



Law & Regulation of the Healthcare Internet

The eHealth Colloquium

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Regulate What?

- What is ehealthcare or what was it?
- Moore's law makes regulation futile
- Convergence of technologies challenges historic context of regulation
 - Internet wired and wireless, genetic engineering, nanomachines, remote sensing, sentient robots
- Bill Joy's question/warning: Will we survive our technology?



Context: Past, Present & Future

- Regulation of healthcare
- Regulation of commerce
- Regulation of communications
- Regulation of content
- Regulation of technology
- Regulation of the future



Fraud and Abuse

- All the same rules apply to the Internet
 - Anti-Kickback Laws
 - Stark Laws
 - Beneficiary Inducement Laws
 - State Fee-Splitting Laws
 - Provider/Supplier Licensure Laws



Fraud and Abuse

- Anti-Kickback laws (federal & state)
 - cannot pay for referrals/recommendations
- Physician Self-Referral laws (federal & state)
 - Physician cannot refer patients to provider with which it has financial relationship
- Example: Hospital pays for/subsidizes development of website for affiliated MD group
 - Disguised kickback?
 - Creation of financial relationship between hospital and physician?



Privacy

- More than Web Page Statements
 - Report of the California Healthcare Foundation
- State Privacy Laws
- Federal - HIPAA and others
- Trans-National: EU and Canada



Data Security

- HCFA Internet Security Policy
- HIPAA Reg. Coming
- Digital Certificates
- Health Data Communication Security Standards



Administrative Simplification

- Code Sets
- UPINs
- WEDI Interoperability



FDA Regulation of Medical Software

- eHealthcare as a Medical Device
- Convergence of EMRs, ASPs, Remote Sensing, and Disease Management
- Good Manufacturing Practices
- Clinical Trials Coming?



FTC Content Regulation

- Fraud
- Validity, Accuracy of Content
- False and Misleading Advertising
- Consumer Privacy



Internet Pharmacies

- Licensure
- Dispensing
- Privacy and Information Sharing
- Intersection with Disease Management
- Off-Shore/Cross Border Pharmacies



Internet Pharmacies

- Internet Prescription Drug Sales Act of 2000
 - Draft bill -- Would require online pharmacies to be licensed in each state where they do business and to notify federal authorities and state board prior to launching a Web site
- Prescription Drug Marketing Act of 1987
 - Generally bans re-importation of drug products into the U.S.
 - May prohibit the purchase of U.S. made drugs from foreign Internet distributors by American consumers



Medical Malpractice: Constraint or Incubator

- Community Standard gives way to Evidence Based Medicine
- Please Define “Community”
- Patient Safety/Medical Errors
- Judicial System Drives eHealthcare



Uniform Electronic Transactions Act (UETA)

- Primary objective of UETA is to establish the legal equivalence of electronic records and signatures with paper writings and manually-signed signatures, removing barriers to electronic commerce
- The Act recognizes electronic records, signatures and writings as legal for most transactions



Uniform Computer Information Transactions Act (UCITA)

- Approved by the National Council of Commissioners on Uniform State Laws
- Applies to computer information transactions
- Extends the UCC to “computer information”
- Controversial due to concerns that UCITA does not adequately protect consumers and allows contract law (not federal copyright law) to govern electronic transactions



Children's Online Privacy Protection Act (COPPA)

- Effective April 21, 2000
 - Applies to the online collection of personal data from children under the age of thirteen



Professional Licensure

- Telemedicine
 - Remote Diagnosis
 - Remote Treatment
 - Remote Surgery
- Medicine Beyond Geopolitical Boundaries
- Who regulates the Professions
- Time for National Licensure/State Reciprocity?



Corporate Practice of Medicine

- States prohibit practice of medicine without a license
- Corporations cannot practice medicine in certain states (e.g., California and Texas)
- Many states allow corporations to “practice medicine” by engaging licensed practitioners
- Other states prohibit corporations from engaging licensed practitioners



Digital Millennium Copyright Act of 1998

- Updates U.S. copyright law for the digital age in preparation for ratification of the World Intellectual Property Organization (WIPO) treaties
 - Key Provisions
 - the circumvention of copyright protection systems
 - fair use in a digital environment
 - online service provider (OSP) liability



Government Reimbursement for eHealthcare?

- Can Government Keep Up with eHealthcare?
- What is the Basis for Medicare Coverage?
 - Where Do Smart Devices Fit? eDisease Management?
 - How Does Society Value the Future
- Can eHealthcare Succeed without Reimbursement?
- Be Careful What you Ask For...



Bill Joy's question/warning:



Bill Joy's question/warning:

Will we survive our technology?



Bill Joy's question/warning:

Will we survive our technology?

**Maybe,
But not without
deft and innovative regulation**



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