

The healthcare interface

NPUC

2007

IBM Almaden
July 9th



Health Care Legal Implications of User Interface Technology

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Overview

- **Health Care Legal Framework:** *Why are legal issues important in the development cycle?*
- **Significant Legal Risks:** *What are the primary health care legal issues affecting development of new technology?*
- **Risk Management:** *What can be done to minimize the risk and maximize business success?*

Health Care Legal Framework

- **Complex:** May be the only framework more complex than the health care system itself. Requires experience and specialized expertise.
- **Arcane:** Lawmakers are not technologically savvy, and neither are the laws. Law lags technology, especially in health care.
- **Uncertain:** Laws are vague, counterintuitive, and broadly interpreted by courts and government agencies. They do not make sense from a business perspective.
- **Punitive:** Civil and criminal penalties that can apply to the company, to management and to other individual employees.
- **High profile:** Enforcement is hot and heavy—a darling of the media.

Key Legal Risks

- **Privacy and Security:** Numerous overlapping federal and state laws apply if your technology touches personal information about patients or consumers in any way.
- **FDA Regulation:** Governs how medical devices—including software—used for diagnosis or treatment is made, packaged, labeled, marketed and sold. Requires early analysis and planning.
- **Medicare Reimbursement:** The top line. If you want anyone to buy your products, they need to fit into the health care reimbursement system: requires consideration early in the development cycle.
- **Fraud and Abuse:** Influencing patient or physician choices can be seen as a “scheme or artifice” to steer health care product referrals. Can affect product design and sales strategy.
- **Malpractice:** Technology may be seen by users as potentially causing mistakes rather than preventing them.

Data Privacy and Security

- **HIPAA:** Privacy and Security Regulations; Transactions Rule.
- **Other Federal Laws:** Drug and Alcohol Abuse Confidentiality Law, Gramm-Leach-Bliley, FTC Act, and many others.
- **State Medical Privacy Laws:** Some, (e.g., FL and CA), much more restrictive than HIPAA; many state laws more restrictive re: genetic, HIV/AIDS, mental health, substance abuse, STD, and other sensitive health data.
- **State Security Breach Notification Laws:** Technology should allow for compliance.
- **Consumer Protection Laws:** Govern collection, use, storage and disclosure of personal information.
- **Common Roadblocks:** Identification (user and record), Authentication, Access controls, Audit trails

Random HIPAA Facts

- **Applies only to covered entities:** Health plans, clearinghouses, certain providers
- **Applies to all EHRs, but not all PHRs:** Can structure to receive PHI that becomes non-PHI upon receipt
- **Individual holds key:** If disclosed to the individual OR with proper authorization, then information is no longer PHI
- **HIPAA Authorizations:** Have specific requirements
- **Or Maybe Not:** Proposals to extend HIPAA-like requirements are gaining steam
- **De-identification:** very strict definition; more than creating anonymous data

Other Privacy and Security Issues

- **Overlapping state laws:** Makes compliance impossible in some cases; need preemption
- **FTC Fair Information Practices:** Disclosure and consent/authorization key best practices
- **Provider Information:** Trend to protect physician-identifiers: NH, VT. Need capability to weed-out specific types of data
- **Security Breach notification:** Can we tag and follow all data?
- **Opposing forces:** Technology vs. privacy—wireless, RFID, video and voice, contextual and ubiquitous computing

Definition of a Medical Device

- **Intended Use:** For diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body—and does not work through chemical action (i.e., is not a drug or biologic)
- **Software:** Included if accessory to a medical device (infusion pump, MRI, pacemaker), or if stand-alone and not exempt (i.e., educational, general purpose use or subject to “competent human intervention”).
- **Can Include:** Decision support software, diagnostic x-ray systems, components of remote monitoring systems, context awareness programs

Medical Device Classifications

- **Class I:** General controls are sufficient for safety (e.g., registration, branding rules, records and reporting, GMP); includes bandages, scalpels, plastic gloves
- **Class II:** Require special controls (e.g., usually premarket notification (510(k)), performance standards, postmarket surveillance); includes general surgery lasers, diagnostic ultrasound, lithotripsy
- **Class III:** Usually require premarket approval (PMA); for use in supporting or sustaining life, preventing impairment of health, or device presents unreasonable risk of illness or injury; includes spinal implants, artificial hearts, ophthalmic lasers

Software as Medical Device

- **Stand-alone:** Intended to receive medically-related data as input and output results to a medical professional or other user (blood bank system controlling donor deferrals and releases, decision support, calculation of drug dose). Exemptions include library functions (research), general purpose (i.e., word processing software), and competent human intervention (function transparent to physician user).
- **Component:** Incorporated into another device (e.g., pacemaker, MRI device). Requires approval.
- **Accessory:** Accessory to another device (radiation treatment planning; conversion and transmission of medical images). Case by case, depends on risk.

FDA Governance

- **Application Can Be Uncertain:** E.g., computer software and hardware used for physician decision support systems or telemedicine. Look at other devices FDA has approved or exempted; read regulations, submit 510(k).
- **Clinical Trials:** Some devices require carefully scripted clinical trials with results reviewed and debated prior to approval—expensive and time-consuming
- **Even Without Clinical Trials:** Approval process complex and can take years
- **Requires Early Analysis:** Factor into business strategy and budget and identify as risk factor to investors

Reimbursement—How Providers and Patients will Pay for your Technology

- **Medicare:** Complex and confusing system of standards and rules that is changing constantly; does not reimburse for all products and services; those that are reimbursed must fall into specific categories with pre-determined amounts allowed
- **Private Payers:** Generally follow Medicare; otherwise case by case, health plan by health plan
- **Consequence:** Failure: a great technology that no one will/can buy



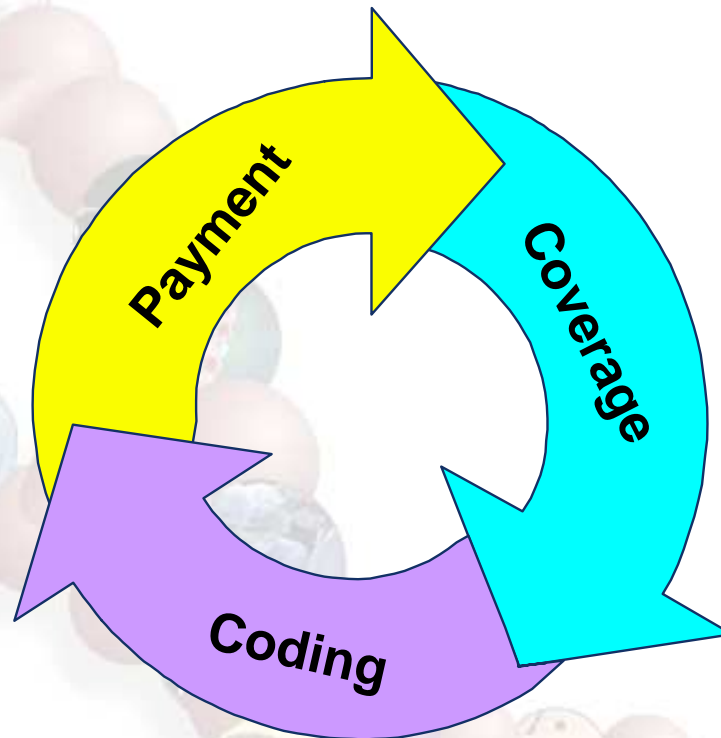
**“Government scientists announced a big breakthrough:
Someone finally figured out how Medicare works!”**

Three Independent Issues

CODING – How will it be billed?

COVERAGE – Will there be any payment at all?

PAYMENT – How much will it be reimbursed?



Reimbursement Nightmares

- **Inpatient Device:** Inpatient stays subject to DRGs; if technology too expensive for amount allowed under the DRG at issue, hospitals will not use it; if it increases the length of stay, despite better outcomes, hospitals will not use it.
- **Outpatient Device:** Procedure must be a covered service and technology a covered product, or no reimbursement will be provided for the technology: e.g., Medicare does not pay for substance abuse treatment, thus related technology may be difficult to market.
- **Self-Pay:** The only market left.

Fraud and Abuse Laws

- **Federal and State:** Anti-Kickback, Stark (self-referral), False Claims, Health Care Fraud
- **Anti-Kickback:** Whoever knowingly and willfully solicits or receives any remuneration (including kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, (A) for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program.
- **Aiding and Abetting:** Analyze product and sales/adoption strategy
- **Enforcement:** In 2006, OIG reported recoveries of \$38.2 billion, exclusion of 3,425 entities and individuals, and filed 272 civil and 472 criminal actions against individuals and entities. OIG, FBI, DOJ and states have pooled resources and are aggressively pursuing cases, including a focus on device manufacturers

Errors and Professional Liability

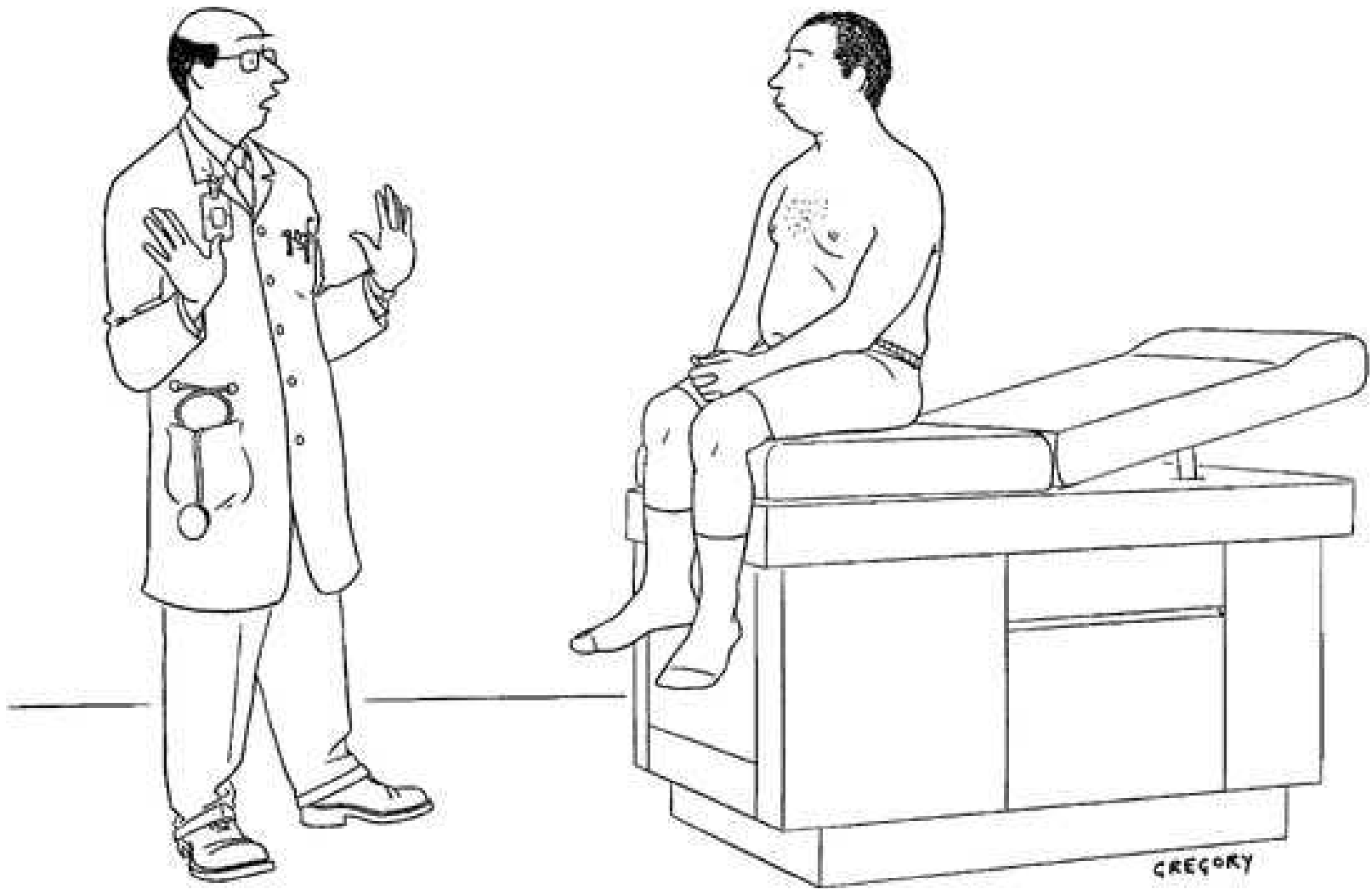
- **Creates Fear of Adoption:** Need to build in protections and sales staff may need to provide rationale to providers and lawyers
- **Insurance Coverage:** Study insurance market re: inclusion or exclusion in coverage
- **Allow for redundancy:** Providers more comfortable testing in environment that has traditional paper-based redundancy
- **Address Process/Training:** If they buy it but don't use it, worse than if not bought at all

Strategies for Managing Risks

- **Identify Risks Early:** Build into budget and timeline; create reasonable expectations for stakeholders
- **Product Development:** Build in flexibility for disclosures to and consents/permissions from users: in some cases may have to sacrifice elegance of user experience for risk mitigation and product success
- **Internal Communication:** Educate all participants in development, production and sales cycles
- **External Communication:** Get involved in D.C. and in trade industry groups to educate lawmakers and regulatory agencies; respond to proposed regulations

Take-Aways

- **Intersection of technology and health care:** the Perfect Legal Storm
- **Putting together the right team from the start is crucial:**
 - Management attuned to importance of getting it right but also not paralyzed by risk
 - Development team not isolated from health care reality
 - Specialized lawyer with ability to interpret and integrate legal advice into a cohesive business strategy
 - All must be strong critical thinkers and good risk managers



"Whoa—way too much information."

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