

HIPAA

Its Uses and Requirements for Clinical Trials

Implications for Sponsors, Clinical Trial Study Sites, IRBs and Informed Consent

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The Health Insurance Portability and Accountability Act (HIPAA) was conceived as an aid in information-sharing as well as protection for the patient's confidential medical history. Congress passed the initial law in 1996 (Kennedy-Kassebaum Act, Public Law 104-191, 21 August 1996) to provide better access to health insurance and to toughen the law concerning healthcare billing fraud. It was the initial phase of the Clinton administration's Health Care Reform Program and has far-reaching implications. Within this act are the corollary sections concerning administrative simplification and healthcare information privacy that have far-reaching implications not only for healthcare providers but also for information collected and used in support of product safety and effectiveness.

Implementation of the act has required rulemaking by HHS on nine elements. The standards have been designated for electronic storage (final rule published in the *Federal Register* on 17 August 2000)¹ and sharing to assure uniformity across platforms, as well as to define security standards that protect the confidentiality and integrity of individually identifiable health information past, present and future (final rule published in the *Federal Register* on 28 December 2000).² Other

elements of HIPAA, such as National Provider Identifier, National Employer Identifier and security, have been drafted but not finalized. Elements that have not had notice of proposed rule making include National Health Plan Identifier, claims attachments, enforcement and first report of injury. The National Individual Identifier standards rule-making requirement has been withdrawn by the Department of Health and Human Services.

The act requires unique health identifiers for individuals, employers, health plans and healthcare providers. These identifiers will be used by Medicare and Medicaid and may be assigned via a federal agency. At this time, the identifiers are likely to be the Tax ID number or Social Security number.

The main issue for RAPS members is to be aware of the implications for clinical trials and data mining of patient databases. **Patients own their data and have been given more oversight of the use of their information.** In addition to the existing requirements with respect to informed consent, conflicts of interest and Institutional Review Board oversight, HIPAA will require oversight by IRBs or privacy boards, de-identification of data and patient authorization of the use of their data. **The privacy final rule becomes**

effective 14 April 2003. It is now time to put a task force in place in your organization to plan for compliance with these new rules.

The information that needs to be communicated within each drug and device company is that this is a new era that includes more government regulatory oversight. Many organizations recommend planning now for the implementation of required infrastructure to ensure timely compliance. Task forces similar to those developed for Y2K may provide the necessary plan development and implementation across company-wide platforms.

The elements for informed consent that are to be communicated in plain language are found in **Table 1**.³

For clinical trials, the consent forms need to contain wording that addresses privacy issues. The health information that is collected as part of a clinical trial may be restricted by the patient after the initial consent has been given. The researcher may find other uses for the laboratory test specimens and should make sure that these are included in the consenting process at the outset.

For uses and disclosures for research purposes, either Institutional Review Board review or review by a privacy board may use or disclose protected



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health information for research, regardless of the funding source.⁴ This review—after approval of the research plan—is provided to the covered institution allowing alteration to or waiver, in whole or in part, of the individual authorization required by Section 164.508 for use or disclosure of protected health information. Privacy boards have members with varying backgrounds and appropriate professional competency to review the effect of the research protocol on individual privacy rights and related interests.⁵ This board must include at least one member who is not affiliated with the covered entity (institution) nor with the sponsor or researcher performing the research and who is not related to such entities and does not have any conflict of interest with the project.

In order to waive consent when information is used for research purposes, the IRB or privacy board must prepare a waiver or alteration statement. The statement may be on letterhead or other material that identifies the board, must bear the date of the authorization and must include a number of elements:⁶

- Use or disclosure of the information involves no more than minimal risk to the individuals;
- Waiver will not adversely affect the privacy rights and welfare of the individuals;
- Research can not be conducted expeditiously without the waiver;
- Research can not be conducted expeditiously without access to and use of the protected health information;

- Privacy risks are reasonable in relation to the anticipated benefits of any individuals and the importance of the knowledge that may result from the research;
- Adequate plans to protect the identifiers from improper use and disclosure;
- Adequate plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research unless there is a requirement for retention by law; and
- Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law.

Other requirements for the waiver include a brief description of the protected

Table 1: Defined Elements for Informed Consent

45 CFR Citation	Defined Element
§164.508 (c) (i)	Description of the information that is to be disclosed and what is identifiable about it.
§164.508 (c) (ii)	Identification of the person(s) or class of persons authorized to make the requested use or disclosure.
§164.508 (c) (iii)	Identification of the person(s) or class of persons who will receive this information.
§164.508 (c) (iv)	An expiration date related either to the individual or to the purpose of the use/disclosure.
§164.508 (c) (v)	A statement that the individual has the right to revoke the permission in writing, instructions as to how to revoke as well as the exemptions to the right to revoke.
§164.508 (c) (vi)	A statement that the information disclosed may be redisclosed by the recipient, at which time the information is no longer protected by this rule.
§164.508 (c) (vii)	Designated space for individual's signature and date.
§164.508 (c) (viii)	If signed by personal representative, description of the authority for this authorization.
§164.508 (d) (1) (i)	A statement that there will not be any conditional treatment, payment or eligibility for benefits.
§164.508 (d) (1) (ii)	A description of each purpose for the information disclosure.
§164.508 (d) (1) (iii)	A statement that the individual may inspect the protected information and refuse to sign the authorization.
§164.508 (d) (1) (iv)	If there is to be payment to the treatment provider from an outside party, a statement that payment will occur.
§164.508 (d) (2)	A statement and action that the healthcare provider provides a copy of the signed authorization to the individual.
§164.508 (f) (1) (ii) (A)	When participating in research that includes health treatment, a description of the extent that the health information will be used to carry out treatment, payment or healthcare operations.
§164.508 (f) (1) (ii) (B)	A description of any health information that will not be disclosed, except when required by law.
§164.508 (f) (2) (i) and (ii)	(Optional to be included in the institution's informed consent) A consent to participate in the research, consent to use or disclose protected health information to carry out treatment, payment or healthcare operations.
§164.508 (f) (2) (iii)	(Optional procedure) A notice of the institution's privacy practices.

health information for which use or access has been determined to be necessary, a statement of the review procedure(s) used for the research study and that the statement is signed by the chair or other member, as designated by the chair.

In addition, reviews in preparation for research may be conducted without board approval or waiver if the institution obtains representations from the researcher that use and/or disclosure is only to review protected health information as necessary to prepare a research protocol or for similar purposes in preparation for research. In addition, the researchers must affirm that no information may be removed from the institution by the researcher in the course of the review and that the health information is necessary for the research purposes.

Sharing of health information

There are instances allowed by this rule in which health information may be shared without consent, authorization or opportunity to agree or object. These instances include use by a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability. This includes the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.⁷ Also covered are instances of public health authority or other appropriate government entity authorized by law to receive reports of child abuse or neglect. FDA personnel are allowed access without consent to:

1. Report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product);
2. Track products if directed by FDA to do so;
3. Enable product recalls, repairs or replacement (including locating and notifying individuals who received products involved in product recalls, withdrawals or other problems; or
4. Conduct post-marketing surveillance in accordance with FDA regulations.

De-identification

De-identification processes are defined in this privacy rule.⁸ De-identification may occur when a qualified person applies appropriate generally accepted statistical and scientific principles to determine that the risk is very small that

there will be disclosure. Documentation of the methods and results of the analysis of the de-identification process is required. Otherwise the following identifiers are removed:

- Names
- All address specifics other than state
- Telephone numbers
- Fax numbers
- Certificate/license numbers
- Web Universal Resource Locators ((URLs)
- Any dates within the record, included but not limited to birth date, admission date, discharge date, death date or age
- Electronic mail addresses
- Health plan beneficiary numbers
- Vehicle identifiers
- Internet Protocol (IP) address numbers
- Any other unique identifying number, characteristic or code
- Medical record numbers
- Social Security numbers
- Account numbers
- Device identifiers and serial numbers
- Biometric identifiers including finger and voice prints
- Full face photographic images and any comparable images

The result is the institution does not have any actual information to identify an individual who is a subject of the information. This leaves access to demographic information including race and sex but not age.

Re-identification is addressed to allow some record identification by using an assigned code for record identification.⁹ The code must not be derived from identifiers related to the individual and the code is not used or disclosed for any other purpose and does not disclose the mechanism for re-identification.

Specification of access to protected information

Upon implementation of the Privacy Rule, an institution must specify those persons or classes of persons in its workforce who need access to protected health information. It also must specify the categories of protected health information appropriate to the class of information needed and any conditions appropriate to this access.¹⁰ Other elements that require implementation include specification of minimum necessary disclosures of protected health information. This includes who is authorized to request this infor-

mation including public officials, workforce members or business associates who may be providing professional services to the institution. After protected health information is requested, the institution has the obligation to review the request and limit access to the protected health information to the elements required for the requester to complete his/her purpose.¹⁰

Marketing revelations

Marketing revelations also are covered, with exemptions when face-to-face communication takes place concerning products or services of nominal value, or when the institution communicates with the individual and discloses it is the party making the communication, whether there is any remuneration to the institution for this communication, and how the individual may opt out or receive further communication. If the marketing information is targeted to a particular group of patients identified by their health status, the institution must determine that the information is beneficial to this group; specify why this health status group is targeted; and explain how the product or service relates to the health of this group.¹¹

Disclosure of health information

Except for group healthcare plans and prison inmates, individuals have the right to adequate notice of the uses and disclosures of their health information by the institution. The institution must comply with Section 164.520(b) for the elements of the notice. The notice must incorporate plain language and specify which information may be disclosed without further consent and which information requires further consent. The notice must inform the individual that he or she may revoke authorization and how to exercise that right. Other statements to be included in the notice are a requirement to maintain the privacy of protected health information; that the institution is required to comply with the terms of the notice; that the institution may amend the terms of its notice; and how it will provide individuals with the revised notice.¹² The institution must provide a notice at the time of first service delivery, whether in person or electronically.

Requests for protected information

The individual may request protected health information except for psychotherapy notes, information compiled for a legal action or proceeding, and information subject to the Clinical Laboratory Improvements Amendments of 1998.

When information is to be given out, the institution must act on the request within 30 days. The information must be provided within 30 days when stored on-site or within 60 days when stored at a different location.

Documentation of procedures

Documentation is required describing the procedures specified above including designation of personnel who are responsible for the development and implementation of the policies and procedures of the institution, designated personnel for handling privacy complaints and personnel who are responsible for the accounting of the privacy requests. Training of the institution's personnel with regard to privacy policies and procedures also must be implemented and documented. The institution must have policies for mitigation of any harmful effect from the use or disclosure of protected health information that is in violation of its policies and procedures. It also must refrain from any intimidating or retaliatory acts and may not require any individual to waive his or her rights as a condition of employment, payment, treatment or eligibility for benefits. Documentation retention is specified as six years from the

date of its creation or the date when it last was in effect, whichever is later.

For most institutions, this rule will require a new subgroup within a department that oversees the documentation of the consents as well as the record-keeping of the requests for disclosure of the protected health information. Wording of the consents may require an additional up-front consultation with the institution's legal counsel. The rule was to become effective initially 26 February 2003, but the effective date has been postponed to 14 April 2003.

For those who wish to know more about HIPAA, there is information regarding HIPAA on the Web in several locations including:

www.aishealth.com
www.hipaadvisory.com
www.ama-a.ssn.org
www.cap.org

There also are training courses available.

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NOTES:

1. Health Insurance Reform: Standards for Electronic Transactions, *Federal Register* 65: 50312-50372; 17 August 2000.
2. Standards for Privacy of Individually Identifiable Health Information Final Rule, *Federal Register*, 65: 82461-82829; 28 December 2000.
3. 45 CFR 164.508 (c), and as applicable, (d), (e) and (f).
4. 45 CFR 164.510 (i).
5. 45 CFR 164.510 (i) (1) (B).
6. 45 CFR 164.510 (i) (2)
7. 45 CFR 164.512 (b) (1) (i)
8. 45 CFR 164.514 (b)
9. 45 CFR 164.514 (c)
10. 45 CFR 164.514 (d) (2) and §164.514 (d) (3)
11. 45 CFR 164.514 (e)
12. 45 CFR 164.520 (e)

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