

**HEALTH CARE FRAUD & ABUSE:  
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**E-HEALTH COMMERCE:  
ENFORCEMENT AND COMPLIANCE ISSUES**

by

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### I. INTRODUCTION

- In September of this year a federal judge in New York held that MP3.com, an online music site, had willfully infringed the copyrights of Universal Music Group, the world's biggest record company, by making its CDs available for play over the Internet. The court ordered MP3.com to pay damages that could total \$250 million. *See UMG Recordings, Inc. v. MP3.Com, Inc.*, 2000 WL 1262568 (S.D.N.Y.) (“MP3.Com”).
- In so holding, the judge sent a strong message to the burgeoning dotcom industry by stating:

Some companies operating in the area of the Internet may have the misconception that, because their technology is somewhat novel, they are somehow immune from the ordinary application of laws of the United States...They

need to understand that the law's domain knows no such limits.

*MP3.Com* at \*6.

## II. ENFORCEMENT TRENDS IN E-HEALTH COMMERCE

- *MP3.Com* is illustrative of a broader trend in dotcom—namely the government's increased interest in and willingness to regulate commercial use of the Internet through the application of existing laws.
- Until recently, government has taken a “laissez-faire” approach to enforcement issues on the Web fearing strict enforcement of the laws could stifle Internet innovation.
- Now, however as is evident from the ruling in the MP3 case, the government is ready to play a more proactive role in monitoring and enforcing legal issues on the Internet.
- This new government attitude could have widespread ramifications for the e-health industry.
- The Office of Inspector General (“OIG”) has yet to release a fraud alert or any advisories dealing with specifically with e-health, although existing advisories could well apply.
- In the meantime, e-health sites are proliferating. Some sites are providing valuable services to on-line consumers while others are not only providing potentially dangerous misinformation and products or simply operating outside of professional licensing laws.
- While we wait for the official word from government agencies, we can look to court decisions in other arenas, such as online music sites, to better gauge what role government may assume in the development of e-health.

A. Trends and Forecasts for E-health

- According to Forrester Research (see *Sizing Healthcare eCommerce*, Forrester, Inc., December 1999; *Full-service Health Sites Arise*, Forrester, Inc., February, 2000; Tyler Chin, *Internet Health Care Business On Verge Of Boom*, American Medical News (Jan. 31, 1999)):
  - Dotcom health care is predicted to hit \$370 billion by 2004. Of the \$370 billion, \$348 billion is expected to be composed of business-to-business health care transactions and \$22 billion is expected to come from on-line consumer purchasing. Fifteen billion of this is expected to be prescription drug purchasing.
  - Thirty-two percent of online consumers today shop for health products on the Web.
  - Forrester also notes that certain e-health companies “blur the boundaries between content and commerce.”
  - Marketers seek site partners, meaning that health care providers are partnering with site providers to offer their products and services, hopefully in a more targeted, cost-effective way.
  - E-health marketing dollars are being targeted at “physician-focused” sites with the “hope to win physician endorsements.” One company reports that by 2002 it will devote fifty-nine of its online health marketing dollars to physician sites.
- These comments and forecasts indicate the enormous potential for growth in the e-health industry in coming years, along with potential fraud and abuse landmines.

## B. Government Enforcement Efforts

- In general, e-health Web sites can be used either for content/information or product purchasing. However, as noted above, these lines are being deliberately blurred.
- There are two distinct levels of dotcom in the health care arena-business to consumer, or “B2C”, and business to business, or “B2B”.
  - B2C generally includes health care providers and businesses targeting their services at consumers, for instance, on-line pharmacies that sells drugs and other products directly to individuals or e-health sites that provide information to consumers.
  - B2B includes e-health arrangements between providers and businesses, such as disease management sites. B2B may ultimately involve use by consumers, as with B2C, but the relationship with legal implications is that between the individuals operating the e-health sites and their sponsors/partners, not consumers.
- To date, government has largely ignored B2B and has focused its enforcement efforts on B2C.
- As discussed in the two remaining sections below, government enforcement in the e-health B2B arena would focus on the application of the various frauds and abuse laws, including the federal Anti-kickback statute and Stark Laws.
- As discussed in the remaining part of this section, government enforcement of B2C e-health commerce has focused on consumer protection, and has involved all levels of government.

1. International Enforcement Efforts — FDA’s “Cyber” Letters

- According to Food and Drug Administration “Talk Paper” issued in February 2000, the FDA issued “cyber” letters to a number of foreign-based Web sites that sell or offer to sell online prescription drugs to United States citizens that may be illegal. *See FDA Launches “Cyber” Letters Against Potentially Illegal, Foreign-Based On-line Drug Sites*, FDA Talk Paper T00-8; Feb. 2, 2000.
- The FDA sent letters to the domain holders for sites warning the Web sites’ operators that they may be engaging in illegal activities.
- These “cyber” letters are similar in content and form to the agency’s traditional warning letters that it distributes to organizations and/or individuals believed to be engaging in suspect activities.
- In the electronic warnings, the FDA explained the laws governing prescription drug sales in the United States, and additionally outlined the nature of the Web sites’ alleged violations.
- The FDA requested a formal response to each issued cyber letter.

2. Federal Legislative Initiatives

- This past spring, the Clinton Administration proposed new legislation entitled, “Internet Prescription Drug Sales Act of 2000,” specifically addressing Internet drug sales and enforcement issues.
- The bill attempts to balance state and federal powers, by maintaining states’ existing

- Authority to crack down on unauthorized Internet drug sales, while adding new federal authorities.
- The legislation would:
  - ⇒ require all Internet pharmacies to be licensed in every state to which they deliver drugs;
  - ⇒ fine violators \$500,000 for each prescription drug sold without a valid prescription;
  - ⇒ give the FDA the power to subpoena online sites' records for investigative purposes; and
  - ⇒ allow the FDA to shut down sites that do not comply with the law.
- As part of the Budget Request for FY2001 the Clinton Administration is also asking Congress to approve \$10 million for the FDA to use in their enforcement of illegal and improper online activities.

### 3. Federal Enforcement – The Agencies Involved

- Potential federal enforcement agencies that could be involved include:
  - The Department of Justice (“DOJ”)
  - The Federal Bureau of Investigation (“FBI”)
  - The Federal Trade Commission (“FTC”)
  - The Food and Drug Administration (“FDA”)
  - The Office of the Inspector General in the Department of the Human and Health Services (“DIG”)
  - The Postal Service.
- The FDA has begun to work closely with a number of organizations and authorities at national and state level including National Association of Attorneys General, National Association of State Medical Boards, National Association of Boards of Pharmacy, and others.

- The National Association of Attorneys General (“NAAG”) is working with the National Association of State Medical Boards and National Association of Boards of Pharmacy to monitor online sales of prescription drugs.
- In May of 2000, Kansas Attorney General, Carla Stovall, testified before the House of Representatives Committee on Commerce Subcommittee on Oversight and Investigations on the topic of online pharmacies and investigative/enforcement issues.
- In her address, Attorney General Stovall called for the preservation of states’ historic authority in matters of regulating commerce and licensing of professionals who practice within the states’ borders, while at the same time, making the argument for cooperation at the federal level to efficiently and expediently regulate online pharmacies.
- NAAG is looking to federal agencies and future legislation to aid current and ongoing state enforcement efforts.
- Specifically, Stovall emphasized the need for nationwide injunctive relief.
- Stovall mentioned the federal telemarketing statute as a model for this type of federal and state enforcement arrangement.
- NAAG also emphasized the need for a national registration or disclosure requirement for entities selling prescription medications across state lines.
- NAAG is spearheading a collaborative effort to better monitor illegal or improper activities of online pharmacies.
- One result of such efforts has been the formation of the Online Pharmacy Working Group that has recently collaborated with representatives from the FDA, DOJ, and FTC.

- Due to the fact that online pharmacies generally sell and distribute drugs to patients in multiple states, the Online Pharmacy Working Group aims to educate states about legal action being taken against individuals and entities in other states.
- In her address, Attorney General Stovall illustrated the need for interstate and federal cooperation by discussing a Kansas lawsuit in which some of the defendants had five other suits filed against them by other states.
- The Online Pharmacy Working Group will notify medical boards where a defendant doctor is licensed, or the board of pharmacy where a defendant pharmacy is located, after a lawsuit is filed.
- It is then up to the state's licensing body to further investigate and take any necessary action against the party.
- The National Association of Boards of Pharmacy has established a system for certifying on-line pharmacies called the Verified Internet Pharmacy Practice Sites ("VIPPS"). *See Kansas Attorney General Carla Stovall Testifies On Illegal Online Pharmacies, State-Federal Cooperation to Protect Consumer*, National Association of Attorneys General, <http://www.naag.org>)
- "Under current law, the FDA has the authority to go after domestic sites that are selling drugs without a valid prescription. According to Jeffrey Shuren a medical officer at the FDA, the agency has some fifty ongoing investigations on various drug-selling Web sites." *Drugs on the Web*, National Journal (Nov. 13, 1999).
- The FTC has authority over "deceptive" medical information found on the Web. Some examples are: a site claiming that a physician is reviewing medical information to write a prescription when in reality there is no physician review or a site claiming

that a consumer's or patient's information will be kept private and then sells it to a direct-mail company. *Drugs on the Web*; National Journal (11/13/99).

- At a Symposium on Health Care and the Internet in March of 2000, Assistant Inspector General, Ted Acosta announced that the HHS Inspector General's office is creating a task force to investigate and address Internet fraud and abuse. *See Medicine and Health* ISSN 1047-8892; vol. 54; issue 14.

#### 4. Federal Enforcement Efforts

- The following are a few illustrative examples of federal enforcement activities in the e-health commerce arena. These examples are not intended to be an exhaustive list.
- Recently the DOJ and the FDA announced that four individuals and a Miami Company had been indicted for participating in a conspiracy to sell prescriptions drugs over the Internet without prescriptions. The criminal indictments, returned in July of this year by a federal grand jury in Montgomery, Alabama, allege violations of the Federal, Food, Drug, and Cosmetic Act. *See Federal Regulators Announce Indictments in Alleged Online Prescription Drug Scam*, HFRA vol. 4, No.17.
- The FDA asked a court in Florida for a permanent injunction to stop the Internet marketing and sale of laetrile, a potentially toxic substance sold as a cancer cure. Judge Shelby Highsmith granted the preliminary injunction, stating that it appears likely that the defendant companies are in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 331 (a) and (b), "by introducing and delivering for introduction into interstate commerce unapproved and misbranded drugs." *See United States v. World Without Cancer Inc.*, No. 00-3163, (S.D. Fla. 2000); BNA's Health Care Daily, vol. 5, No. 179 ISSN 1091-4021.

- The FDA also sought a permanent injunction against a New Jersey Corporation's marketing of unproven claims for unapproved drugs on Internet Web sites, books, and articles. *See FDA Talk Paper T99-56* (Dec.10, 1999).

5. State Enforcement Efforts

- The following are a few illustrative examples of state enforcement activities in the area of e-health commerce. These examples are not intended to be an exhaustive list.
- Kansas. In February of 1999 Kansas Attorney General Carla Stovall and the Kansas Board of Pharmacy brought suit against an Internet company for deceptive advertising and offering prescription drugs without appropriate physician evaluation. The Attorney General alleges that the company conducted its business in violation of the Kansas Consumer Protection Act by misrepresenting its services and its products. *See Attorney General Stovall and Kansas Board of Pharmacy File Lawsuit Against Company Selling Viagra on the Internet*, Attorney General Press Release, <http://www.ink.org/public/ksag/contents/news-releases/news99/viagra.htm>.
- Michigan. In August 2000, Michigan Attorney General Jennifer Granholm filed Notices of Intended Action ("NIA") (AG File No. 20009353) against pharmaceutical company Searle, a division of Pharmacia Corporation, alleging that Searle used Pharmatrack to install cookies on the browsers of visitors to Searle's Web site without disclosing this practice on the Web site. The practice enabled Searle to interact with visitor's browsers and determine what other Web sites that visitor had been looking at. The NIA alleged that this practice violated the states Consumer Protection Act and constituted a deceptive business practice.
- In December of 1999, Michigan also filed NIAs against ten online pharmacies selling and/or distributing prescription drugs illegally without appropriate physician

supervision. The NIAs allege that the online pharmacies' practices of distributing prescription-only drugs are in violation of Michigan's Consumer Protection Act that requires prescription drugs to be dispensed by licensed pharmacies and physicians.

*See Attorney General Press Release*, (Dec. 15, 1999):

[http://167.240.254.37/AGWebSite/-press\\_release/pr10157.htm](http://167.240.254.37/AGWebSite/-press_release/pr10157.htm).

- Illinois. In October of 1999, Illinois Attorney General Jim Ryan filed four lawsuits against online pharmacies for illegally selling prescription drugs over the Internet without proper licensing. The lawsuits were filed against out-of-state Internet companies, their operators, associated doctors and pharmacies. The lawsuits charge that the defendants violated Illinois' Consumer Fraud and Deceptive Business Practices Act, the state Medical Practices Act and the Illinois Pharmacies Act by failing to disclose to consumers that their companies, doctors, and pharmacies were not licensed or registered to do business in Illinois. Attorney General Ryan sought a permanent injunction, legal costs, a \$50,000 penalty and an additional \$50,000 penalty for each violation of the Consumer Fraud Act. *See Attorney General Press Release*: <http://cait.wiu.edu/press/pressfrm.html>
- Texas. Texas Attorney General John Cornyn sued three online pharmacies Web sites for filling drug prescriptions on the basis of on-line consultations in violation of the Texas Deceptive Trade Practices Act. *See Texas v. MedPrescribe.com L.L.C.*, No. GV-001933, ( Tex. Dist. Ct. 2000); *Texas v. Expressmed Services Corp.*, No. GV-001934 (Tex. Dist. Ct. 2000); *Health Care Fraud Report*; BNA 8/23/00 vol. 4, No. 17 pg. 599.

### III. APPLICABLE HEALTH CARE FRAUD AND ABUSE LAWS

**DISCLAIMER:** The statutes discussed here are very complicated. This brief overview is intended merely to provide sufficient information to discuss e-health fraud and abuse risks and is not intended to be an exhaustive review of these statutes. Please refer to other materials for more details.

#### A. The Anti-Kickback Statute

- The federal Anti-kickback Statute (“Statute”) makes it a criminal offense to:

***Knowingly and willfully*** offer, pay solicit or receive any ***remuneration, directly or indirectly, to induce referrals or recommend the ordering*** of items or services reimbursable in whole or in part by any federally-funded health care programs.

42 U.S.C. § 1320a-7b(b).

- To understand the Statute’s potential application to the e-health industry it is useful to break down and analyze the key terms of the Statute.

##### 1. “Knowingly and Willfully”

- The Statute creates a specific intent crime requiring that the government prove a defendant knowingly and willfully violated the Statute.
- Federal courts have set forth various interpretations of the knowing and willful requirement of the Statute.
- However, in 1998 the Supreme Court set forth its interpretation of the *mens rea* requirement in the context of the Firearm Owners’ Protection Act. In *Bryan v. United States*, 524 U.S. 184 (1998), the Supreme Court held that “a willful act is one undertaken with a bad purpose...with the knowledge that the conduct is unlawful.” *Bryan* at 193.

- In the same year the Eleventh Circuit Court of Appeals applied the knowing and willful standard articulated in *Bryan* to the Anti-kickback Statute. *See United States v. Starks*, 157 F.3d 833 (11<sup>th</sup> Cir. 1998).
- Previous interpretations of the *mens rea* requirement of the Statute have come out with similar results:
  - In *United States v. Jain*, 93 F.3d 436, 440 (8<sup>th</sup> Cir. 1996), the Eighth Circuit held that a defendant must know his/her conduct was “wrongful.”
  - In *Hanlester Network et al. v. Shalala*, 51 F.3d 1390, 1400 (9<sup>th</sup> Cir. 1995.) The Ninth Circuit held that a defendant must (i) know the statute prohibits offering or paying remuneration to induce referrals, and (ii) engage in prohibited conduct with the specific intent to disobey the law.

## 2. “Remuneration”

- The term “remuneration” in the Statute is intended to broaden the reach of the Statute beyond merely kickbacks, bribes and rebates. *See Hanlester* at 1398. Remuneration includes the transfer of anything of value in cash or in kind (*e.g.* goods), whether made directly or indirectly, and whether made openly or secretly. *See Fed. Reg.* 39,592, 39,958 (July 29, 1991).
- Such a broad definition raises many questions in the e-health context. For example, would any of the following be considered remuneration under the Statute?:
  - The provision of generally available information in a more efficient, user-friendly manner through a Web site or Personal Digital Assistant (PDA)
  - Educational information to physicians or their patients
  - Advertisements
  - Credibility
  - Goodwill

### 3. “Directly or Indirectly”

- This language suggests that indirect forms of remuneration are covered to the same extent as direct forms of remuneration.
- This raises the issue in the context of e-health whether a questionable arrangement between a pharmaceutical company and a physician is somehow cleansed when the benefits that accrue to the physician are provided by the e-health company, but through funding provided by the pharmaceutical company.
- The answer may depend on the structure of the arrangement and the nature of the inducement. In other words, there are arrangements with e-health companies, sponsoring pharmaceutical companies and physicians that may well remove any taint that would have been present if the arrangement was only between the physician and pharmaceutical company.

### 4. “To Induce”

- Whether or not a payment or remuneration is intended, as an illegal inducement will depend on a variety of factors.
  - The form of the payment may be significant.
  - Per-click payment methodologies, standing alone, are not *per se* illegal. But per-click payments combined with other features of a B2B e-health arrangement should be closely reviewed.
    - Per-click payment methodologies are generally less troublesome when the “click” is merely a link to another web site that provides information.
    - Per-click payment methodologies that need to be closely reviewed are where the “click” is directly tied to an on-line purchase.

- In *United States v. Greber*, 760 F.2d 68, 72 (3<sup>rd</sup> Cir. 1985), the Third Circuit interpreted the Anti-kickback Statute to mean that “if one purpose of the payment is to induce referrals, the Medicare statute has been violated.” *See also United States v. McClatchey*, 217 F.3d 823 (10<sup>th</sup> Cir. 2000), *petition for cert. pending*; *cf. United States v. Kats*, 871 F.2d 105 (9<sup>th</sup> Cir. 1989) (materiality standard), *United States v. Davis*, 132 F.3d 1092 (5<sup>th</sup> Cir. 1998) (rejects sole purpose test); *but cf. United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1<sup>st</sup> Cir. 1989) (“the key to a Medicare Fraud Case is the reason for the payment – was the purpose of the payments primarily for inducement”).
- In the context of e-health the “one purpose rule” raises serious questions about a variety of seemingly legitimate arrangements.
  - Most e-health Web sites provide services offering multiple benefits. For example, a disease management site’s goal may be to provide patients and providers with accurate and useful information, but that goal may also incidentally generate business for a provider involved in the operation of the Web site and/or sponsor.
  - Under the “one purpose rule” a violation of the Statute may be found if any one of these benefits increases a health care provider’s volume of business.

##### 5. “Referrals” and “Recommend Items and Services”

- The Anti-kickback statute prohibits payments to induce referrals or to recommend the ordering of services and products.
- On the Internet, an actual referral could potentially exist in many forms. For example, a Web site that links physicians with pharmacies where the physician enters a prescription would likely constitute a referral.

- There is little clear guidance as to what conduct is sufficient to be classified as “recommending items or services” within the meaning of the Statute.
- In *Modern Medical Laboratories, Inc. v. Smith-Kline Beecham Clinical Laboratories, Inc.*, 54 F.Supp.2d 850 (N.D.Ill. 1994), the court considered whether an arrangement wherein one laboratory agreed to market, manage and operate another laboratory’s business and facilities in exchange for 90% of the revenue generated, violated the Statute. The court held that although individuals were not referred for the furnishing of services, the arrangement nonetheless violated the Statute because remuneration was received for arranging a service. The court interpreted the Statute to criminalize “broker-style arrangements whereby one entity receives remuneration for placing business with another entity.” *Id.* at 852.
- In *Nursing Home Consultants v. Quantum Health Services, Inc.*, 926 F.Supp. 835 (E.D. Ark. 1996), the court held that a marketing agreement between a marketer of medical equipment and a supplier of medical equipment violated both the “referring” and “recommending” prohibitions of the Statute. Under the agreement, the marketer identified nursing home residents in need of medical supplies and the supplier would then sell its products directly to the nursing home, with the marketer’s compensation directly pegged to the number of sales generated.
- The following categories may be useful in examining whether “recommending” has taken place:
  - Generalized marketing;

- Specific recommendation of a particular physician or item or service, but not for specific patients;
- Specific recommendation of a specific item or service for a particular patient.
- On the Internet, serious questions arise as to what is “recommending.”
  - Is the provision of a Web link to a sponsor a recommendation of that sponsor?
  - Is neutral, professionally reviewed content a recommendation?
  - Are exclusive agreements suspect because they more likely give the appearance as a recommendation?

B. The Stark Law

- The Stark Law prohibits physicians from making Medicare and Medicaid referrals for certain designated health services to entities with which they have financial relationships unless certain exceptions exist.
  - Outpatient prescription drugs are one of the listed designated health services.
  - Financial relationships include ownership or investment interests or compensation arrangements.
  - A referral includes the request by a physician for an item or service.
  - The Stark Law on its face does not appear to cover “recommending items or services.”
- There are several compensation exceptions that can protect e-health arrangements if it is found that the Stark law applies. These compensation exceptions generally require that services be provided at fair market value.

### C. HIPAA

**NOTE:** This section was written before the HIPAA regulations were finalized.

- The HIPAA Proposed Regulations require that any health plan, health care clearing-house or health care provider that electronically maintains or transmits individually identifiable health information must adopt policies, practices, and procedures to protect the confidentiality of that information.
- While HIPAA directly covers health plans, health care clearing houses, and health care providers, the regulations reach beyond those entities.
- If information protected under HIPAA is transferred by a health plan, health care clearing-house, or health care provider to an entity not directly covered by HIPAA, then “the covered entity is responsible for receiving satisfactory assurances” that the patient-identifiable information will be adequately protected by its affiliated entity.
- Accordingly, entities directly covered by HIPAA must enter into business partner agreements with business partners (or agents or subcontractors) not directly covered by HIPAA.
- Such business partner agreements are designed to prevent further disclosure of information -- other than that which is permitted by the Notice of Proposed Rulemaking.
- E-health companies can be considered “business partners” of entities subject to the HIPAA Regulations and are therefore subject to “chain of business partner agreements.”
- Because HIPAA extends beyond health care plans, health care clearing-houses, and health care providers, e-health companies exchanging information electronically with

such entities directly covered by HIPAA are responsible and accountable for protecting the integrity and confidentiality of that data.

#### IV. SPECIFIC FRAUD AND ABUSE ISSUES IN E-HEALTH

##### A. Sponsorship Arrangements, Marketing On-Line & Suspect Links Hypotheticals

###### Hypothetical #1

- Dotcom company markets free PDAs and PDA-based practice management software (including dictation and charge capture information) and disease state management programs for physicians sponsored by pharmaceutical companies.
- Pharmaceutical Company pays the Dotcom Company a flat fee to have its logo put on physicians' PDA sync screen as a banner ad.
- The compliance programs are content neutral and 3<sup>rd</sup> party peer-reviewed and include information and programs from other pharmaceutical companies.
- Through the use of cookies, dotcom company tracks physicians' use of compliance programs. No patient identifiable information is tracked.

###### Questions

- Anti-kickback Statute
  - Is the physician being provided with remuneration?
  - If so, is the remuneration illegally intended to induce a referral or the recommendation of items and services?
  - What additional complications arise if the one-purpose rule applies?
- Stark Law
  - Has the arrangement created a financial arrangement between the pharmaceutical company and the physicians?

- Is the answer any different if the pharmaceutical company retains legal ownership of the PDA?
- Is the answer any different if the physicians pay fair market value for practice management software, but still receive the compliance program for free?
- Does the dotcom company have any Stark Law issues?

#### Hypothetical #2

- Same facts as Hypothetical #1, but pharmaceutical company has an exclusive agreement so that there are no other corporate logos on the PDA sync screen, and the only compliance programs offered on the PDA are those of the sponsor pharmaceutical company.

#### Questions

- Anti-kickback Statute – What anti-kickback concerns are raised by the exclusivity and the absence of neutral content?
- Stark Law – Has the Stark Law analysis changed?

#### Hypothetical #3

- Same facts as Hypothetical #2, but the program is only marketed to certain specialty groups and the information contained on the PDAs is targeted to those specialty groups.
- Each targeted compliance program provides specific recommended drug information for a particular disease state.

#### Questions

- Anti-kickback Statute – What additional anti-kickback concerns are raised by the targeting to specialists and the specific recommending of drugs?
- Stark Law – Has the Stark Law analysis changed?

#### Hypothetical #4

- Same facts as Hypothetical #1, but the PDA has Internet capability as an option for the physicians to purchase at fair market value.
- The pharmaceutical company's home page is provided as a link on the physicians' PDA sync screen, and the pharmaceutical company pays the dotcom a supplemental fee per click on the Web site.
- The pharmaceutical company also pays the subscription costs of an on-line prescription drug reference services providing PDA point-of-access to clinically relevant information on all U.S. prescription drugs.

#### Questions

- Anti-kickback Statute
  - Is this per click fee troubling in this situation?
  - What issues are raised by the pharmaceutical company's sponsorship of the on-line prescription drug reference service?
  - Would the answers change if the pharmaceutical company also picks up the costs of the Internet access fees for the PDAs?
- Stark Law – Has the Stark Law analysis changed?

#### Hypotetical #5

- Same facts as No. 4, but a pharmacy company pays the dotcom company to have a Web link provided on the physicians' PDA sync screen. The link is to its home page where there is a prominent link to its e-pharmacy.
- The pharmacy company pays the dotcom a per click fee based on the number of clicks to its home page. The discussions reveal:
  - The pharmacy company is primarily interested in marketing to the physicians;

- There is only a minor correlation between visits to the home page and e-pharmacy purchases;
- The parties recognize that there will be some physicians ordering prescription drugs through the e-pharmacy that are an inherent part of the arrangement.

#### Questions

- Anti-kickback – What additional considerations arise by the presence of the pharmacy on the physicians’ PDA sync screen?
- Stark Law – Has the Pharmacy Company created a financial arrangement with the physicians such that a compensation exception is needed.

#### Hypothetical #6

- Same facts as No. 5, but a pharmacy company pays the dotcom to have its Web link to its e-pharmacy (the link bypasses the pharmacy’s home page and goes directly to the e-pharmacy link) put on the physicians’ PDA sync screen.
- The pharmacy pays the Dotcom Company an “access fee” based on each time a physician clicks to the e-pharmacy. In negotiations, it becomes clear that virtually every time a physician clicks on to the e-pharmacy he/she actually orders a prescription.
- The pharmaceutical company sponsor makes it a condition of payment under the agreement that a minimum of \$250,000 per year of its products must be ordered through the e-pharmacy.

#### Questions

- Anti-kickback Statute
  - What steps would be considered to revise the part of the deal between the dotcom company and the pharmacy?

- Is the pharmaceutical company implicated?
- Is your answer different if the pharmaceutical company does not impose the minimum purchase requirement?
- Stark Law
  - Has the Stark Law analysis changed?

B. HIPAA Hypotheticals

Hypothetical # 7

- Dotcom company provides general health care information to the public and supports its Web site through advertising.
- One advertiser is an online pharmacy.
- The online pharmacy pays for its advertising based on the number of “clicks” it receives on its site through the dotcom company and the payments increase if the patient makes a purchase from the pharmacy

Questions

- If the dotcom company tracks consumer profile information is this “personally identifiable health information” under HIPAA?
- Does the answer to the question change if the consumer merely browses the Web for information rather than makes a purchase of a health care product?
- If the dotcom company shares consumer information with the pharmacy is it a violation of HIPAA?

Hypothetical # 8

- Same facts as Number 5 or 6, but the cookies that are used for tracking the physicians use of the compliance programs picks up all information on the PDA, and tracks physicians’ prescription ordering practices of specific drugs for specific patients.

## Questions

- What consents does HIPAA require?
- Would you advise your client to adopt this business strategy?

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