Meaningful Use White Paper Series
Paper no. 9: Comments on EHR Certification Standards
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Overview of AHIMA's Comments on EHR Certification Standards

Preceding papers in this series have reviewed the requirements in the notice of proposed rulemaking on meaningful use, published by the Centers for Medicare and Medicaid Services in January 2010. The eighth paper offered an overview of AHIMA's comments on the proposal. This ninth and final paper highlights AHIMA's comments on the related interim final rule on standards for certification, including the accounting of disclosure standard.

In order to be eligible for the meaningful use incentive program, healthcare providers must use EHR technology that meets certification standards set by the federal government. On January 13 the Office of the National Coordinator for Health IT (ONC) published an interim final rule for these standards, which became effective February 12. However, the rule is not final, and the comments that ONC receives until March 15 could affect the content of the eventual final rule.

AHIMA's comments on the IFR were prepared by members and staff. AHIMA has been involved in both the creation of standards through active participation in standards bodies such as Health Level Seven International (HL7) and as a founder of the Certification Commission on Health Information Technology (CCHIT).

[*Note:* As this paper was written, AHIMA's comments were still under review. Readers are urged to refer to the final set of comments when published March 15 at www.ahima.org/arra.]

General Comments on the IFR

AHIMA begins its general comments by asking for clarification of the various bodies that now could be involved with the establishment of health IT standards as well as certification criteria, testing, and other roles that have previously involved groups such as the Healthcare Information Technology Standards Panel, standards bodies, and CCHIT. AHIMA also notes the current involvement of health information management professionals with standards and the need for a national approach and consistent interoperability formats.

The Association stresses the need for ONC and the Department of Health and Human Services to continue to communicate clearly to the industry on the impending HIPAA 5010 and ICD-10-CM/PCS implementation deadlines to ensure that providers do not ignore these requirements while pursuing the meaningful use program.

AHIMA calls for ONC to expand the definition of a qualified EHR to include the ability to produce a health record for legal, business, and disclosure purposes. AHIMA goes on to raise questions on

ONC's definition of disclosure, noting concerns regarding disclosures from the EHR and disclosures that might occur within or between health information exchange organizations. (This is also a concern related to the accounting requirements.)

The Association's comments also request specific criteria that would ensure a qualified product meets the need for a legal EHR and cites the HL7 Records Management and Evidentiary Support Functional Profile as an established source for those criteria.

AHIMA's comments also reflect recommendations from the Health IT Policy work groups related to incorporation of clinical lab test results into the EHR as structured data and the need for more detail on how to calculate reporting metrics to substantiate meaningful use functionality reporting.

The Association requests clarification on the "electronic access" described in the IFR. AHIMA suggests that the objective be restated to "Provide patients with *secure* and timely electronic access." Further AHIMA requests that ONC address the necessary security and encryption requirements needed to support the objective.

In Support of the CCD and QRDA

There is some debate on whether the rule should adopt the CCR or CCD format. Within its comments AHIMA comes out clearly in favor of the CCD because it has already been approved by the Health Information Technology Standards Panel.

AHIMA likewise comes out in favor of using the HL7 Quality Reporting Document Architecture (QRDA) standard and Implementation Guide, indicating the value of this standard and its relationship to the HL7 Clinical Document Architecture. AHIMA urges ONC to include QRDA as an adopted quality reporting standard during meaningful use stage 1, noting that "adopting QRDA now will prevent switching of standards and rework for vendors in the future."

Citing the Health Information Exchange work group's recommendations at a recent Health IT Policy Committee meeting, AHIMA states its support to extend the same certification criteria for hospital lab reports to all lab result reporting and not just to public health as proposed. AHIMA notes that clarifying this expectation will support hospital laboratory results delivery to eligible professionals attempting to comply with the meaningful use requirements.

Gaps in the Certification Standards

AHIMA raises its concern that the proposed standards are targeted to specific functionality and do not address standards for basic EHR functionality. AHIMA notes that CCHIT has already developed consensus-based certification criteria for both inpatient and ambulatory EHRs; however, ONC made a conscious determination to not adopt previously recognized certification criteria in the IFR.

This, AHIMA states, leaves a large gap between the previous standards and the new limited targets that ONC proposes, and the Association makes several recommendations to eliminate this gap. AHIMA comments, "We are concerned that the proposed standards will not adequately support the stated goals of healthcare improvement and adequate privacy and security because of missing foundational requirements for EHR systems and modules. Meaningful use will not be effectively achieved if the underlying data is not accurate, complete, and of unassailable integrity. The

government has not identified any standard for underlying EHR systems or modules that support system and data integrity, authentication standards, and non-repudiation."

AHIMA ends its comments by raising several questions with regard to collection of information regarding the use of the EHR and the required audit logs.

Accounting of Disclosures

The IFR includes a simple standard for the accounting of disclosure provisions called for under ARRA, which extends the HIPAA accounting of disclosure provision to include disclosures from EHRs for uses of treatment, payment, and operations.

AHIMA commented on this standard in a separate letter because the accounting of disclosure issue is of such concern to its members.

In its comments AHIMA notes that although the standard is simple—calling for the capture of just four data elements—it still represents a major challenge for the industry because few EHR products are currently capable of tracking disclosures. Accounting is still a manual process in most provider organizations, and disclosures are typically decentralized across multiple departments and IT systems.

AHIMA agrees that consumers have a right to know to whom their record was disclosed. However, given the number of legacy systems to be adapted and the cost of adopting new systems, the Association believes the industry cannot meet the timetable set by the statute, and not without significant cost. It recommends that ONC modify the compliance deadlines to better reflect the work and cost involved.

Further, AHIMA suggests that it would be helpful to the healthcare industry and consumers to understand the issues and costs associated with the accounting of disclosure requirement. Because disclosures occur through systems beyond the EHR, this estimate should include all systems in an entity that must track disclosure, not just the EHR system.

Extending the original HIPAA accounting provisions to include treatment, payment, and operations raises questions and concerns about how the IFR intends to define an entity (e.g., a specific provider or an entire enterprise) and exactly what transfers are covered (e.g., disclosures to physicians in a hospital EHR network who are not hospital employees).

AHIMA also notes that while the certification standards apply to the EHR, many of the disclosures possible under its interpretation of the rule come from systems outside the EHR. The Association asks for clarification on whether ONC intends to suggest that an EHR is all records within the medical enterprise, or at a minimum any system that contains protected health information.

Although the standard identifies the data elements to be captured, AHIMA's notes in its comments that the industry will require standards for how those data are to be represented (e.g., the formats for date, time, and patient name). The Association also comments that the description of the disclosure will of necessity be a coded process, and it asks who will designate a code set for this use.

Given the volume of disclosures that even a small physician practice will log, even abbreviated descriptions will come to require considerable server space. AHIMA notes that striving for simplicity and uniformity in the rule will help minimize administrative costs.

For more ARRA resources and ongoing analysis of future regulation, visit www.ahima.org/ARRA.

References

Centers for Medicare and Medicaid Services. "Medicare and Medicaid Programs Electronic Health Record Incentive Program." *Federal Register* 75, no. 8 (Jan. 13, 2010): 1844–2011. Available online at http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf.

Office of the National Coordinator for Health Information Technology, Department of Health and Human Services. "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology." *Federal Register* 75, no. 8 (Jan. 13, 2010): 2014–47. Available online at http://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf.