transmit to third party)

Comment Request

We seek comment on whether we should require another transmission method as part of this certification criterion in addition to the one just discussed.

AHIMA Comment

Per the 2017 criteria, in order to prevent re-testing and the associated additional healthcare costs, it is essential that medical images be viewable, downloadable, and transmissible by patients or their representatives and should be of diagnostic quality to enable patients or their representatives to enable coordination of care. Cloud technology with the appropriate security provisions could be ideal for this and should be supported. The same should be applicable to any and all other non-text data in the EHR, including wave forms such as ECGs. Full patient access to <u>all</u> information and data in EHRs is necessary to foster patient engagement. Perhaps more than even other data, open notes are essential and are potentially a powerful patient teaching tool and must therefore by supported by EHR certification criteria.

Duplicate Patient Records

Comment Request

We seek comment on provider demand for/interest in these types of capabilities in addition to any capabilities that should be included or excluded from this potential certification criterion.

AHIMA Comment

AHIMA recommends that more attention should be placed on developing an accurate testing procedure to certify the accuracy of the patient matching reports so healthcare organizations can be made aware of what types of duplicate records they are missing. Each matching algorithm should be rated on how many real duplicates along with how many false duplicates (false alarms) they report and finally how many real duplicates they miss (false negatives).

Disaster Preparedness

AHIMA Comment

Please refer to the following AHIMA resource:

 "Disaster Planning and Recovery Toolkit", ISBN: 978-1-58426-088-2. AHIMA Product No.: ONB189013 http://journal.ahima.org/2013/08/28/planning-for-the-unthinkable-ahima-introduces-disaster-planning-and-recovery-toolkit/

Comment Request

Whether there could be a standardized naming convention for EHR technology to use for temporarily naming unidentified patients during disaster and emergency events?

AHIMA Comment

AHIMA believes that standard naming conventions are needed because there can be issues with trauma patients with duplicate names, i.e., John Doe 1 and they are important to patient identity and data integrity.

Comment Request

Whether EHR technology should be able to denote care provided during disasters or public health emergencies and allow for designation of care provided under situations which demand contingency or crisis standards of care?

AHIMA Comment

E-codes in ICD-9 can be assigned to each patient treated in a disaster situation to enable identification of those specific patients.

Conclusion

Thank you for providing AHIMA the opportunity to comment on these important criteria. We look forward to continuing our work with you to advance our nation's healthcare system. If you have any comments or questions, please do not hesitate to contact me at Lynne.ThomasGordon@AHIMA.org or Meryl Bloomrosen, AHIMA's Vice President for Public Policy Government Relations, at Meryl.bloomrosen@ahima.org or at 202-659-9440.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA

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CEO

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