Designation: E 2017 – 99

An American National Standard

Standard Guide for Amendments to Health Information[1]

This standard is issued under the fixed designation E 2017; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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:*

E 1762 Guide for Electronic Authentication of Health Care Information[2]

E 1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Computer-Based Patient Records[2]

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. **(E 1869, E 1762, 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. **(E 1869)**

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], E 1869)**

3.1.9 *information*, *n*—data to which meaning is assigned, according to context and assumed conventions **(E 1869)**

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 entries and documents must both be displayed and must be consistent across both domains. Comparability does not rule

[1] This guide is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.20 on Data and System Security for Health Information.

Current edition approved May 10, 1999. Published September 1999.

[2] *Annual Book of ASTM Standards*, Vol 14.01.

[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).

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 E 1762).

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

attending physician reviewing the work of a student, resident, physician assistant or advanced practice registered nurse.

7.2.5 A patient requests the opportunity to amend personal health information, which he or she deems to be in error, for example, a patient disagrees with the health care practitioner's statement of his or her use of alcohol.

7.2.6 A system programmed for possible error detection detects a possible data error or questions the reasonableness of data, for example, laboratory values that are impossible for the stated test.

7.3 Individuals authorized to request an amendment to health information may include the following:

7.3.1 The author of a health information entry or document.

7.3.2 The individual ordering, providing service or evaluating care that is documented in that health care entry.

7.3.3 An individual supervising, responsible for or evaluating another health care practitioner's care of a patient.

7.3.4 A patient or guardian who requests an amendment to his or her own personal health information.

7.3.5 A human or system-process that flags an error in the health information entry.

7.4 Policies and procedures must be established to accurately track the process from error identification, or request for amendment, through the completion of the amendment. If amendments are requested but deemed unsuitable upon review, organizational policies and procedures should be in place to delineate when this denial should itself be documented. The amendment process to health information should include the following:

7.4.1 Possible error is detected by human or system-process or a request for amendment is made.

7.4.2 If appropriate, as defined by organizational policies and procedures, an authorized entity, that is, person, device, or process, makes the amendment.

7.4.3 The entity making the amendment is identified and recorded and is associated directly with the amended entry and is readily apparent to anyone who views or reviews that amended entry.

7.4.4 The date and time of the amendment is recorded. Inclusion of the date and time that the amendment is made also should be associated directly with the amended entry and readily apparent to anyone who views or reviews that amended entry.

7.5 Organizational policy should state that amendment(s) must be made in a timely fashion and must be able to be linked to the original document(s).

7.6 For all amendments to health information, the original entry, handwritten, printed, facsimile, copied, electronic or computer-generated, must be retained during and after the amendment process. The original entry must remain accessible, be clearly readable, and retain its original meaning. Acceptable methods for meeting this requirement are as follows:

7.6.1 For handwritten amended entries, the use of a clean line drawn through the original entry is acceptable, as long as the original entry still is readable and clearly and unmistakably decipherable.

7.6.2 For amended entries in computer-based information systems where information has been deleted or modified, the use of strike-through characters is acceptable, as long as the original entry still is readable and clearly and unmistakably decipherable. For amended entries where information has been inserted at a later date, this text must be identified clearly by appropriate convention (for example, *right quadrant*).

7.7 If more than one copy of the original entry or document exists, known recipients should be notified of the amendment, whether the amendment is handwritten, on a printout, a copy, facsimile, electronic, or computer-based. This includes data transferred from one enterprise system to another system, including smart cards, which requires notification on the part of the sender that the recipient of the data must ensure that appropriate amendments and destruction are carried out.

7.8 Any amendment of a previous amendment is subject to the exact same rules and procedures as an amendment to the original document.

7.9 The presence of amended entries and documents must be explicit in paper-based, electronic, and computer-based records. There also must be an explicit, clear, legible, and obvious indication in paper-based, electronic, and computer-based records that amended entries and documents exist.

8. Keywords

8.1 confidentiality; health care; health information; health record; privacy

ANNEX

(Mandatory Information)

A1. AMENDMENT PROCESS SCENARIOS

A1.1 Amendments commonly are used to change transcribed reports when the author identifies a need. It is important to understand that original transcribed reports cannot be deleted from a system if there is the possibility that a patient care decision has been made based on the health information contained within the report. Both the original and the amended report must be retained, and it must be clear to a reader that he is reading an amended report. The following scenarios illustrate how an organization might handle the amendment process.

A1.1.1 *Scenario 1: Initial Assessment*—In this scenario, the process differs if the organization has an organization-wide computer system that allows on-line editing.

A1.1.1.1 Health care practitioner dictates an initial assessment.

A1.1.1.2 Transcriptionist types report using a word processing system.

A1.1.1.3

IF the organization	THEN the	AND the
has an enterprise-wide computer system	report is uploaded	report is viewable throughout enterprise as "pending" or "preliminary"
does not have an enterprise-wide computer system	report is delivered to usual location[5]	report is readable by one person at a time

A1.1.1.4 The dictating health care practitioner reviews the document for authentication and finds that it does not include the patient's history of colon cancer.

A1.1.1.5

IF the organization	THEN the	AND the
allows on-line editing	• edits are made on-line • report is electronically authenticated	report is labeled "final"
does not support on-line editing	• report is corrected by hand OR • report is authenticated by hand OR • practitioner dictates amendment	new report is transcribed and labeled as "amended report"

[5] Location can be an inpatient unit, onsite or satellite clinic, skilled nursing facility, home health unit, mental health unit, etc.

A1.1.1.6 Hard copy amended report is resent to the usual location[5] where both the original and amended reports are filed in the health record or the electronic "amended report" replaces the original "pending report" in the organization's computer system and both are retained in the system.

A1.1.2 *Scenario 2: Report "Version"*—In this scenario, this organization's policy states that health care practitioners may dictate report versions.

A1.1.2.1 Health care practitioner dictates an "Interim Summary" which is entitled "Version 1: Preliminary" by the transcription system.

A1.1.2.2 A hard copy of the transcribed report is sent to the practitioner for review and authentication.

A1.1.2.3

IF version 1	AND	THEN
is uploaded or circulated throughout the enterprise, or both	report could be used for patient care	the report is labeled "Version 1: Preliminary"
meets practitioner's expectations	practitioner authenticates by signing the hard copy	report is filed in medical record and health information management staff update the report as "final" in the deficiency system. NOTE: The deficiency system automatically updates the enterprise system to "Version 2: Final."[A]
does not meet practitioner's needs	practitioner either makes corrections by hand or dictates changes	• written changes are obvious • report is labeled Version 2 when retranscribed and the system titles each version with the appropriate version number and both versions are retained in the system

[A] Deficiency system refers to a tracking methodology used by health information management departments to manage documentation requirements in the medical record.

RELATED MATERIAL

Code of Medical Ethics: Current Opinions, American Medical Association Confidentiality Statement, pp. 25–27.

Conditions of Participation: Medical Record Services, Health Care Financing Administration, 42 CFR, Chapter 4, 482.24.

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