

HIPAA Online: Background and Issues for eHealth

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Legal and Regulatory Background

Online Privacy Protection

- State and Federal Laws
 - Patchwork approach
 - Video rentals - "Borked"
 - Children's Online Protection Act
- EU Directive influence in US
 - General approach to individual privacy
 - Trusted partner approach to transfers
- Proposed US laws and regulations
 - FTC "online profiling" proposal - safe harbors for self-regulators

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Healthcare "Intensifiers"

Current "Hot" Buttons for eHealth

- California Healthcare Foundation Reports
 - Survey of Consumer Attitudes
 - Report on Health Web Site Privacy
- Security for medical-record level info
 - Kaiser incident with inadvertent leakage
- Laws and regulations
 - State and federal laws on medical records
 - HIPAA security and confidentiality regs

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Media Scrutiny

California Healthcare Foundation Reports

- Survey of consumer attitudes
 - Together with Internet Healthcare Coalition and CyberDialogue
 - Showed increased concern about health information
 - Perception of potential for invasion of privacy
- Report on Health Web Site Privacy
 - Review of 21 major health web sites
 - Serious concerns for most
 - DoubleClick "data leaking" issue
- Extensive media coverage resulted

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Privacy Quotes

(Graphics omitted to save space)

- Three may keep a secret, if one is dead.
 - Ben Franklin, Poor Richard's Almanac
- Two may keep a secret, if one is dead.
 - Cardinal Richilieu
- One may keep a secret, if their computer is dead
 - On the Internet

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Overview of Presentation

HIPAA Regs: Background and Issues for eHealth

- Medscape overview (short)
- Does HIPAA apply to web sites?
- Practical Examples of eHealth HIPAA Issues
- HIPAA privacy/security as "best practice"
- Self-Regulation: Current efforts
 - Privacy Policies in general
 - Ethical codes

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What is Medscape?

And why should you care what I have to say?

The Foundations of Medscape

MedicaLogic pioneered and leads the online medical record industry, with more than 13 million digital patient records and 19 thousand clinical users.

Medscape has been rated the #1 site among physicians for reliable health information for 5 years running. Medscape currently serves 440,000 physicians, 1.2M allied health professionals, 2.4M total users.

CBS HealthWatch is rated by Yahoo! as the top consumer health Web site, with \$150M in media support from the CBS partnership.

Total eMed brings leadership in web-based transcription for ambulatory care.



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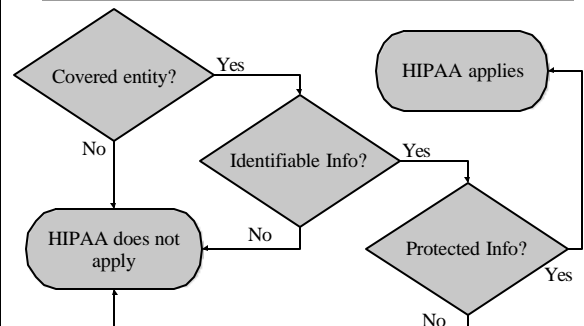
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Does HIPAA Apply to Web Sites?

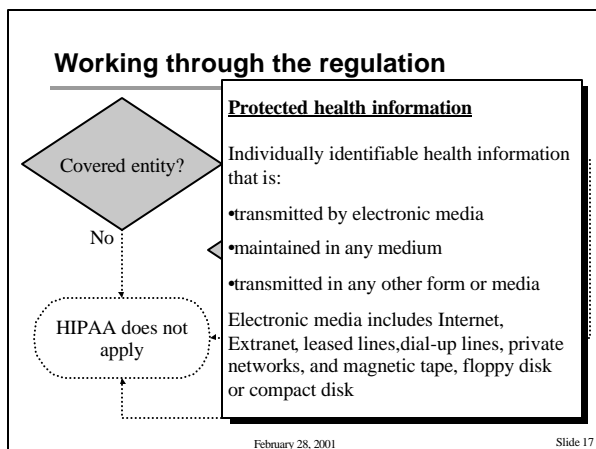
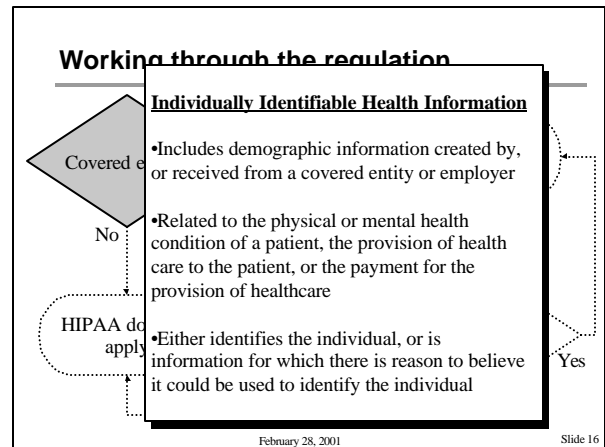
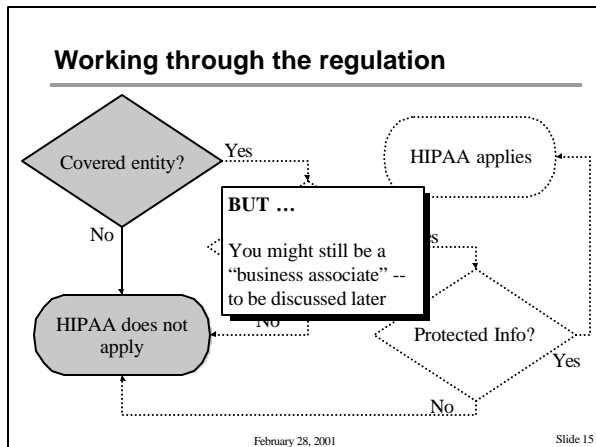
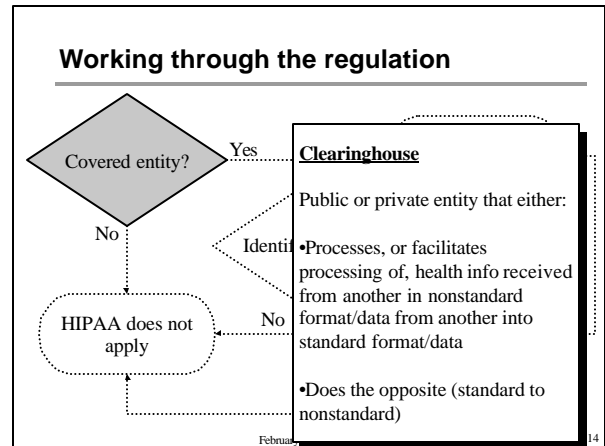
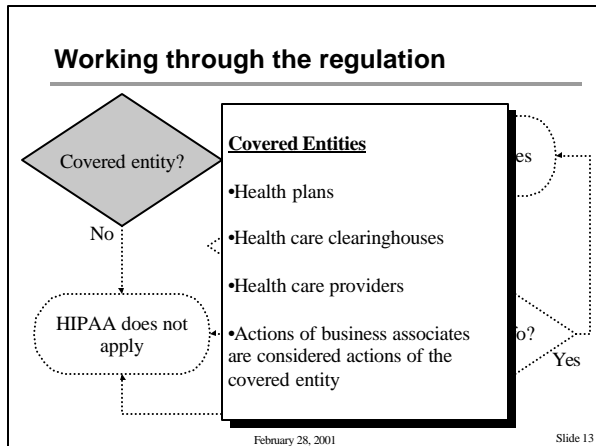
**It depends ...
on what they do!**

Working through the regulation



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Business Associate Definition

An Entity or Person that:

- On behalf of a covered entity or organized healthcare arrangement in which the entity participates, performs:
 - a function involving use/disclosure of individually identifiable info (e.g., claims processing or practice management)
 - Or any other HIPAA-regulated function or activity
- Or provides to a covered entity/arrangement :
 - legal, accounting, actuarial, consulting, data aggregation, management, administrative, accreditation, or financial services
 - where the services involve disclosure to the person of individually identifiable info by either the covered entity/arrangement or another of its business associates

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Business Associate vs. Covered Entity

Implications for Covered Entities

- Actions of business associate deemed to be actions of covered entity
 - Covered entity should obtain assurances that associate will protect info appropriately
 - Written contract with associate required
 - Specific contract provisions required (e.g., amendment, audit)
- Covered entity must act on known violations of confidentiality by the business associate
- Covered entity can be associate of another covered entity

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Web Linking Arrangements

Chains of Trust

- Web site not covered entity by itself
- Pharmacy or other covered entity partner
- Clearinghouse: standard <> nonstandard data/format
- Business associate: processes individually identifiable info
- Multiple layers of business associates?
 - Web site owner
 - ISP/ASP/hosting facility
 - E-commerce provider

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Some Practical Examples

(Screen captures omitted to save space)

- Medscape.com
- CBSHealthwatch.com
- AmericasDoctor: www.americasdoctor.com
- UltimateRX: www.ultimaterx.com

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HIPAA as "Best Practice"

Even unregulated entities can use it!

- Notice, "related uses," and informed consent
- Ability to view and amend personal info
- Guidelines for marketing and other "unrelated" uses
- Guidelines for de-identification
- "Chain of Trust" approach
- Training of employees
- Policies and procedures for handling identifiable info

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Self-Regulation

From privacy to ethics

Self-Regulatory Systems in eHealth

Alternative Enforcement for Healthcare?

- Hi-Ethics
 - Association of "destination" health web sites
 - Limited membership
 - Ethical principles (practical, implementable, auditable)
- Internet Healthcare Coalition
 - Ethics summit (www.ihealthcoalition.org)
 - eHealth Code of Ethics (global, high-level, aspirational)
- Other models and codes exist
 - Health on the Net Foundation (HONCode)
 - AMA Guidelines for Web Sites

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Health Internet Ethics (“Hi-Ethics”)

Who are they?

- Formed in November 1999
- Privacy, advertising and content quality issues for Internet health consumers
- Member companies donate resources
- Represented a significant portion of the Internet health space
- March Media Metrix report: Hi-Ethics sites combined:
 - 11.5 million unduplicated unique users
 - 15.9% reach of all Internet visitors

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Hi-Ethics Process

Collaboration of closed membership

- Drafting of principles by member companies
 - adam.com, allHealth.com/iVillage, America Online, AmericasDoctor, CareInsite, Discoveryhealth.com, drkoop.com, HealthCentral.com, Healthon/WebMD, HealthGate, HEALTHvision, Healthwise, IntelliHealth, LaurusHealth.com, Mediconsult/Physicians'Online, MedicaLogic/Medscape, OnHealth, PersonalMD, PlanetRx, and WellMed
 - Chair: Don Kemper, Healthwise, Inc.
 - Outside counsel: Christine Varney at Hogan & Hartson
- Draft released this Spring, compliance promised by Nov 1 2000

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Hi-Ethics Goals

- Providing health information that is trustworthy and up-to-date;
- Clearly identifying online advertising and disclosing sponsorships or other financial relationships that significantly affect content or services;
- Keeping personal information private and secure, and employing special precautions for any personal health information; and
- Empowering consumers to distinguish online health services that follow the principles from those that do not.

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Hi-Ethics Principles

Privacy Provisions: Chain of Trust

- General privacy policy: fair information practices
- Enhanced Privacy Protection for Health-Related Personal Information
- Safeguarding Consumer Privacy in Relationships with Third Parties

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Hi-Ethics Principles

Continued...

- Disclosure of Ownership and Financial Sponsorship
- Identifying Advertising and Health Information Content Sponsored by Third Parties
- Promotional Offers, Rebates, and Free Items or Services
- Quality of Health Information Content
- Authorship and Accountability
- Disclosure of Source and Validation for Self-Assessment Tools

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Hi-Ethics Principles

Continued...

- Professionalism
- Qualifications
- Transparency of Interactions, Candor and Trustworthiness
- Disclosure of Limitations
- Mechanism for Consumer Feedback

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Hi-Ethics/TRUSTe eHealth Seal Program

Announced Dec 12, 2000

- TRUSTe will be the compliance, authentication and verification partner for the Hi-Ethics Principles
 - TRUSTe will develop a seal program
 - The program will be open to all consumer web sites
 - TRUSTe will review and assess compliance with the Principles
 - TRUSTe will take action against violators, up to and including referral to federal or state authorities for enforcement action
 - TRUSTe/Hi-Ethics audit partners: PriceWaterhouse Coopers and NCQA
- Hi-Ethics retains control over the content of the Principles

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eHealth Code of Ethics - Coalition Summit

Broadly Similar to Hi-Ethics Code

- Candor & Trustworthiness
- Truthfulness & Nondeception
- Quality
- Informed Consent
- Privacy
- Professionalism in Online Health Care
- Responsible Partnering
- Accountability

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Self-Regulation

(Screen captures omitted to save space)

- Hi-Ethics web site:
 - www.hiethics.org
- Internet Healthcare Coalition web site:
 - www.ihealthcoalition.org
- Medscape General Medicine comparison of codes:
 - www.medscape.com/Medscape/GeneralMedicine/journal/public/mgm.journal.html

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Self-Regulation: Who needs it?

Enforcement is the Key

- Self-regulation, by definition, requires the agreement of a self-regulated group
 - It establishes quality and trust
 - It does not affect fringe players
- To be meaningful, it must have compliance controls
 - US: Broadcast advertising
 - UK: Code of Practice Authority/ABPI
- Government/laws must serve as a backstop to self-regulation

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Q & A Period

Follow-up Questions:
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