

## Self-Regulation: eHealth, Ethics, and HIPAA

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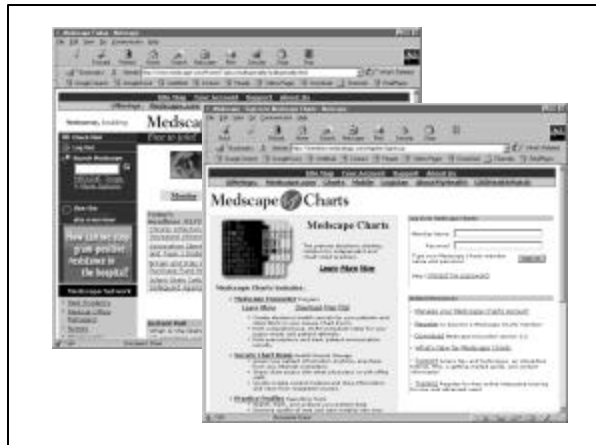
## Overview of Presentation

### *HIPAA and Self-Regulation: Issues for eHealth*

- Medscape overview (short)
- Do Privacy Policies Work?
- HIPAA and Web Sites
- HIPAA privacy/security as "best practice"
- Self-Regulation: Current efforts

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## Do Privacy Policies Work?

### History of Privacy Policies

- 1997: Most web sites did not have policies; those that did were weak (EPIC study)
- 1998: FTC report on privacy online
  - Only 14% of web sites provided notice
  - Efforts fell "far short of what is needed to protect consumers"
- 1999: Mary Culnan study of top 361 biz sites
  - 35% had no policy
  - failure to address fair information practices
- 2000: 82 of top 100 have policies (EPIC)
  - Failure to fully address fair information practices

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### Anti-Privacy Policy



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## Privacy Statement



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**Assertion:** In their current state, most privacy policies are drafted by lawyers with the goal of protecting companies rather than consumers.

## 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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## Pharmatrak issue



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## Pharmatrak script in source code



```
<!-- begin //pharmatrak NETcompare -->

<script language="JavaScript" type="text/javascript"
src="http://tr.pharmatrak.net/javascript/ww.celebrex.com/indexhtm.gif">
</script>
<!-- end //pharmatrak NETcompare -->
```

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## Resulting Cookie file



www.pharmatrak.net FALSE / FALSE 977091592 Apache 165.121.53.1.465969315289781

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## “Fair info practices” in policy?

It is our intent to balance our legitimate business interests in collecting and using information received from and about you with your reasonable expectations of privacy....

**Collective Data:** This web site may deposit certain bits of information called "cookies" in a visitor's computer. Cookies are sent back only to the web site that deposited them when a visitor returns to that site.

This technology does not collect personal identifiable information; the information collected is in an aggregate, non-identifiable form. With the information we can learn through this technology, we hope to improve our sites.

**Personally Identifiable Information:** We collect personally identifiable information, such as names, addresses, e-mail addresses, health information and the like, only when voluntarily provided by a website visitor. We will notify you as to the uses we intend to make of that information, at no time will the information be sold.

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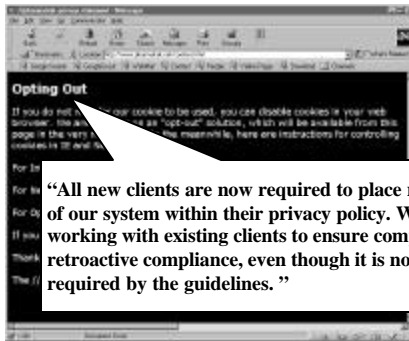
## Cross-site tracking



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## Back and fill by Pharmatrak



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## The media isn't buying it...



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## Nor is the government

### Current Actions against Pharmatrak

- FTC investigation of general online profiling
- Attorney general threatens action in Michigan
  - Against G.D. Searle for using Pharmatrak
- Class action lawsuits
  - Now: Against Pfizer for using Pharmatrak
  - Threatened: Against Pharmatrak and other customers
- Specific attention by DC-based privacy advocates
  - Janlori Goldman, Georgetown Univ Privacy Center

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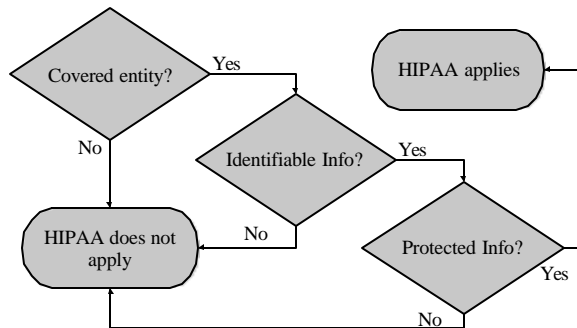
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**If privacy policies have failed to build trust, what are the alternatives?**

## Government Regulation: Does HIPAA Apply to Web Sites?

It depends ...  
on what they do!

### Working through the regulation



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### Business Associate vs. Covered Entity

#### Regulation by "Chain of Trust" Agreement

- Performs actions for covered entity
  - Involving identifiable info
  - Not by workforce
- Actions of business associate deemed to be actions of covered entity
- Covered entity must act on known violations of confidentiality by the business associate

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But my web site  
can't wait for HIPAA!

### 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: An alternative available today

### Self-Regulatory Systems in eHealth

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#### *Alternative Enforcement for Healthcare?*

- Hi-Ethics
  - Association of "destination" health web sites
  - Ethical principles (practical, implementable, auditable)
- Internet Healthcare Coalition
  - Ethics summit ([www.ihealthcoalition.org](http://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
  - URAC Health Web Site Accreditation

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## What is Hi-Ethics?

### Health Internet Ethics ("Hi-Ethics")

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#### *Formed in November 1999*

- Privacy, advertising and content quality issues for Internet health consumers
- Significant percentage of all eHealth Internet traffic
- Member companies donate resources
- Drafting by closed group concluded Spring 2000
- Initial compliance by self-assessment Fall 2000

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### Hi-Ethics Goals

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- 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

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#### *Privacy Provisions: Chain of Trust*

- General privacy policy: fair information practices
- Enhanced Privacy Protection for Health-Related Personal Information
  - Concept of "related use"
  - Authorization for unrelated third-party disclosures
  - Need to "freshen" consent for changes in policies
- Safeguarding Consumer Privacy in Relationships with Third Parties
  - "Chain of Trust" approach - policies flow with information
  - Covenant not to re-identify for de-identified disclosures

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## Hi-Ethics Principles

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### *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

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### *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

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### *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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## Hi-Ethics web site: [www.hiethics.org](http://www.hiethics.org)

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## eHealth Code of Ethics - Coalition Summit

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### *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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## Web site: [www.ihealthcoalition.org](http://www.ihealthcoalition.org)

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## Self-Regulatory Codes and HIPAA

### A simple comparison

	HIPAA	Hi-Ethics	eHealth Code
Notice and consent	Yes	Yes	Yes
Chain of Trust	Yes	Yes	Maybe
Health Info is Special	Yes	Yes	Yes
Pages	> 1500	8	9
Available	Almost	Now	Now

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## Comparison of self-regulatory codes

### Medscape General Medicine - [www.medscape.com](http://www.medscape.com)



<http://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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## Health Affairs - [www.healthaffairs.org](http://www.healthaffairs.org)

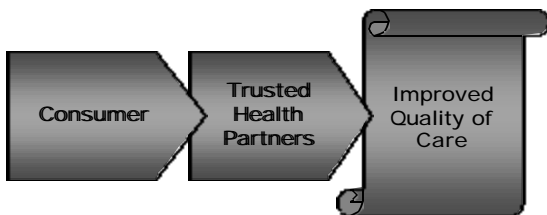
### Boulding Article - "Self-Regulation: Who Needs It?"



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## Reintermediation: Building Trust



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## Q & A Period

Follow-up Questions:  
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[cbs.healthwatch.com](http://cbs.healthwatch.com)

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