



Fraud and Abuse in 'E-Health' Arena

BY LINDA ABDEL-MALEK

THE EXPLOSION of e-health Web sites and the move toward automating various types of health-care transactions, such as those among patients, physicians and pharmaceutical companies, have increased efficiencies in the industry, given patients greater control over their healthcare, and allowed businesses involved in the health-care field greater freedom in structuring new and innovative business models. However, it is critical to be aware of the myriad federal and state laws and regulations which have been deemed by regulatory oversight agencies to apply to these transactions. Despite the fact that such regulations have not been drafted to keep pace with the constantly changing environment of the Internet, these "bricks and mortar" laws and regulations can and must be applied to e-health transactions.

Relevant laws, regulations and additional guidance discussed herein must be analyzed in connection with the e-health arrangement being structured to determine whether the underlying transactions meet the requirements of federal and state provisions, as applicable. E-commerce revenue strategies in structuring e-health Web sites take multiple forms, but basic characteristics are common to many such sites, including the following: (1) portal agreements; (2) corporate sponsorship arrangements; (3) marketing arrangements; (4) discount arrangements; or (5) joint ventures.

Case Study

For purposes of this article, a "case study" will be used to illustrate some of the pertinent issues that should be considered by Internet companies contemplating arrangements to establish e-health Web sites. After summarizing the key provisions of the federal and New York state laws mentioned above, this case study will be analyzed through application of the guidance presently available.

Assume that the e-health arrangement at issue contemplates a Web site in which primary care physicians would be targeted and listed on the site in exchange for a fee. Patients could communicate with such physicians through the site, which would contain links to educational and product information regarding certain pharmaceutical products provided through a pharmaceutical company as well as durable medical equipment (DME) products and services being provided through a DME company.

In addition to providing information about such products and services, links to both companies' Web sites will be provided on the e-health site for a fixed fee. Any necessary prescriptions would be provided by the physician, but non-prescription pharmaceuticals, as well as prescription drugs (pursuant to a prescription issued by the primary care physician) could be purchased directly by the patient. The same would be true of DME products and services, as applicable. The products and services at issue could ostensibly involve those reimbursable under the Medicare or Medicaid programs.

Although the analysis below is not exhaustive, key concerns relevant to this case study will be addressed.

Federal Anti-Kickback Law

The federal anti-kickback law applies to arrangements involving goods or services which may be reimbursable under a federal program. In general, the anti-kickback law makes it a criminal offense to knowingly and

willfully offer, pay, solicit or receive any remuneration "in return for" referring an individual, or for recommending or arranging for the purchase, lease or ordering of any item or service for which payment may be made by a federal program, including, but not limited to the Medicare and Medicaid programs.¹

The law applies to both sides of a transaction, which would necessarily include the parties paying for a referral or the furnishing of federally reimbursable services, as well as the parties receiving or arranging for such payment.² The law is essentially concerned with "quid pro quo" arrangements which are intended to induce referrals of federally reimbursable goods or services in exchange for remuneration, or other arrangements which result in increased reimbursement costs to the federal government.

Additionally, the law seeks to prevent arrangements which could, by their nature, interfere with a healthcare provider's judgment to provide services that are in the best interests of the patient. The Office of Inspector General of the U.S. Department of Health and Human Services (OIG) has stated in numerous advisory opinions that even if such laws and regulations are implicated by an arrangement, it will seek to impose sanctions on the requester of the OIG opinion only if it finds that the requisite intent to induce referrals is present.³

The law contains several exceptions which, if met, would shield an arrangement from prosecution by the OIG, and in subsequent regulations promulgated in 1991, the OIG added an additional 10 safe harbors to

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the statute.⁴ Some of the salient exceptions and safe harbors likely to apply to the case study above include the following.

First, the marketing arrangement between the e-health company and the physicians appears to be a "referral service" to the extent that the company has targeted certain primary care physicians and, in exchange for a fee, has agreed to list such physicians on its Web site. The OIG has stated in its "referral service" safe harbor that in order to fall within the protection of such safe harbor, the arrangement must meet the following requirements:

- (1) the referral service cannot exclude as a participant an entity that meets the qualifications for participation;
- (2) payment by the participants to the referral service must be uniform, and based only on the cost of operating such service, and not on the volume or value of any referrals or business otherwise generated;
- (3) the referral service cannot impose requirements on the manner in which the participant provides services to a referred person, except in certain limited circumstances; and
- (4) the referral service must make certain disclosures enumerated in the regulation to the patient seeking the referral.⁵

The criteria used to target primary care physicians would need to be crafted carefully in this case study in order to ensure that eligible participants are not excluded. Additionally, since the physicians are paying a fee in order to be listed on the Web site, the e-health company would need to assess a fixed fee that complied with the criteria for this safe harbor. Disclosures to patients regarding the referral service could ostensibly be made on the e-health Web site itself and it would be required to document all uses of the site which lead to a referral to any participating physicians.

With respect to the pharmaceutical educational and product information being provided to patients in the case study, a "Special Fraud Alert" issued by the OIG in December 1994 is relevant. The Special Fraud Alert provides that where a pharmaceutical company offers "valuable, non-medical benefits" to physicians or patients in exchange for selecting its brand of prescription drugs, the anti-kickback statute is implicated because of the concern that "the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient."⁶

In this context, it could be argued that both the e-health company and the participating physician are "recommending" pharmaceutical products to a patient. The key element to look for is any "quid pro quo" arrangement which would violate the anti-kickback statute. In the case of the e-health company, it is unlikely that the fee being paid by the pharmaceutical company to the e-health company is in exchange for the e-health company recommending a particular product through the Web site. In the case

of the physician, the concern is whether the physician is motivated to endorse any particular pharmaceutical product and any such concern would need to be mitigated by prohibiting any financial incentives for the physicians.

State Anti-Kickback Law

New York's anti-kickback law applies to individuals who are licensed by the New York State Department of Education. To the extent that the Web site in the case study involves New York state licensed physicians, such physicians, rather than the e-health company establishing the Web site, would be subject to this anti-kickback law.

New York's anti-kickback law provides that a licensed individual shall be prohibited from "directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or in connection with the performance of professional services."⁷ This provision is obviously not confined to federal- or state-funded health-care programs, and therefore should be taken into account in the broader context of any arrangement in which no federally reimbursable business is at issue.⁸

Stark II Law, Regulations

The Stark II statute generally forbids a physician with a "financial relationship" with an entity from making a referral of Medicare or Medicaid patients to that entity, for the provision of "designated health services."⁹ The statute broadly defines "financial relationship" as any arrangement involving remuneration between a physician and an entity, subject to certain exceptions.¹⁰

For purposes of our case study, "designated health services" are defined to include DME and supplies, and outpatient prescription drugs.¹¹ The definition generally excludes services provided personally by a physician or under the supervision of another physician in the same group practice. Pursuant to the statute, a "financial relationship" arguably does not exist between the physicians participating in the e-health Web site and the pharmaceutical and DME companies, but rather is confined to the e-health company, which would not be covered by the statute, because no referrals are being made to it.

However, it is important to note that Stark II regulations were released on Jan. 4, 2001 (as of the date of this article, the comment period has been extended to June 4, 2001) which, among other things, clarify the statutory definition of "financial relationship" and "designated health services," and set forth guidance regarding the types of arrangements that would be protected under the regulations.¹²

For example, in order for a financial relationship to be permissible under the regulations, compensation must be "set in advance." If the case study had included a portal agreement between the physician and the pharmaceutical and DME companies that included a "per click" fee payable

to the physician for each of her patients who clicked through to the DME or pharmaceutical Web site through the e-health Web site and made a purchase, such an arrangement would be subject to a regulatory analysis regarding whether the rate of payment is fair market value and does not vary during the term of the agreement.¹³

The regulations provide a new "fair market value" exception, which includes, among other things, that the agreement must

- (1) be in writing;
- (2) stipulate a specific time frame for the arrangement;
- (3) set the compensation in advance in a manner which is not dependent on the volume or value of referrals;
- (4) be commercially reasonable;
- (5) fall within an anti-kickback law or a safe harbor or be approved by the OIG in an advisory opinion; and
- (6) comply with other relevant federal and state laws.

The problem when analyzing whether an e-health arrangement complies with this new exception is that it introduces the same difficulty present when analyzing compliance with the anti-kickback law, namely, the violation is dependent on the intent of the parties, which is often difficult to determine in the absence of an OIG opinion addressed to the specific arrangement. Additionally, the new Stark II regulations clarify concepts such as "fair market value" and compensation "set in advance" in ways that the anti-kickback statute and regulations do not, so that determining whether the arrangement complies with both sets of laws and regulations is further complicated.

Telemedicine Laws

The New York State Education Department has issued substantive guidance on the issue of telemedicine. The Department defines "telepractice" as "the provision of professional service over geographical distances by means of modern telecommunications technology."¹⁴

Although New York State law does not specifically address telemedicine, it does provide that only occasional consultation are permitted between physicians licensed in their home state and New York State licensed physicians.¹⁵ The purpose of the law is to restrict the practice of medicine in New York by physicians who are not licensed in New York.¹⁶

Additionally, the Department of Education has stated that it is concerned with its ability to "hold a professional license in another jurisdiction, who is not licensed in New York State, accountable for serving a client in New York State through telepractice when those services are provided negligently or incompetently."¹⁷ This provision is implicated in the case study discussed herein to the extent that any physicians who are not licensed in New York are participants in the Web site and are providing medical advice through the site to patients in New York.

New York State licensed physicians who participate in the Web site might encounter these issues in the event that they communicate medical opinions through the site to patients residing in other states. For example, California, Texas and Florida have requirements similar to those of New York.¹⁸ Because telemedicine laws vary among states, it would be prudent for any e-health Web site to prohibit physicians participating in the site from offering medical opinions or from performing other functions that could be construed as the "practice of medicine" via the Web site.

Prescription Drug Issues

The Food and Drug Administration (FDA) has become increasingly active in the regulation of prescription drugs purchased over the Internet.

Federal law prohibits the sale of prescription drugs without a valid prescription.¹⁹ The FDA's initiatives have included the issuance of "cyber" letters to Web sites engaged in the illegal sale of prescription drugs on-line, warning them regarding their violations of the law.²⁰ Additionally, the FDA entered into an agreement in 1999 with the National Association of Boards of Pharmacy (NABP) and the Federation of State Medical Boards in order to gain assistance from these organizations in enforcing state and federal laws regarding the unlawful sale of prescription drugs.²¹

Industry self-regulation has also gained momentum in recent years. In 1999, the NABP launched its Verified Internet Pharmacy Practice Sites (VIPPS) program, which is a voluntary certification program in which an on-line pharmacy must, in order to be accepted into the program, agree to certain requirements such as maintaining licenses in good standing, allowing inspection of its operations by an NABP-sanctioned team, and displaying and maintaining the VIPPS seal and a link to the VIPPS Web site.²² Also in 1999, the American Medical Association adopted guidelines for physicians regarding Internet prescriptions that address, among other things, standards of care such as examination of the patient, discussion of the risks and benefits of the drug, and follow-up with the patient for any side effects.²³

The e-health Web site in the case study contemplates the issuance of prescription drugs to a patient only in the context of a prescription issued by the patient's physician.²⁴ In order to meet the FDA's requirements, the e-health company should take steps to ensure that no prescriptions are issued in the absence of a physician-patient relationship. Additionally, it would be advisable for the e-health company to include, as part of the arrangement, a pharmaceutical company that meets VIPPS requirements.

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- (1) 42 U.S.C. §1320a-7b.
 - (2) *Id.*
 - (3) See, e.g., OIG Op. 99-11.
 - (4) See 42 U.S.C. §1320a-7b(b)(3)(A)-(F); 42 CFR §1001.952.
 - (5) See 42 CFR §1061.952(f).
 - (6) 59 Fed. Reg. 65372, Dec. 19, 1994.
 - (7) NY Educ. Law §5530(18).
 - (8) Even if an e-health Web site uses no direct referrals of federally reimbursable business in the contemplated arrangement, the OIG has opined that the federal anti-kickback statute is implicated if any of the customers are federal health program beneficiaries, and if some of the services subsequently provided by physicians to these customers may be reimbursable by a federal healthcare program. See OIG Op. 99-8.
 - (9) 42 U.S.C. §1395nn.
 - (10) *Id.*
 - (11) *Id.*
 - (12) See 66 Fed. Reg. 856 (2001).
 - (13) *Id.*
 - (14) See Report presented at December 1999 meeting of New York State Board of Regents, at www.op.nysed.gov (hereinafter "Department of Education Report").
 - (15) NY Educ. Law §6526(3).
 - (16) See Department of Education Report.
 - (17) *Id.*
 - (18) *Id.*
 - (19) 21 U.S.C. §353(b).
 - (20) See "Compliance Activities", at www.fda.gov.
 - (21) See "Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites'", at www.fda.gov.
 - (22) *Id.*
 - (23) *Id.*
 - (24) There may also be legal issues related to the validity and form of any prescriptions which may be issued via the Internet, but such issues are beyond the scope of this article.