

Davis Wright Tremaine LLP



eHealthcare Legal and Regulatory Issues
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Part I

Introduction



What Is E-Health Law?

- ◆ Healthcare Law
- ◆ Copyright Law
- ◆ Commercial Law
- ◆ Internet Law
- ◆ Much More



eHealth — Market Considerations

- ◆ Web content related to healthcare is proliferating rapidly — the Alta Vista search engine identified 5,000 pages indexed by “health” in December 1996; 18,000 in October 1998; 13,749,000 in January 2000; 23,551,210 in May 2000; 24,934,700 in July 2000; 21,854,255 in October 2000; 21,106,330 in January 2001
- ◆ In 1999, 25 million adults used the Internet for healthcare purposes. That number is expected to grow to 30 million by the end of 2000
- ◆ 70% of physicians have office internet and physician-patient e-mail has tripled in the last year
- ◆ By 2003, 156.7 million persons will be online and 19% of the online population will be 50 or older (Jupiter Communications)



Regulating eHealth

- ◆ Healthcare is among the most regulated of American industries
- ◆ The explosion of healthcare-related activity on the Internet has generated considerable attention from state and federal regulators
- ◆ Attorney General's working group reviewed unlawful healthcare conduct on the Internet and concluded significant new substantive legislation not necessary
- ◆ OIG, DOJ, DOC, FTC, FDA and FBI all have federal jurisdiction
- ◆ A variety of state agencies/organizations may have jurisdiction depending on the situation



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Part II

Online Pharmacies



Pharmaceuticals and the Internet

- ◆ Pharmaceuticals are at the center of complex, cutting edge legal issues
- ◆ The role of On-Line Pharmacies (“OLPs”) is expanding rapidly
- ◆ In 1999, total sales of \$1.9 billion by OLPs, \$160 million for prescription drugs
- ◆ During 2003, \$1 billion in prescription drugs will be sold by OLPs (Jupiter Communications)



History of Regulation

- ◆ Regulation of Pharmaceuticals
- ◆ State Regulation
 - ❖ Practice of Pharmacy
 - ❖ Practice of Medicine
- ◆ Mail Order Pharmacies
- ◆ State and Federal Enforcement Efforts



OLP Models

- ◆ Three types of business activity
 - ❖ Traditional pharmacy business
 - ❖ Business combining pharmacy activity with prescribing regimen
 - ❖ Offshore pharmacy



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Business # 1

**The Traditional
Pharmacy Goes
Online**



State Licensure Issues

- ◆ Licensed in the state in which they operate
- ◆ Compliance with state laws where patients located
- ◆ Licensure or regulatory approval required in each of the states in order to maintain compliance



Protection of Patient Confidentiality

- ◆ Potential liability for damages caused by inappropriate disclosure of patient information
- ◆ Pharmacies must use latest technology available for data encryption
- ◆ Must take other appropriate electronic security measures



Other Legal Issues

- ◆ Risk management and professional liability
 - ❖ Prescription appropriately written
- ◆ Verification Activities
 - ❖ Ensuring prescription is valid
 - ❖ Physician is authorized to write prescription
 - ❖ Physician has appropriate licensure



Health & Product Information

- ◆ Must be accurate and not misleading
- ◆ Inappropriate information could result in potential liability
- ◆ State consumer protection or Federal Trade Commission action



Survey Regarding - DTC Advertising of Pharmaceuticals

Of those people surveyed:

- A. 1/3 reported asking their doctor for information about a drug they had seen or heard advertised and 1/4 asked for and usually got the drug
- B. 50% believe the FDA approves all DTC drug ads
- C. 43% believe only safe drugs can be advertised
- D. 22% believe drugs with serious side effects are banned
- E. 21% believe only extremely effective drugs can be advertised



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Business # 2

**Pharmacies that
Prescribe**



Pharmacies That Prescribe

- ◆ Combines the pharmacy function with a prescribing function
- ◆ Online user to access pharmaceutical information, fills out patient encounter forms, and orders pharmaceuticals
- ◆ Patient does not independently seek medical advice nor have an independently obtained prescription
- ◆ Online process includes a physician “consultation”



Legal Issues & Risks

- ◆ Internet development has challenged traditional boundaries
- ◆ A licensed physician or authorized health care professional is required to make prescription decision
- ◆ Without valid prescription, pharmacy could violate the practice of medicine prohibitions



Reducing the Legal Risk

- ◆ Organizations should retain licensed physicians to provide appropriate patient review and prescriptive authority
- ◆ Physicians face the risk of violating the practice of medicine laws in various states
- ◆ Attorney General and state enforcement initiatives



Site Design Challenges

- ◆ Sufficient patient information must be obtained
- ◆ Role of the physician in the review
- ◆ Physicians who prescribe without sufficient patient contact risk ethical, regulatory, and legal challenges



Health Care Specific Regulatory Issues

- ◆ Fraud & Abuse
- ◆ Stark and State Anti-referral statutes
- ◆ AMA Code of Ethics



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Business # 3

**Offshore
Pharmacies**



Offshore Pharmacies

- ◆ Most problematic from a regulatory and enforcement perspective
- ◆ Allows consumers on the Internet to obtain pharmaceuticals without prescription from a physician
- ◆ Allows consumers to obtain pharmaceuticals without quality control standards



Legal Issues

- ◆ Most of these companies are designed not to comply with applicable federal and state laws
- ◆ Ability to track down and enforce American legal standards on these organizations is difficult to achieve



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**Policy Issues,
Enforcement &
Certification**



The Future of OLPs (and E-Health)

- ◆ Legal and regulatory environment struggles to respond
- ◆ Will a model act for pharmacy/internet interface and practice of medicine over the Internet be developed?
- ◆ Will comprehensive and pre-emptive federal legislation emerge?



Internet Prescription Drug Sales Act of 2000

- ◆ OLPs must be licensed in each state into which they deliver prescription drugs
- ◆ OLPs must comply with all Federal and State laws applicable to pharmacies
- ◆ Before launching site, OLPs must provide information to Health and Human Services and relevant Pharmacy Boards.
- ◆ Big penalties (\$500,000) for violations



National Association of Boards of Pharmacy

- ◆ Established a self-regulating seal of approval for companies that operate on the Internet in the pharmaceutical area
- ◆ Organizations that comply with the criteria of NABP may display its “seal of approval”
- ◆ Require online pharmacies be licensed in every state they ship drugs
- ◆ Sites must meet standards for patient privacy, quality assurance, authentication and security of prescriptions and communications between patient and pharmacist



Regulatory & Enforcement Context

STATES

- ◆ Regulation: Licensure of Providers & Pharmacies
- ◆ Enforcement: Consumer Protection & Provider Issues

FEDERAL

- ◆ Regulation: Pharmaceuticals
- ◆ Enforcement: Consumer Protection



FDA tips to Consumers Regarding OLPs

1. Check with NABP regarding good standing
2. Don't buy if no physical exam, no prescription, or not FDA approved drug
3. Don't buy if no registered pharmacist to answer questions
4. Avoid sites that don't identify who you are dealing with or that have no US address and phone #
5. Don't purchase from foreign websites -- illegal to import and little US government can do if "you get ripped off."



The E-Health Policy Issues For Licensure

Considerations for Regulation/Licensure/ Enforcement

- ◆ Consumer Protection (Education, Fraud, Privacy)
- ◆ Quality Oversight
- ◆ Support Clinical/Business Innovation
- ◆ Unburdensome Regulation with clear guidance



State Approaches

- ◆ Coordinated State Initiatives
- ◆ Model UCC, Uniform Acts (Limited Partnership, LLC)
- ◆ Coordinating Approach - FSMB/NAPB
- ◆ Challenges - Coordination, Multiple Parties, Turf Battles



Federal Licensure

- ◆ FDA proposed regulation
- ◆ Model - ERISA
- ◆ Challenges - Regulatory expertise, against historical approach and state interests
- ◆ US Jurisdiction/International



Enforcement Initiatives

- ◆ State
- ◆ Federal
- ◆ International
- ◆ Tailor Effort to Evolving E-Commerce Market



Part III

Overview of General E-Health Legal Issues



Cybermedicine Liability Issues

- ◆ When does providing medical information through a website become the practice of medicine?
- ◆ States' laws determine what constitutes the practice of medicine.
- ◆ Generally, a physician-patient relationship is formed when a physician exercises independent medical judgment on behalf of a patient.
- ◆ Telephone or online diagnosis appears to qualify as the practice of medicine in many states.



Cybermedicine Liability Issues (cont'd)

- ◆ Physicians providing online medical advice may subject themselves to the jurisdictions of many states, each with its own definition of the practice of medicine.
- ◆ Corporate practice of medicine issues — medical information sites that use physicians to provide advice or information directly to individual patients may be at risk.



Cybermedicine Liability Issues (cont'd)

- ◆ The Internet creates the potential for greater confusion regarding who is the provider of care.
- ◆ Linking arrangements create the possibility of creating the appearance of integration or affiliation among healthcare providers that may not exist.



Information Torts

- ◆ Healthcare provider liability actions will most likely involve information torts.
- ◆ An information tort arises from the quality of information interchange between provider and patient, rather than interpersonal acts or quality of care.
- ◆ Examples: informed consent and failure to warn.



Information Torts (cont'd)

- ◆ Courts will have to decide how to allocate the risk for erroneous medical information disseminated online: it's becoming cheaper and easier for physicians to give advice and for patients to access advice and information.
- ◆ Is it reasonable to hold a single physician responsible to a hundred recipients of medical “advice”?



Telemedicine Laws

- ◆ State telemedicine statutes generally do not permit physicians to directly provide care to patients in other states via the Internet without appropriate state licensure.
- ◆ Exceptions are often permitted for emergencies, consultations and educational purposes.
- ◆ State legislatures are seeking to continue to control the practice of medicine in their states.
- ◆ It's unlikely that telemedicine laws will be loosened to make the practice of medicine in multiple states through the Internet any easier.



Chat Room Liability

- ◆ Erroneous medical information may be spread by users or patients through a chat room or message board sponsored by a provider.
- ◆ Should the chat room content be monitored or moderated?
- ◆ For providers, ethical considerations may control.
- ◆ For non-providers, monitoring content may increase responsibility (and liability).
- ◆ *Zeran v. America Online*: how much protection does this case offer to providers?



False Advertising Issues

- ◆ Every web site is essentially an advertisement.
- ◆ Providers should take the same care with web site content as they do with advertising.
- ◆ Providers should carefully review any factual statements made on web sites regarding response times or success rates.



Federal Trade Commission Enforcement

- ◆ FTC is targeting fraud, violations of consumer privacy and deceptive marketing practices on the Web.
- ◆ FTC conducts “surf days” to scan the Internet for fraud.
- ◆ Areas of focus: online pharmacies and healthcare products making deceptive claims.



Provider - Patient E - Mail

- ◆ Whether providers realize it or not, patient e-mails are part of the medical record and should be treated as such.
- ◆ Security of patient e-mails must be guarded — a patient sending an e-mail to drsmith.com may have an expectation that it is being read solely by Dr. Smith, when it may be printed out and left on a desk where the entire office staff and other patients may read it.
- ◆ Encryption of provider-patient e-mail will be required by HIPAA — it is advisable today.
- ◆ Handling of e-mail communications should be consistent with the provider's general standard of practice.



Provider - Patient E - Mail (cont'd)

- ◆ One of the appeals of e-mail is that you can answer whenever you like.
- ◆ Court cases have established that a physician may be negligent for failing to return a patient's phone call within a reasonable period.
- ◆ Providers should establish specific expectations for e-mail response time.
- ◆ Providers should consider whether certain types of communications (like test results) should be communicated by e-mail in the absence of appropriate encryption.



Privacy Issues — Overview

- ◆ A maze of contradictory and competing laws, both within and outside the U.S., may apply to sites that collect personal data about users.
- ◆ Electronic Funds Transfer Act.
- ◆ The Fair Credit Reporting Act.



Privacy Issues — Overview (cont'd)

- ◆ European Union Privacy Directive.
- ◆ The Children's Online Privacy Protection Act.
- ◆ FDA electronic submission regulations.
- ◆ HIPAA.



HCFA Internet Security Policy

- ◆ Unlike HIPAA, the November 1998 HCFA Internet Security Policy is being enforced today.
- ◆ Serves as a stop-gap until HIPAA becomes effective.
- ◆ Applicable to entities that contract with HCFA and handle Medicare beneficiary information (carriers, intermediaries, state Medicaid programs, Medicare+Choice plans).



H C F A I n t e r n e t S e c u r i t y P o l i c y (c o n t ' d)

- ◆ A covered entity transmitting Medicare beneficiary information over the Internet must have the following measures in place:
 - ❖ encryption
 - ❖ authentication or identification of users
 - ❖ use of an effective password/key management system.



Privacy Policies

- ◆ A web site privacy policy should not be a generic document — it must reflect your actual privacy practices.
- ◆ Deceptive or incomplete privacy policies may violate state consumer protection or false advertising laws.
- ◆ Possibility of FTC scrutiny.



Common Privacy Policy Mistakes

- ◆ Failure to disclose use of cookies.
- ◆ “Puffing” regarding level of security protections — there’s no such thing as “100% secure.”
- ◆ Failure to address Children’s Online Privacy Protection Act (when applicable).



Common Privacy

Policy Mistakes (cont'd)

- ◆ Failure to clearly and accurately describe use of aggregate or de-identified user data.
- ◆ Failure to address employee training and discipline.
- ◆ Exclusion of “consent to policy updates” through continued use of site.



New Theories of Liability

- ◆ Failure to comply with a site's posted privacy policies may violate state unfair and deceptive acts and practices statutes, as enforced by state Attorneys General.
- ◆ Possibility of negligence actions against sites for security breaches, including acting as a host for hacker attacks.
- ◆ A class action lawsuit has even been filed in Texas seeking to apply the Texas anti-stalking law to Yahoo's use of cookies.



Terms of Use Disclaimers

- ◆ No medical advice.
- ◆ No warranty regarding goods or services.
- ◆ Limitation of liability, including consequential damages.



Terms of Use Disclaimers (cont'd)

- ◆ Not responsible for chat room and message board postings.
- ◆ Not responsible for privacy practices of linked sites.



Terms of Use

- ◆ Remember to adapt the Terms of Use for new functionalities that may give rise to liability, such as a drug interaction checker or medication reminder.
- ◆ Clarify any ambiguities regarding corporate entities and affiliations.



Terms of Use (cont'd)

- ◆ For content licensing or co-branding arrangements, make sure it's clear whose Terms of Use and Privacy Policy apply.
- ◆ Do the terms of use create a binding contract with users?
- ◆ *Ticketmaster Corp. v. Tickets.com, Inc.*



Regulatory Issues in Cyberspace

- ◆ Example: a medical information site charges pharmacies each time someone visiting the site clicks a link to the pharmacy to have prescriptions filled.
- ◆ The medical information site may be viewed as violating the federal anti-kickback statute if payments are being made to induce the referral of services (like pharmaceuticals) reimbursed by the Medicare program.



Hospital-Physician Networks

- ◆ Hospitals and health systems may wish to place hardware and software in the hands of affiliated physicians.
- ◆ These arrangements raise difficult issues under the federal anti-kickback statute, the Stark statute and state analogs.
- ◆ Network arrangements may also raise private inurement and private benefit issues for tax-exempt hospitals.



Hospital-Physician Networks (cont'd)

- ◆ Personal uses of the equipment should be limited.
- ◆ Turning a blind eye to personal uses and add-on of personal hardware and software is problematic.
- ◆ Unfortunately, good intentions are not an excuse.



E - Health Ethics Initiatives

- ◆ Health on the Net Foundation's Code of Conduct for Medical Web Sites.
- ◆ Hi-Ethics Alliance.
- ◆ Internet Healthcare Coalition draft "International e-Health Code of Ethics."



E - Health Ethical Issues

- ◆ Disclosure of financial relationships.
- ◆ Distinguishing content from advertising.
- ◆ Utilizing credible sources of medical information and providing authoritative attribution of sources.



Provider - Sponsored Sites

- ◆ Web sites intended to operate as a business may become entwined with healthcare regulatory issues when providers are involved.
- ◆ For this reason, many providers operate web sites through separate legal entities that do not directly provide healthcare services.



It May Be Legal, But Is It Ethical?

- ◆ A theme that will probably be repeated in the e-health arena: entrepreneurial providers whose actions are called into question based upon the “white coat syndrome.”
- ◆ Healthcare providers are not judged by the same ethical (and legal) standards as other business people — particularly when they are engaged in activities related to the healthcare profession.



Part IV

Select Website Legal Audit Issues



Legal Audit of Provider Websites

- ◆ The law of the Internet changes rapidly — so do the content and functions of most sites.
- ◆ Compliance is a moving target.
- ◆ Periodic legal audits, including updates to privacy policies and terms of use, are a virtual necessity.



Internet Legal Audit

1. Do you have a written agreement with your web site developer that addresses these issues?
 - ◆ Protection of your ownership of all intellectual property developed in connection with the site, including all code and graphics developed specifically for your site.
 - ◆ Your license to use (without payment of royalties) any prior intellectual property the developer owns that is it is bundling or using in your site.
 - ◆ The developer's duty to fix any bugs or faulty links, including the time frame for necessary corrections.



Internet Legal Audit (cont'd)

2. Do you collect personal data regarding users?



Internet Legal Audit (cont'd)

3. Do you have a policy regarding maintaining privacy of personal data? Is it sufficiently accessible to users?



Internet Legal Audit (cont'd)

4. Are you sure that you own the intellectual property or other content offered on your site?



Internet Legal Audit (cont'd)

5. Have you placed a copyright notice on your site? Have you considered periodically registering the evolving content of your site with the U.S. Copyright Office?



Internet Legal Audit (cont'd)

6. Have you considered registering an agent for notice of claimed infringements with the U.S. Copyright Office under the Digital Millennium Copyright Act?



Internet Legal Audit (cont'd)

7. Have you patented any technology that is made available through your site?
 - ◆ Do you qualify for a business process patent?



Internet Legal Audit (cont'd)

8. Have you considered registering your domain name as a trademark?



Internet Legal Audit (cont'd)

9. Have you considered in which jurisdictions your business may be sued? Have you taken appropriate measures to limit those jurisdictions through disclaimers or other measures?



Internet Legal Audit (cont'd)

10. Have you considered in which jurisdictions you may be subject to state and local taxation? Have you take measures to limit those jurisdictions through properly structuring your sales operations?



Internet Legal Audit (cont'd)

11. If your site contains hypertext links or frames, have the links or frames been constructed in a manner that minimizes your potential liability with respect to trademark infringement, trademark dilution and unfair competition claims?



Internet Legal Audit (cont'd)

12. Does your site include appropriate disclaimers with respect to:
- ◆ Liability arising from inaccurate information provided through the site?
 - ◆ Warranties of merchantability and fitness for a particular purpose for goods offered through the site?
 - ◆ Liability arising from content made available through hyperlinks to other sites?



Internet Legal Audit (cont'd)

13. Have you taken appropriate measures to ensure that any online contracts are binding and enforceable?



Internet Legal Audit (cont'd)

14. If you engage in e-commerce, are your refund and return policies appropriately disclosed to customers? Have you considered whether you must comply with state laws regarding Internet refund and return policies?



Internet Legal Audit (cont'd)

15. Have you reviewed your Internet advertising for compliance with state and federal laws regarding false and deceptive advertising?



Internet Legal Audit (cont'd)

16. Have you implemented reasonable security and encryption measures to protect your company's client information and other confidential and proprietary information?



Internet Legal Audit (cont'd)

17. Do you have actual knowledge that you receive personal information from children under age 13? If so, you may be required to comply with the Children's Online Privacy Protection Act ("COPPA").



Internet Legal Audit (cont'd)

18. Do you collect or transmit patient identifiable information?
If so, you should develop policies and procedures for compliance with HIPAA electronic data security and privacy standards, the HCFA Internet Security Policy and applicable state medical records privacy laws.



Internet Legal Audit (cont'd)

19. Is medical information or advice provided through your site?
If so, you should consider whether such activities may constitute the practice of medicine or another licensed profession.



Internet Legal Audit (cont'd)

20. Do you operate a medical chat room or message board? If so, you should assess the potential liabilities arising from erroneous medical information provided by users, consider appropriate disclaimers and evaluate whether chat room or message board communications should be monitored or moderated.



Internet Legal Audit (cont'd)

21. Do you provide a product, such as clinical diagnostic software, that may constitute a medical device subject to FDA regulation?



Internet Legal Audit (cont'd)

22. Does your site involve transactions between healthcare providers, whether through e-commerce, advertising or in-kind exchanges? If so, you should consider whether your site complies with the federal Stark II statute and applicable state laws prohibiting self-referrals.



Internet Legal Audit (cont'd)

23. Does your site directly or indirectly relate to the referral of patients? If so, you should consider whether your site complies with the federal anti-kickback statute and applicable state laws prohibiting payments for patient referrals.



Internet Legal Audit (cont'd)

24. Do you have an insurance policy that addresses liabilities arising from web site operations?

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