



November 14, 2008

Office of the National Coordinator for Health Information Technology
Attention: Use Case Team
Mary Switzer Building
330 C Street, S.W. Suite 4090
Washington, DC 20201

Dear Use Case Team:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office of the National Coordinator's Consumer Adverse Event Reporting (CAER) Extension/Gap.

AHIMA is a not-for-profit professional association representing more than 52,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

AHIMA and its members participate in a variety of projects with other industry groups and federal agencies related to the use of healthcare data for a variety of purposes including direct care, quality measurement, reimbursement, public health, biosurveillance, research, and personal health information management.

In addition, AHIMA sponsors a national effort to raise consumer awareness and knowledge around the important issues concerning personal health information management and security. AHIMA members provide local consumers with education on the proper development and maintenance of personal health records and free information, tools, and resources available at www.myPHR.com, AHIMA's free, consumer Web site for comprehensive, unbiased and peer-reviewed information.

Our comments focus on those areas of particular interest to our members. We believe the extension/gap is a good foundation; however, we have outlined some recommendations as ONC continues to expand the document.

3.0 Functional Needs

- “Guidelines” are mentioned multiples times throughout this section of the document but it is unclear whether these guidelines are simply informational in nature or intended to be formally incorporated into electronic systems. The term "guidelines" should be more clearly defined.

5.0 Issues and Obstacles

- Although confidentiality, privacy and security are addressed in the Public Health Case Reporting Use Case, consumer reporting of adverse event data may be inhibited if consumers lack the knowledge and understanding of privacy and security measures in place. Consider adding a statement addressing this point in the Issues and Obstacles section of the Consumer Adverse Event Reporting Extension/Gap.
- The Issues and Obstacles section does not contain reference to challenges related to timeliness of consumer adverse event reporting. Consider adding a statement addressing this point.

5.0/E. Significant Change in the Quality of Adverse Event Reports

- This section describes how the increase in adverse event reporting will cause additional workload for organizations involved in investigational follow-up. The title of this section states “quality of adverse event reports” but there is no description of the issues associated with data quality and validity. Consider adding another sub-bullet (E.i.b.) to describe potential data quality and validity challenges.

6.0 References to Use Case Scenarios (Figure 6.2)

- Page 11 states, “The events and information flows that are pertinent to the Consumer Adverse Events Reporting Extension/Gap are shown in bold. All other events and information flows have been faded out.” In Figure 6.2 (far right column), the consumer action is grayed out. If consumers are intended to be an information source and/or recipient, the consumer action should be shown in bold.
- In situations where adverse events directly impact a consumer, it may be useful for provider EHR systems to report adverse event data to consumer PHR systems. This type of information flow will keep consumers informed, help maintain consumer PHR data, and support future clinical care management.

8.0 Consumer Health Event Reporting Dataset Considerations

- True interoperability will not occur until data definitions and codes are standardized and incorporated into technical standards. AHIMA recommends including additional information describing how the data sets created for consumer health event reporting will be aligned with other healthcare data sets (for example, AHRQ Common Formats, etc.). Adding this guidance to the data set considerations will support a movement toward interoperable systems and support the collection of data once so it can be repurposed multiple times.

Appendix B: Analysis and Examples

- The HL7 PHR System Functional Model (PHR-S FM) should be described in the analysis and examples section of the extension/gap. The PHR-S FM identifies the features and functions necessary to create and manage an effective PHR. The PHR-S FM is an ANSI approved draft standard for trial use (DSTU) and has been submitted to the Certification Commission for Health Information Technology (CCHIT) for review. This extension/gap will help strengthen and refine the conformance statements described in the PHR-S FM. The PHR-S FM will support the integration of the required functionality into future PHR systems.

As an active developer and promoter of technical standards, we look forward to a day when all uses of data, whether produced for patient care, quality measurement, or public health reporting, accurately portray the diagnoses, severity, and services provided. AHIMA welcomes the opportunity to work with ONC and the healthcare industry to see that all these goals are met.

We thank you for this opportunity to submit our findings on this very critical phase of public health reporting. If AHIMA can provide any further information, or if there are any questions or concerns in regards to this letter and its recommendations, please contact me at (312) 233-1537 or crystal.kallem@ahima.org or Donald Mon, AHIMA's Vice President of Practice Leadership, at (312) 233-1135 or donald.mon@ahima.org.

Sincerely,



Crystal Kallem, RHIA
Director, Practice Leadership

cc: Donald T. Mon, PhD Vice President of Practice Leadership, AHIMA