



Standard Guide for Individual Rights Regarding Health Information¹

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1. Scope

1.1 This guide outlines the rights of individuals, both patients and providers, regarding health information and recommends procedures for the exercise of those rights.

1.2 This guide is intended to amplify Guide E 1869.

2. Referenced Documents

2.1 ASTM Standards:

E 1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Computer-Based Patient Records²

3. Terminology

3.1 Definitions:

3.1.1 *access, n*—the provision of an opportunity to approach, inspect, review, retrieve, store, communicate with, or make use of health information system resources (for example, hardware, software, systems or structure) or patient identifiable data and information, or both. **E 1869**

3.1.2 *authorize, v*—the granting to a user the right of access to specified data and information, a program, a terminal or a process. **E 1869**

3.1.3 *confidential, adj*—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 both, and shall be disseminated only to authorized individual or organizations with an approved need to know. 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**

3.1.4 *disclose, v*—as related to health care, to access, release, transfer, or otherwise divulge protected health information to an entity other than the individual who is the subject of such information **E 1869**

3.1.5 *health information, n*—any information, whether oral or recorded in any form or medium (1) that is created or

received by a healthcare provider; 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 organizations, 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; 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. **E 1869**

3.1.6 *information, n*—data to which meaning is assigned, according to context and assumed conventions. **E 1869**

3.1.7 *informational privacy, n*— (1) a state or condition of controlled access to personal information, (2) the ability of an individual to control the use and dissemination of information that relates to himself or herself, (3) the individual's ability to control what information is available to various users and to limit redisclosures of information. **E 1869**

3.1.8 *privacy, n*—the right of an individual to be left alone and to be protected against physical or psychological invasion or misuse of their property. It includes freedom from instruction or observation into one's private affairs the right to maintain control over certain personal information, and the freedom to act without outside interference. **E 1869**

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *external disclosure, n*—disclosure outside an organization.

3.2.2 *internal disclosure, n*—disclosure within an organization.

4. Background

4.1 The health information in patient records documents the course of a patient's illness and treatment during each episode of care. It serves as an important means of communication between the physician, other healthcare professionals, and subsequent caregivers.

4.2 Health information primarily supports the delivery of patient care but is commonly used for health care payment, research, public health, management and oversight purposes.

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

Health information may migrate from the healthcare delivery system to other business record systems (insurance, employment, credit, etc.). In addition to health professionals, individually identifiable health information is available to many others not directly involved in patient care.

4.3 Understanding and improving the performance of the healthcare system requires reliable data to assess public health and patterns of illness and injury, identify unmet community healthcare needs, evaluate healthcare expenditures for inappropriate, unnecessary, or potentially harmful treatments, identify cost-effective methods and providers, and improve the quality of care in all healthcare settings.

5. Significance and Use

5.1 While the needs of legitimate users shall be met, patients and providers shall be protected from unauthorized, inappropriate, or unnecessary intrusion into the highly personal information in their records. Besides diagnostic and treatment information, health records may include details of a patient's family history, genetic testing, history of diseases and treatments, history of drug use, sexual orientation and practices, testing for sexually transmitted diseases, and psychiatric disorders. In addition, aggregate health information, across patients and patient populations, can be used to profile provider practice patterns, quality of care, and outcomes.

5.1.1 The provision of healthcare services requires that patients provide complete information. Patients shall be assured that the information they share with healthcare providers will not be disclosed or misused in an unauthorized manner. Otherwise, patients may withhold critical information that could affect the quality and outcome of their care, as well as compromise the reliability of the information.

5.1.2 The provision of healthcare services requires accurate and complete documentation by healthcare providers. Providers shall be assured that the information they document will not be disclosed or misused in an unauthorized manner. This applies to both individual patient data and aggregate data compiled to define practice patterns. Otherwise, providers may avoid explicit documentation of information that could affect the quality and outcome of care, as well as compromise the reliability of the information.

5.2 The confidentiality of health information has been protected through two primary sources: (1) the historical ethical obligations of healthcare providers to maintain the confidentiality of health information and (2) the legal right to privacy. The present legal system, however, does not provide consistent, comprehensive protection for the confidentiality of health information.

6. Rights

6.1 *General Right to Privacy*—Although a right to privacy is not set forth in the Bill of Rights, the Supreme Court has protected various privacy interests, based on the first, third, fourth, fifth, and ninth amendments to the U.S. Constitution. Broadly, privacy may be described as the right to be let alone.

6.2 *Informational Privacy*, see Guide E 1869.

6.3 *Fair Health Information Practices*—Patients have the right to know what information is collected about them, by whom, for what purpose the information is collected, and the

circumstances under which it may be disclosed. Patients have the right to inspect and seek correction of their health information. Information may be withheld from a patient only as provided by law or regulation or to prevent harm to the patient or others who provided the information. Confidential health information may be disclosed only as provided by law or regulation or with written authorization from the patient or his legal representative.

6.4 *Procedures to Exercise Rights:*

6.4.1 *Access to Information*—Upon written request and with reasonable notice, patients shall have access to health information collected and maintained about them. Patients should be permitted to review their records without charge. The provider or entity collecting or maintaining the information shall explain what information is collected, the purpose for which it is collected, and the conditions under which it may be disclosed.

6.4.2 *Amendment of Health Information*:—If disputing documented health information, the patient or his legal representative shall discuss the issue with the healthcare provider who made the entry in question. If the healthcare provider agrees the entry contains an error, he should make the correcting entry in the patient's record.

6.4.3 If the responsible healthcare provider does not agree that a correction is warranted, he should discuss the matter with the patient or his legal representative. The patient or his legal representative may make a separate statement in writing or on computer disputing the information and offering an amendment. Such a statement should then be filed with the record or made part of it and then included with any future disclosures.

6.5 *Valid Authorization for External Disclosure*—To be valid, a patient's authorization to externally disclose confidential health information shall do the following:

6.5.1 Identify the patient.

6.5.2 Generally describe the healthcare information to be disclosed.

6.5.3 Identify the person or entity to whom the healthcare information is to be disclosed.

6.5.4 Describe the purpose of the disclosure.

6.5.5 Limit the length of time the authorization will remain valid.

6.5.6 Be given in writing, dated and signed by the patient or his legal representative or be in electronic form, dated and authenticated by the patient or the patient's legal representative using a unique identifier.

6.5.7 Not have been revoked.

6.6 *Revocation of Authorization for External Disclosure*—A patient or his legal representative may revoke the patient's authorization at any time, unless disclosure is required for payment for health care that has been provided to the patient or other substantial action has been taken in reliance on the patient's authorization.

6.7 *Uses or Disclosures Not Requiring Authorization*—Generally, authorization from the patient or his legal representative is not required to disclose confidential health information in the following circumstances:

6.7.1 Continued patient care.

6.7.2 Communicable disease, vital statistics, abuse and neglect and other reporting required by federal or state law or regulation.

6.7.3 Research projects approved by an institutional review board, healthcare facility management and oversight functions, accreditation and federal and state licensure surveys.

6.7.4 Under a valid subpoena or court order.

6.8 *Uses or Disclosures Requiring Authorization*—Unless otherwise provided by federal or state law or regulation, all other disclosures should be made with written authorization from the patient or his legal representative. Generally, authorization is required to disclose confidential health information to the following:

6.8.1 Attorneys, without a valid subpoena or court order.

6.8.2 Employers.

6.8.3 Government or voluntary welfare agencies.

6.8.4 Insurance companies or other third party payers, or law enforcement officials.

6.9 Patients have the right to prohibit their information being released to family members.

7. Healthcare Providers

7.1 *Acceptable Public Disclosures*—Public disclosure of practice pattern or other information related to healthcare providers is acceptable if it:

7.1.1 Involves information and analytic results from properly conducted studies.

7.1.2 Is based on valid, reliable data.

7.1.3 Is accompanied by appropriate educational or explanatory material.

7.2 *Rights*—Healthcare providers who will be identified in a public disclosure should have the right to:

7.2.1 Obtain all data required to perform an independent analysis of the information to be disclosed and to do so within a reasonable time period prior to the disclosure.

7.2.2 Have comments from their own analyses or explanation of findings accompany publication of the information.

7.3 *Procedures to Exercise Rights*—To exercise these rights, healthcare providers should contact the individual or agency analyzing the data for public disclosure.

7.4 Providers shall agree to the distribution of practice patterns unless mandated by federal and state regulations.

7.5 Healthcare providers may require as a condition of treatment the ability to document that care.

7.6 Healthcare providers shall be provided with timely, fair, or equitable rights to review and correct data, and due process for resolution of errors, complaints, and contested disclosures.

8. Keywords

8.1 confidentiality; health information; health records; individual rights; patient information; privacy

REFERENCES

- (1) American Health Information Management Association, *Health Information Model Legislative Language*, 1993.
- (2) Brandt, M. D., *Maintenance, Disclosure, and Redisclosure of Health Information*, American Health Information Management Association, Chicago, IL, 1995.
- (3) Donaldson, M. S., and Lohr, K. N., eds., *Health Data in the Information Age: Use, Disclosure, and Privacy*, National Academy Press, Washington, DC, 1994.
- (4) Public Law 104-191, The Health Insurance Portability and Accountability Act of 1996, Section 264.
- (5) U.S. Congress, Office of Technology Assessment, "Protecting Privacy in Computerized Medical Information," OTA-TCT-576, U.S. Government Printing Office, Washington, DC, September 1993.
- (6) National Research Council, *For the Record: Protecting Electronic Health Information*, National Academy Press, Washington, DC, 1997.

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