

# CCH Healthcare Compliance LETTER

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## California ID theft law could affect privacy measures nationwide

by Jennifer Carsen, J.D., Contributing Editor

A new California law effective July 1, 2003, could have a major impact on how health care providers protect personal information and provide notice of security breaches—even if they have no obvious ties to California.

SB 1386 requires all state agencies, or persons or businesses conducting business in California, that own or license computerized data that includes personal information to disclose any breach of data security to California residents whose information may have been acquired by unauthorized persons. The disclosure must be made in the most “expedient” time possible and “without unreasonable delay.”

The law defines “personal information” as a person’s first name or first initial and last name in conjunction with any one or more of the following, when either the name or the data elements are not encrypted: (1) Social Security number; (2) driver’s license number or California Identification Card number; (3) account number, credit or debit card number, in combination with any required access code or password. It does not include information available through public records.

A security breach is defined by the law very broadly as the unauthorized acquisition of computerized data that “compromises the security, confidentiality, or integrity of personal information” maintained by the agency, person, or business. Notice of security breaches may be provided in writing, electronically or via substitute notice (e-mail, conspicuous posting, and media notification) if the cost of providing notice would exceed \$250,000, the affected class of people exceeds 500,000, or there is insufficient contact information. Entities with their own notification procedures may continue to use them if they satisfy the law’s timing requirements.

The law has nationwide significance for several reasons. First, because SB 1386 protects the personal information of California citizens, health care organizations with even a few California customers will have to comply with its requirements. If customer information is not readily segregable by state, many national organizations may find it necessary to apply SB 1386’s provisions across the board. Second, because the law protects only unencrypted personal information, there may be a push to encrypt this data to avoid the burdens imposed by SB 1386. Finally, the law provides a private cause of action for customers injured by a violation of SB 1386—which opens the door to the possibility of both individual and class-action lawsuits. The full text of the bill is available at [http://info.sen.ca.gov/pub/01-02/bill/sen/sb\\_1351-1400/sb\\_1386\\_bill\\_20020926\\_chaptered.html](http://info.sen.ca.gov/pub/01-02/bill/sen/sb_1351-1400/sb_1386_bill_20020926_chaptered.html). ■

CCH Chicago Bureau, July 9, 2003

### Letters to the Editor

The CCH Healthcare Compliance team welcomes comments regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Jeff Reinholtz, Managing Editor, at [reinholj@cch.com](mailto:reinholj@cch.com). For more information about the CCH Healthcare Compliance Portfolio visit our online store at <http://health.cch.com>.

### Court issues mixed rulings regarding discovery dispute

by Jennifer Carsen, J.D.,  
Contributing Editor

Last year, a Louisiana district court ordered whistleblowers Mary Jane Stewart and Margaret Catherine McGinty to re-draft their FCA complaint against The Louisiana Clinic because it failed to meet Rule 9(b) specificity requirements (*FCA claims denied for failure to "state with particularity,"* CCH Healthcare Compliance Letter, Volume 5, Issue 15, August 5, 2002). Their second amended complaint satisfied the 9(b) requirements with respect to some of the counts and some of the defendants. The parties are currently embroiled in a bitter discovery dispute that highlights the importance of good quality assurance practices that help prevent litigation in the first place.

**Preliminary discovery requests favor whistleblowers.** Stewart and McGinty alleged various claims against the Clinic and several of its doctors, including upcoding, zoning, and improper waiving of co-payments that resulted in "patient buying." The claims against the hospital were eventually dismissed, leaving just the doctors as defendants. The doctors sought a protective order concerning the disclosure of non-party patient billing and medical records. However, the court ruled in December 2002 that plaintiffs were entitled to see these, given that the case turned on allegedly fraudulent reimbursements for services rendered to Medicare and Medicaid patients. The court also ruled that the United States was entitled to receive copies of nonparty patient records, even though it had declined to intervene in the case.

**Requests for information denied.** In the current case, the court dealt several blows to the doctors' attempts to get more information from Stewart and McGinty. It disposed of the motions as follows:

- Rejected doctors' requests for more information about the allegations against them. Some of the information sought was protected by attorney-client privi-

lege, some had already been sufficiently provided, and some was simply an attempt to "harass" Stewart and McGinty.

- Rejected as "burdensome" doctors' requests for a narrative summary of why and how each of the plaintiffs' documents supported their claim.
- Concluded that a doctor failed to show the "exceptional circumstances" necessary to justify Stewart and McGinty's identification of a non-testifying expert—in this case, a consultant brought in specifically to analyze medical records and bills in anticipation of litigation.

**Possession extends to ability to obtain.** The court also overruled the doctors' general objections regarding "possession" of discovery materials, such as patient records. The doctors claimed the Clinic—now a non-party—had possession, not them. The court said documents are deemed to be within the "possession, custody, or control" of a party for discovery purposes if the party has the legal right to obtain the documents on demand or has the practical ability to obtain the documents upon request.

**General scope of discovery limited.** In the one positive aspect of the case for the defendant doctors, the court sustained their general objections to the scope of discovery. The court ruled that limiting the scope of the discovery time-wise, from June 1993 to June 1999, made sense because "the issue of a menacing scheme or conspiracy is wholly absent in this case and all claims against The Louisiana Clinic have been dismissed." The court decided to narrowly focus discovery on proving the few claims alleged against individual doctors.

The court also rejected Stewart and McGinty's request to compare the alleged instances of wrongful billing practices with the defendants' billing practices involving non-Medicare patients. The court said this would "most assuredly prove misleading." Any evidence of fraudulent intent would have to be shown in light of the circumstances surrounding a particular patient claim, not by an overall examination of a doctor's general billing practices.

The court said the defendant doctors had sufficiently demonstrated that compliance with "temporally and topically

overly broad" discovery requests would threaten normal business operations and "would likely yield voluminous data" with little relevance to the alleged false claims. Therefore, the court limited the scope of the requests in both respects.

Following this ruling, said the court, the parties were to meet and confer to resolve any remaining discovery issues. If no agreement could be reached, the court would hold a hearing in chambers to "amicably" hammer things out. ■

*U.S. v. The Louisiana Clinic, E.D. La., No. 99-1767, June 4, 2003, ¶305,271*



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Unless otherwise noted, all paragraph references are to the CCH Healthcare Compliance Reporter.

### Employee's bias claims allowed to proceed in part

by Jennifer Carsen, J.D.,  
Contributing Editor

When Joan Harewood was fired from Beth Israel Medical Center at the age of 57—after having worked there for nearly 40 years—she sued. Although her case was far from open-and-shut and insufficiently pled in some respects, a New York district court allowed certain parts of the case to proceed. The case illustrates the importance of treating long-time employees fairly and consistently.

**JCAHO certification requirements.** During Harewood's long tenure at Beth Israel, she consistently fulfilled the requirements of her position as a dietary aide. In November 1998, Beth Israel informed Harewood that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) would be conducting an inspection and that all employees needed to be up to date with their certifications.

Harewood completed the first four segments of the next available certification program and asked Barry Schlossberg, head of food and nutrition services, to have Beth Israel cover the tuition for the following semester. Schlossberg never responded to the request, and Harewood failed to complete the remainder of the program. Despite this, the hospital never warned Harewood again that she needed to be certified or mentioned anything about the tuition payment.

**Employee hospitalized, fired.** In October 2000, Harewood suffered an aneurysm that landed her in the hospital. Evelyn Gacula, the director of food and nutrition services, told Harewood she had to work the following weekend. Two days after returning to work, Harewood checked back into the hospital with a blood clot, which resulted in her going on disability leave. Myrna Mercado, Harewood's supervisor, told Harewood to instruct her doctor to send her back to work.

Harewood attempted to return to work a few months later, but Mercado advised her to go on permanent disability. That same

day, Harewood was fired. She claimed her position was filled by a younger, non-disabled person. Later, when Harewood applied for unemployment insurance benefits, Beth Israel objected to her application.

**Charge and lawsuit filed.** Harewood filed an EEOC charge on January 10, 2002, alleging age and disability discrimination. The EEOC dismissed her charge, finding insufficient evidence, and issued her a right-to-sue letter. Harewood then filed suit in a New York federal district court. Beth Israel's motion to dismiss was granted in part and denied in part.

The court ruled that many of Harewood's allegations of discriminatory conduct fell outside the 300-day statutory limitations period. Harewood's termination was the only potentially discriminatory event that occurred within that time. Harewood also failed to properly state a claim for retaliation—she never indicated that the basis for her EEOC charge was retaliation, or that she viewed the opposition to unemployment benefits as a retaliatory act. However, the court said it was possible there were facts that could suggest retaliation and excuse Harewood's failure to alleged the retaliation

claim in her EEOC complaint. The judge dismissed Harewood's retaliation claims and gave her 10 days to re-plead them.

Similarly, Harewood had failed to allege that she had a disability within the meaning of the Americans with Disabilities Act (ADA). However, Harewood raised a possible "regarded as" issue of disability discrimination, namely, that Beth Israel mistakenly believed that she had a disability, or that a nonlimiting impairment substantially limited one or more major life activities.

Lastly, the hospital argued that Harewood had not alleged sufficient facts to show she was terminated on account of her disability. The court disagreed, stating the pleading requirements demand only a "short and plain statement of the claim" that shows a plaintiff's entitlement to relief and gives the defendant fair notice. Harewood had met her burden to sustain her ADA claim by alleging both a qualifying disability and that she was terminated and replaced by someone non-disabled, despite her alleged ability to adequately perform the responsibilities of her job. ■

*Harewood v. Beth Israel Medical Center, S.D.N.Y. No. 02 Civ. 5511 (HB), June 13, 2003, ¶305,270*

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# The New Face of Corporate Governance

by Paul DeMuro, J.D.

*Corporate and accounting scandals, including Enron, led to the passage of the Sarbanes-Oxley Act of 2002 (the "Act").<sup>1</sup> The Act seeks to improve the quality of disclosure and financial reporting. It also seeks to ensure the independence of audit firms and expands the role of audit committees. In addition, management's responsibility for corporate disclosures and financial statements are increased. The Securities Exchange Commission (the "SEC") and the Securities Exchanges have issued rules which further address corporate governance matters.*

**CEO and CFO Certifications.** The Act has two certification provisions, Sections 302 and 906, which require that CEOs and CFOs of reporting companies certify certain matters in periodic reports filed with the SEC. Section 302 amends the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 906 amends the federal criminal code.<sup>2</sup> Section 906 certification requires each "periodic report containing financial statements" filed under Section 13(a) or 15(d) of the Exchange Act by a domestic or foreign issuer to be accompanied by "a written statement" or certification by the CEO and CFO (or their equivalents). The Section 302 certification applies both a materiality standard and a knowledge standard to the CEO's and CFO's statements regarding the financial statements, financial information, and the issuer's reporting controls, both financial and non-financial. The new officer certifications for periodic reports must cover "disclosure controls and procedures."

**Regulation of Officers and Directors.** There is a ban on most loans to executive officers and directors. Section 402 of the Act amends Section 13 of the Exchange Act to prohibit most loans by an issuer to its executive officers and directors.

Section 403 of the Act amends Section 16(a) of the Exchange Act to shorten the due date for Section 16 insiders (directors, executive officers and greater than 10-percent beneficial owners) who file Section 16(a) transaction reports to two business days after the transaction has been executed.

There is also a requirement that bonuses, incentive-based or equity-based compensation be disgorged if a restatement is required due to the material noncompliance of the issuer, as a result of misconduct, with any financial reporting requirements under the securities laws. The period for disgorgement is within a twelve-month period following the first public issuance or filing with the Commission, whichever is first, of the documents with the noncompliant report.

There is a prohibition on insider traders during pension fund blackout periods in section 306(a) of the Act. The provision applies only to securities acquired by a director or executive officer in connection with his or her service or employment as a director or executive officer.

**New Disclosure Requirements.** The SEC implemented section 401(b) of the Act by adopting final rules and regulations which require pro forma financial information to be presented in a manner that does not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the pro forma financial information, in light of the circumstances under which it is presented, not misleading; and is reconciled with the financial condition and results of operations of the issuer under generally accepted accounting principles (GAAP).

Section 401(a) of the Act requires that each financial report be prepared in accordance with (or reconciled to) GAAP to reflect all material correcting adjustments that have been identified by an issuer's "registered public accounting firm" as defined in the Act, in accordance with GAAP and SEC rules.

The reporting company is encouraged to disclose its website access to its periodic reports. In addition, the reporting company must disclose whether or not the company had adopted a written "code of ethics" that applies to the company's principal executive officer, principal financial officer, principal accounting officer or controller. If the company does not have a code of ethics, it needs to say why not. Of course, it is unlikely that any company would want to report that it does not have a code of ethics.

The reporting entity also must disclose in its periodic report whether it and its committee include at least one "audit committee financial expert" and if not, why.

**Audit Committee.** The SEC has adopted final rules requiring the national securities exchanges and national securities associations to prohibit the listing of any security of an issuer that is not in compliance with the audit committee requirements of section 301.<sup>3</sup> Section 33(a)(58) of the Exchange Act defines the "audit committee" as a committee established by and amongst the board for the purpose of overseeing the accounting and financial reporting processes of the issuer and audits of the financial statements of the issuer.

The requirements include provisions addressing independence, responsibility, whistleblower procedures, engagement of advisors, and the payment of expenses. Each audit commit-

tee member must be “independent,” which means that the member may not, other than in his or her capacity as a member of the audit committee, the board or any board committee (1) accept any consulting, advisory or other compensatory fees from the company or any of its subsidiaries, or (2) be an “affiliated person of the issuer” or any of its subsidiaries.

Each audit committee is directly responsible for the appointment, compensation, retention and oversight of the work of the outside auditor, including resolving any disagreements between management and the auditor regarding financial reporting, for the purposes of preparing or issuing an audit report or performing other audit, review or attest services for the issuer, and the outside auditor must report directly to the audit committee.

Each audit committee must establish “whistleblower procedures”—procedures for the receipt, retention and treatment of complaints received by the issuer regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.

Each audit committee has the authority to engage independent counsel and other advisors as it determines necessary to carry out its duties. In addition, each reporting company must provide for the appropriate funding for the audit committee compensate the outside auditors engaged for the purpose of preparing or issuing an audit report, or performing other audit, review or attest services; any advisors employed by the audit committee; and any ordinary administrative expenses of the audit committee that are necessary or appropriate in carrying out its duties.

**Auditor Independence Rules.** In January 2003, the SEC adopted final rules amending section 10A of the Exchange Act addressing key aspects of auditor independence.<sup>4</sup>

It is not lawful for an auditor not to be independent. Sections 201(b) and 202 of the Act state that all audit and non-audit services provided to an issuer by the independent auditor must be pre-approved by the audit committee. The audit committee can either pre-approve the specific service to be rendered by the accounting firm, or the auditor can render services which were pre-approved by the audit committee when it established its pre-approval policies and procedures, provided the policies and procedures are detailed as to the particular service pre-approved by the audit committee; the audit committee is informed of each service that is rendered to the company consistent with the policies and procedures; and such policies and procedures do not include delegation of the audit committee’s responsibilities to management.

Each audit committee should specifically approve the annual audit engagement terms and fees because of the importance of the committee’s responsibilities.

Audit committees may address audit-related and tax services in their policies and procedures as they typically do not

create independence concerns and are consistent with the SEC’s rules on auditor independence for services outside of these areas. Audit committees should specifically approve the services on an engagement-by-engagement basis.

The following principles form the basis for prohibiting the non-audit services: the auditor cannot function in the role of management, an auditor cannot audit his or her own work, and an auditor cannot serve in an advocacy role for his or her client.

The prohibited non-audit services are: bookkeeping, financial information systems design and implementation, appraisal or valuation services, fairness opinion or contribution-in-kind reports, actuarial services, internal audit outsourcing, management functions, human resources, broker-dealer, legal and expert services.

Audit partners must be rotated every five years. The SEC amended the auditor independence rules to address the practice of accountants being compensated by their firms for selling non-audit products and services to their audit clients. These rules apply only to the audit partners. The SEC does not want audit partners to be offered an incentive to sell non-audit services to their clients.

### **Criminal Sanctions, Enforcement and Litigation.**

The Act creates new criminal offenses and substantially increases the penalties for existing offenses. Public companies should develop or review existing compliance programs and document retention policies, and be prepared to investigate thoroughly any creditable evidence of internal wrongdoing.

New criminal sections address the destruction or tampering of records, retaliation against informants, new securities fraud offenses and penalty enhancements. The SEC has certain enforcement rights, including the power to freeze payments, and bars officers and directors from participating in public companies.

**MD&A and Critical Accounting Estimates.** In 2002, the SEC adopted rules accelerating the due dates for annual and quarterly reports under the Exchange Act. The SEC issued rules and guidance for MD&A requirements, including disclosures concerning liquidity and capital resources, disclosures concerning off-balance-sheet arrangements, disclosure about contractual obligations, option trading activities disclosures, and the effects of transactions with related and certain other parties.

The SEC has a proposed rule requiring the disclosure of the critical accounting estimates a company makes in applying its accounting policies, and the initial adoption by a company of an accounting policy that has a material impact on its finances and presentation.

**Attorney Professional Responsibility.** On January 23, 2003, the SEC adopted new rules establishing standards of professional conduct for attorneys who appear and practice before the Commission.<sup>5</sup> On that same date,

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the SEC extended the public comment period for portions of its original Part 205 proposal regarding “noisy withdrawal” by attorneys under certain circumstances and proposed an alternative reporting mechanism in such instances.<sup>6</sup>

Section 307 of the Act required the Commission to issue minimum standards of professional conduct for attorneys appearing and practicing before the Commission in any way in the representation of issuers. Specifically, the statute mandated standards that require attorneys to report “evidence of a material violation of securities law or breach of fiduciary duty or similar violation” by the issuer or its agents to the issuer’s chief legal officer (CLO) or chief executive officer (CEO); and if the officers do not “appropriately respond” to such evidence with remedial measures or sanctions, to report up the ladder to the issuer’s audit committee, to another committee of independent directors, or to the full board of directors.

In Part 205, the SEC established new requirements for attorneys who appear and practice before the SEC on behalf of issuers (including in-house attorneys) to report evidence of certain violations by issuers or other agents to the issuer’s CLOs and/or CEOs. An officer receiving such a report is required to conduct an inquiry, take appropriate remedial action if warranted, and report back to the attorney who submitted the initial report. If the reporting attorney does not receive an appropriate response, then the attorney must report “up the ladder” within the issuer, to a committee of independent directors of the issuer or even to the board itself. Issuers have the option of establishing qualified legal compliance committees consisting of independent directors, to receive, investigate, and respond to reports from attorneys pursuant to Part 205.

**What Does All This Mean?** There is a new focus on corporate governance considerations. Audit, compensation and disclosure committees have been increasingly important. Issues involving conflicts of interest and true independence of directors are at the forefront.

Not only should there be a majority of independent directors, the definition of independent director is narrower. Non-management directors should meet periodically in execution session without management.

The nominating/corporate governance committee should be composed entirely of independent directors. It should have a written charter addressing the committee’s purpose regarding the identification and selection of board members. The committee’s goals and responsibilities should include the criteria for selecting new directors and oversight of the evaluation of management.

The compensation committee should be composed entirely of independent directors. It should have a written charter addressing the committee’s purpose, including to discharge the board’s responsibility relating to compensation for the company’s executives and to produce an annual report on executive compensation.

The compensation committee’s duties and responsibilities should include a review and approval of corporate goals and objectives relevant to CEO compensation goals and objectives, evaluation of CEO’s performance, and compensation fund. The committee should make recommendations to the board with respect to executive compensation plans and equity-based plans. The corporate governance guidelines should include director qualification standards, director responsibilities, director access to management and, as necessary and appropriate, independent advisors, director compensation, director orientation and continuing education, and management succession.

There also should be a disclosure committee to ensure that appropriate disclosures are made. All committees should have annual performance evaluations.

Audit committees should be composed entirely of independent directors, and they should provide assistance to the board of directors in fulfilling the board’s oversight and responsibilities regarding the company’s accounting and system of internal controls, the quality and integrity of the company’s financial

reports, and the independence and performance of the company’s auditors. The audit committee shall review and discuss with management and the outside auditor any material off-balance-sheet arrangements or other material financial arrangements of the company that do not appear on the financial statements of the company. In addition, the audit committee should also discuss transactions with related parties.

Companies should adopt and disclose a code of business conduct and ethics for directors, officers and employees and promptly disclose any waivers of the Code for directors and executive officers. The most important topics to address are conflicts of interest, protection and proper use of company assets, compliance with laws, rules and regulations and encouraging the reporting of any illegal or unethical behavior.

There will be greater scrutiny of and a possible reduction in off-balance sheet financial arrangements, including hedging transactions, special purpose entities, timing of asset sales with short-term repurchases, particularly with respect to related-party transactions.

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<sup>1</sup> 107 Pub.L. No. 204, 116 Stat. 745.

<sup>2</sup> Section 906 has been codified as Section 1350 of Title 18 of the U.S. Code.

<sup>3</sup> See Final Rule: Standards Relating to Listed Company Audit Committees, Release Nos. 33-8220; 34-47654; IC-26001 (April 9, 2003).

<sup>4</sup> Final Rule: Strengthening the Commission’s Requirements Regarding Auditor Independence, Release No. 33-8103; 34-47265; IC-25915, IA-2103 (January 28, 2003).

<sup>5</sup> Final Rule: Implementation of Standards of Professional Conduct for Attorneys, Release Nos. 33-8185; 34-47276 (January 29, 2003), codified at Part 205 of Title 17 of the Code of Federal Regulations.

<sup>6</sup> Proposed Rule: Implementation of Professional Conduct for Attorneys, Release Nos. 33-8186, 34-47286 (January 29, 2003).

### Fixed subscription fee for ambulance services permitted

by **Geraldine S. Stroka, R.N., J.D., M.S.N.**

A nonprofit corporation has been permitted to collect a fixed annual subscription fee for providing emergency ambulance services to its Medicare Part B members, instead of collecting their cost-sharing amounts required under that federal healthcare program. The Office of Inspector General (OIG) concluded that the arrangement could potentially generate prohibited remuneration under the Antikickback statute if the intent to induce referrals was present, but that it would not impose administrative sanctions.

**Ambulance service and cost sharing.** Since 1963, this nonprofit corporation has provided emergency ambulance services for two classes of subscribers, individuals and businesses. The annual fee structure for the services is as follows: an individual pays \$20.00, while the fee for businesses is dependent on the number of employees—\$30 for those with less than twelve employees and \$50 for those employing 12 or more people. The corporation does not collect Medicare Part B cost-sharing amounts (other than supplemental insurance coverage of the subscriber's obligation) from its subscribers, but does collect such balances from nonsubscribers.

When requesting this advisory opinion, the corporation made two certifications. First, the corporation certified that the subscription revenue currently exceeded, in the aggregate, the cost-sharing amount waived for all subscribers. Second, it certified that the subscription revenues collected for all Medicare Part B subscribers currently exceeded, in the aggregate, the cost-sharing amounts waived for those individuals.

**Antikickback analysis.** The Antikickback statute makes it a criminal offense to knowingly and willfully offer, solicit or receive any remuneration to induce or reward referrals for items or ser-

vices reimbursable by the federal healthcare programs, Soc. Sec. Act §1128B(b). Under that statute, this arrangement could be construed as a routine waiver of the Medicare Part B cost-sharing amounts.

The issue is whether (1) in the aggregate, the subscription fees collected are approximately the same amount that the subscribers would spend for the cost-sharing amounts during the course of the subscription, or (2) the amounts collected from Medicare Part B beneficiaries are approximately the same as they would anticipate paying for their cost-sharing amounts. If the subscription amounts are not comparable to the uncollected cost-sharing amounts under either (1) or (2), this plan could be considered as an illegal practice to disguise the routine waiver of Medicare Part B cost-sharing amounts.

**Subscription plan permitted.** OIG permitted the nonprofit corporation's emergency medical services subscription plan. OIG stated that the subscription amounts that the nonprofit corporation collected from Medicare Part B beneficiaries, in the aggregate, exceeded the cost-sharing amounts that Medicare Part B beneficiaries would be expected to pay during the length of time covered by the subscription agreement. Therefore, OIG concluded that it would not impose administrative sanctions.

*OIG Advisory Opinion 03-11, May 28, 2003, ¶150,208*

### MRI joint venture allowed

by **Geraldine S. Stroka, R.N., J.D., M.S.N.**

Failure to qualify under the applicable safe harbor did not doom a joint venture involving the only open magnetic resonance imaging (MRI) facility in a medical center's three-county service area. The Office of the Inspector General (OIG) permitted a proposed joint venture between a medical center and a radiology group to own and operate an outpatient open MRI and several related ancillary agreements, based on the totality of the facts and circumstances presented.

### Safe harbors and certifications.

The medical center owns and operates a radiology department, which provides inpatient and outpatient radiology services. The radiology group, the exclusive provider of radiology services for the medical center, meets the requirements of the group practice safe harbor, 42 C.F.R. § 1001.952(p). Both the medical center and radiology group have certified that the compensation the radiology group receives from the medical center for its services is at fair market value in arms'-length transactions. The radiology group formed a holding company with all radiologists owning an equal share, in order to invest in the open MRI joint venture.

**The arrangement.** The medical center and radiology group will own 51 percent and 49 percent respectively with all profits and losses distributed according to capital contributions. Neither referrals nor the amount of business that might be generated from the investor to the MRI was considered in determining the terms for investment interests in the venture.

The arrangement had multiple safeguards built into it. Some of the assurance given by the medical center were that: (1) all patients would be given written notification of the medical center's investment interest, (2) all federal healthcare program patients would be treated in a nondiscriminatory manner; (3) it would not claim payment from any federal healthcare program unless required by that program; and (4) it would limit its ability to control referrals by making certain certifications about the referral process, promising to annually notify all affiliated physicians of these certifications.

In order to operate, the MRI facility would enter into four written ancillary agreements, two service and two pass-through. The two service agreements included a professional services agreement and a staffing agreement. The pass-through agreements include an equipment sublease and an assignment of the lease for the space for the MRI facility. Both the medical center and

the radiology group have certified that the payments for the ancillary agreements would be at fair market value in arms'-length transactions. Also, they certified that the space lease and equipment sublease meet all the requirements of the applicable safe harbors, 42 C.F.R. §1001.952(b)(c), except for the one-year term requirement.

**No small entity safe harbor.** The proposed arrangement failed one of the safe harbor's two "60-40" tests (the investor test) which requires that at least 60 percent of an entity's investment interests be held by persons that are not in a position to make or influence referrals or otherwise generate business for the entity, 42 C.F.R. §1001.952(a)(2)(i). Here the medical center would be in a position to influence referrals to the facility and both the medical center and the group will furnish services to the facility.

**Arrangement permitted.** Although the proposed arrangement failed to meet the requirements of the applicable safe harbor, OIG permitted the joint venture. OIG stated that the following facts mitigated the risk of fraud and abuse: (1) physician investors were not referral sources for the facility or the medical center; (2) the medical center certified that only a small percentage of the referrals would come from the medical center or physicians employed by the center; (3) the medical center also certified that it would take steps to limit its ability to direct referrals; (4) the return on investment to the medical center and radiology group will be proportional to their respective capital investments and not based on the volume of referrals; and (5) the four ancillary agreements do not appreciably increase the risk of fraud and abuse.

**Importance.** The federal government has been relentless in its efforts to eliminate fraud and abuse in healthcare. It has also, through its various agencies and their initiatives, turned its focus on improving quality in healthcare.

The utilization of MRI technology has been shown to affect the treatment decisions of healthcare providers. However, patients, concerned about undergoing a procedure with the space limitations necessitated by regular MRI technology, may refuse the test. Open MRI technology, offered by this joint venture, should make this diagnostic aid a viable alternative for more patients. Hopefully, better diagnostic tools improve patient

outcomes, which is the goal of all the participants in the healthcare process—the doctors, patients, and the payers, including the federal government.

OIG reviewed all the facts and circumstances of this particular arrangement. It determined that risks were sufficiently low and that it would not impose administrative sanctions under the anti-kickback law. ■

*OIG Advisory Opinion 03-12, May 29, 2003, ¶150,209*

### To our readers

**July 21, 2003**

We recently received a number of comments regarding the article "Study: inadequate encryption of protected health information in e-mails violates HIPAA" (Volume 6, Issue 13). Specifically, several readers took issue with the statement, "it is clear many organizations are either unaware of or indifferent to the fact that federal legal requirements exist under HIPAA that prohibit the unencrypted transmission of PHI." We, at CCH INCORPORATED, are aware that there are no express provisions in HIPAA that mandate encryption of e-mails containing protected health information. However, we do stand behind the assertion that HIPAA requirements are ever changing and that pursuant to the "addressable requirements" of the Security Rule, it may be considered reasonable and appropriate to encrypt e-mails that contain PHI. We apologize if this view had been miscommunicated and for any confusion this may have caused.

With regard to the Zix Corporation study, which was the focus of the article, CCH INCORPORATED does not have any agreements—express or implied—nor does CCH maintain any affiliation with the Zix Corporation. The purpose of the article was to reveal the data provided by the study and to analyze its impact on the health care field. The purpose of the article was not intended to advertise or promote the Zix Corporation or any of its products.

CCH INCORPORATED and its team of dedicated health care compliance writers and analysts always strive to maintain the highest quality of reporting and analysis that our readers expect from all CCH products.

Sincerely,

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