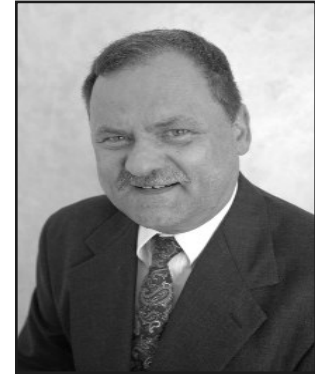


HIPPA and Business Associate Agreements

The John Marshall Law School

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1.0 Background

1.1 Why the need? What do health care organizations and E-commerce have in common?

1.2 Perspective - Substantial growth in use of electronic health care records and automation of provider payment process.

2.0 HIPAA - The Legislation

2.1 The Health Insurance Portability and Accountability Act of 1996 - HIPAA. HIPAA is in Pub. L. 104-191 (21 Aug. 1996), and is codified at 42 U.S.C.A. § 1320d et seq. (2002); found under Part C - Administrative Simplification.

2.2 Scope - Covers health plans, health care clearinghouses and health care providers.

2.3 Applicability - Health care providers are covered only if electronic health information, as defined, is transmitted. If these providers keep paper records and do not electronically transmit health information? 42 U.S.C.A. § 1320d-1 (a)(3).

2.4 Penalties - Fines and Prison. If IIHI, see below, is disclosed for commercial gain, potential penalty is up to \$250K +/- or 10 yrs. in prison. 42 U.S.C.A. § 1302d-6.

3.0 HIPAA Regulations

3.1 Standards (regulations) for HIPAA appear under 45 C.F.R. Parts 160 and 164. Part 164 contains the Privacy Rule.

3.1.1 Final rule adopted on 28 December 2000 at 65 F.Reg. 82462.

3.1.2 Privacy Rule amended on 14 August 2002 at 67 F.Reg. 53182.

3.2 Other related regulations pending - Security, Code Sets, "Patient Identifier".

4.0 Key Terms

4.1 Business Associate. Defined in 45 C.F.R. § 160.103. Includes any person or entity who provides a function or service involving Individually Identifiable Health Information. Not a Health Care Provider, but it could be.

4.2 Covered Entity. Defined in 45 C.F.R. § 160.103. Includes health plans, health care clearinghouses and certain health care providers.

4.3 Individually Identifiable Health Information (IIHI). Defined in 45 C.F.R. § 160.103. Information created by a health care provider relating to a condition of

or services provided to an individual, or payment for services, in which the individual is identified. This is a key term in the Privacy Rule.

- 4.4 Enforcement. Enforcement of the Privacy Rule is handled in part by the Dept. of Health & Human Services, Office of Civil Rights, and part by the Centers for Medicare & Medicaid Services (Fed.). HHS may investigate complaints of Privacy Rule violations.
- 4.5 Elements of Privacy. This is similar to the FTC's Fair Information Practices, requiring Notice, Minimum Necessary Disclosure, Right to Access and Correct, and Security, including audit trails (tracking and accounting for disclosures).
- 4.6 Standards for Electronic Notice of Privacy Practices. 45 C.F.R. § 164.520 (c)(3).
- 4.7 Exceptions. Federal officials may gain access to IIHI for health oversight.

5.0 Business Associate Agreement Standards

- 5.1 Standards required of Business Associate Agreements in 45 C.F.R. § 164.504 (e). See copy in attachment.
- 5.2 Contract Requirements.
 - 5.2.1 Covered Entity must act if it knows of violation by Business Associate (BA), and terminate for breach of privacy. 45 C.F.R. § 164.504 (e)(1)(ii).
 - 5.2.2 BA use of IIHI must be consistent with Privacy Rule. § 164.504 (e)(2)(I)
 - 5.2.3 List of other BA Agreement requirements. § 164.504 (e)(2)(ii)
- 5.3 Language for BA Agreements is an Appendix to the Privacy Rule, and not part of the Rule itself. Appendix of BA Agreement terms begins at 67 F.Reg. 53264. See attachment.
 - 5.3.1 The Appendix is sample language, but not a full A - Z Agreement. These terms are for use with any Service Agreement between Covered Entity and BA.
 - 5.3.2 Use of terms are not mandatory. These are for guidance, not safe harbors.
 - 5.3.3 The BA Agreement allows for use of agents. If BA uses an agent, it must require the agent to either return to the BA or destroy all IIHI on termination.
- 5.4 Contractual undertakings required in BA Agreement.
 - 5.4.1 BA must mitigate harmful effect caused by disclosure contrary to Agreement.
 - 5.4.2 BA must provide access to and/or amend IIHI as directed by Covered Entity.
 - 5.4.3 BA must keep record of disclosures made and give record to Covered Entity.
 - 5.4.4 BA must return to the Covered Entity or destroy all IIHI used on termination of the Agreement, or if "infeasible", BA is required to maintain the protections for as long as it continues to hold the IIHI(!).
 - 5.4.5 BA Agreement may be modified at any time on notice from Covered Entity to permit Covered Entity's compliance with Privacy Rule.

- 6.0 Web Sites with More HIPAA Information. Photocopies of some Web Sites are attached.
- 6.1 U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, Administrative Simplification: aspe.hhs.gov/admnsimp/. This Site has useful FAQs related to HIPAA & its regulations.
- 6.2 U.S. Department of Health & Human Services, Office for Civil Rights: <http://www.hhs.gov/ocr/hipaa> or <http://www.hhs.gov/ocr/hipaa/assist.html>.
- 6.3 Centers for Medicare & Medicaid Services (U.S.): <http://www.cms.gov/hipaa>.
- 6.4 American Health Lawyers' Assn.: <http://www.healthlawyers.org/>. This professional organization has info & text books re: HIPAA available to purchase.
- 6.5 Healthcare Information & Management Systems Society, HIPAA Source page. <http://www.himss.org/>. Includes FAQs and links.

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