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An American National Standard

Standard Guide for Amendments to Health Information[1]

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1. Scope

1.1 This guide addresses the criteria for amending individually-identifiable health information. Certain criteria for amending health information is found in federal and state laws, rules and regulations, and in ethical statements of professional conduct. Although there are several sources for guidance, there is no current national standard on this topic.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1762 Guide for Electronic Authentication of Health Care Information

E1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records

3. Terminology

3.1 *Definitions:*

3.1.1 *amendment*, *n*—alteration of health information by modification, correction, addition, or deletion.

3.1.2 *authentication*, *n*—provision of assurance of the claimed identity of an entity, receiver, or object. **(E1869, E1762, CPRI[3])**

3.1.3 *author*, *n*—person(s) who is (are) responsible and accountable for the health information creation, content, accuracy, and completeness for each documented event or health record entry.

3.1.4 *commission*, *n*—act of doing, performing, or committing something. **(Webster's 1993)**

3.1.5 *confidential*, *adj*—*(1)* status accorded to data or information indicating that it is sensitive for some reason and needs to be protected against theft, disclosure, or improper use, or all three, and must be disseminated only to authorized individuals or organizations with an approved need to know; *(2)* private information, which is entrusted to another with the confidence that unauthorized disclosure that will be prejudicial to the individual will not occur. **(E1869)**

3.1.6 *delete*, *v*—*(1)* to eliminate by blotting out, cutting out or erasing; *(2)* to remove or eliminate, as to erase data from a field or to eliminate a record from a file, a method of erasing data. **(Webster's 1993, Webster's New World Dictionary of Computer Terms, 1994)**

3.1.7 *error*, *n*—act involving an unintentional deviation from truth or accuracy.

3.1.8 *health information*, *n*—any information, whether oral or recorded, in any form or medium *(1)* that is created or received by a health care practitioner; a health plan; health researcher, public health authority, instructor, employer, school or university, health information service or other entity that creates, receives, obtains, maintains, uses or transmits health information; a health oversight agency, a health information service organization, or *(2)* that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payments for the provision of health care to a protected individual; and, *(3)* that identifies the individual with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. **(HIPAA[4], E1869)**

3.1.9 *information*, *n*—data to which meaning is assigned, according to context and assumed conventions **(E1869)**

3.1.10 *omission*, *n*—something neglected or left undone, the act of omitting. **(Webster's 1993)**

3.1.11 *permanence*, *n*—quality of being in a constant, continuous state.

4. Significance and Use

4.1 The purpose of this guide is to assure comparability between paper-based and computer-based amendments. Paper-based and computer-based amendments must have comparable methods, practices and policies, in order to assure an unambiguous representation of the sequence and timing of documented events. Original and amended health information

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] CPRI (Computer-Based Record Institute), 4915 Saint Elmo Ave., Suite 401, Bethesda, MD 20814 (http://www.cpri.org).

[4] HIPAA (Health Insurance Portability and Accountability Act), 1996 (http://www.hcfa.gov/hipaa/hipaahm.htm).

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entries and documents must both be displayed and must be consistent across both domains. Comparability does not rule out, however, the use of capabilities specific to the electronic world, which do not have paper-based counterparts, for example, displaying the amended text with a pop-up window, which can show the text prior to its amendment.

4.2 Traditional paper-based health records and policies support the need of authorized authors of health information to amend entries and documents in the health record under appropriate circumstances. In a paper-based health record, amending entries is accomplished by drawing a line through the erroneous entry, writing in the correct information, and authenticating the amendment by signing and dating the change. Such corrections always display the original documentation along with the amendment. This procedure is used to assure an unambiguous representation of the sequence and timing of documented events and any appropriate amendments.

4.3 Current and emerging technologies for health records, including, but not limited to, computer-based health records, employ different input and display methodologies than the traditional paper-based record and, therefore, different amendment alternatives for health record or health information entries, or both. Health information may be entered directly into an automated, electronic, or computer-based health record system, for example, by voice, keyboard (either by the care practitioner, transcriptionist, or other intermediary), mouse, pen, tablet, a personal digital assistant, or through the use of structured data entry. Unlike a written record, which essentially is always viewed in its original handwritten or typewritten form, the presentation and display of electronic and computer-based health information often is transformed. This transformation occurs when information is transferred from one computerized system to another system or filtered by different display characteristics or views of the data. In addition, in contrast to the paper-based record, computers and computer systems can modify display of the data directly, for example, in nonchronological order or filtering through queries. Amended electronic records should display a distinct and obvious notation of their amended state. Access to the original health information should be immediately available, that is, prior amendments back to and including the original record.

5. Authentication of Authorship

5.1 Under this guide, authentication is used to prove authorship of each documented event or health record entry.

5.1.1 For handwritten records under this guide, authentication of the author is provided through the act of signing or initialing an entry.

5.1.2 For computer-based health information systems under this guide, authentication of the author is provided through the use of a digital signature (see Guide E1762).

6. Health Information Permanence

6.1 Health information attains permanence when it is authenticated by its author(s) as a complete and final document, as established by organizational policies and procedures. Organizational policies and procedures, regulations from regulatory, accreditation, and standards organizations and agencies, professional associations, as well as legislative and legal requirements, define explicit rules as to what constitutes a permanent entry into a health record and whether or not that entry or document must be authenticated by the author.

6.2 Once an entry is complete, final and authenticated by its author(s), permanent health information can be altered only through the process of amendment.

6.3 Organizational policies and procedures that define permanence must consider the following:

6.3.1 Authenticated or unauthenticated health information in paper or electronic form is permanent when it becomes available for viewing or reading by any health care practitioner other than the author for concurrent or subsequent direct care of the patient about whom the health information is documented.

6.3.2 Unauthenticated health information used in the direct provision of health care or in the process of health care decision making, must be marked clearly, legibly, and obviously as unauthenticated or defined and clearly understood as unauthenticated. Examples of unauthenticated health information are as follows:

6.3.2.1 *Dictated or Transcribed Reports*—Notes, histories and physicals, discharge summaries, consult reports, letters, procedure notes and reports, diagnostic study reports.

6.3.2.2 *Preliminary Reports*—Diagnostic studies, laboratory values, images and image reports.

6.3.2.3 Unsigned handwritten, typed, copied, facsimile, printed or computer-based health information.

6.3.2.4 Handwritten notes or documents that also have been dictated and eventually will be transcribed.

7. Amending Health Information

7.1 Amending health information is appropriate when an explicit error is recognized, information is disputed, or there is an error of omission or commission in documentation. Any request to amend or modify health information must be documented and retained as part of the health record, including acceptance or denial of the request.

7.2 An amendment may be appropriate when the following occurs:

7.2.1 An explicit error is detected while reviewing health information, for example, when an image technician reviews health information and determines the abnormal mammogram actually belongs to the patient's mother who has the same last name.

7.2.2 The author determines further health information needs to be added to an existing document, which constitutes an error of omission, for example, the dictating physician realizes that he or she left something out during the original dictation.

7.2.3 The author determines that the entry or document contains information that does not actually apply to what has transpired with a patient and about whom the information has been entered or documented, which constitutes an error of commission, for example, when a physician realizes that he or she has documented a more complete physical exam than was actually performed on the patient.

7.2.4 A health care practitioner who is responsible for supervising or overseeing another health care practitioner determines there is an error in the record, for example, an