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E-health ventures pose complex compliance risks

Licensure, Stark, and the kickback statute are among the land mines in e-health's regulatory landscape

While the regulatory landscape of e-health is only beginning to take shape, hospitals and physicians are running a serious risk if they believe this area is immune from existing regulatory constraints, experts warn. "A lot of people believe that because this is e-commerce, the basic rules don't apply, but the important point is that they do," argues **Edward Kornreich**, a health care attorney with Proskauer Rose in New York City.

According to Kornreich, all of the fundamental principles regarding licensure and tax exemption and, most importantly, compliance with Stark and the anti-kickback statute apply to e-health.

Kornreich says one critical issue for not-for-profit hospitals is how they structure their relationships regarding on-line transactions with sponsors and others. How they structure them could result in inurement or taxable income, he warns.

Health care attorney **Guy Collier** of Shaw Pittman in Washington, DC, says that, among the current Web-based models, equity sometimes is offered to hospitals and health systems in part based on volume of purchases. **Gadi Weinreich**, a partner with the same firm, adds that arrangements can also be flat-fee or based on the number of hits, as well as discount arrangements.

Kornreich says the second critical issue

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Nursing homes to face tougher federal scrutiny

Nursing homes should brace for tough government scrutiny on a number of fronts, including quality of care and payment for Part B therapy. Last week, the Eastern District of Pennsylvania claimed its sixth nursing home victim when it announced a $60,000 settlement with Ashton Hall Nursing and Rehabilitation Center in Philadelphia. Notably, the case was based on the government's charge that Ashton Hall provided inadequate nutrition and wound care involved care provided to a single resident in 1998, reports Assistant U.S.

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Successful negotiation may ease CIA complexity

Despite publicized attempts by the Department of Health and Human Services Office of Inspector General (OIG) to reign in the complexity of corporate integrity agreements (CIAs), the size and scope of these OIG-mandated agreements continue to grow. **(See related story, page 3.)** "The evolution of the technical portion of CIAs over the last several years is astronomical and something we need to play close attention to," asserts **Robert Bacon**, director of compliance for the University of Pennsylvania Health System. "No two are the same; they are all different."

According to Bacon, there is tremendous variation in the specific criteria in the CIAs that are signed today compared to the settlement that his health system agreed to in 1995. For example, specific hours and training by full-time equivalent type are now frequently specified, whereas earlier agreements merely included a

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providers must consider is licensure. That means hospitals must make sure they are appropriately licensed in every jurisdiction in which they provide services. For example, if patients are receiving care through telemedicine, providers must be certain the person providing those services is licensed in the state in which the patient is located.

"You need to look at licensure and whether or not you are practicing medicine across state lines," concurs Collier. But he adds that other provider licensure laws that govern nonphysicians who happen to be licensed by state law also must be considered. "The same range of issues arises there," he says.

The third key component for hospitals is to make sure they are compliant with anti-kickback and Stark self-referral laws, Kornreich says. "That is probably the area where they will most easily find themselves out of compliance," he contends. Kornreich says hospitals may be tempted to offer physicians benefits in order to facilitate the implementation of e-health by their medical staff. Benefits as simple as providing telephone lines can raise anti-kickback issues.

Collier agrees that the most obvious land mines are the federal anti-kickback laws and state all-payer statutes that capture nonfederal program-related business. But he adds that while state laws mimic the federal anti-kickback statute in many respects, the state laws prohibiting self-referral are sometimes even more restrictive.

Collier also cautions that while there is no shortage of existing laws that govern Web-based relationships between hospitals, Web site vendors, physicians, suppliers, and patients, the e-health landscape is changing rapidly.

For example, he notes that a tremendous number of content-based providers that previously attracted private sector money but were not producing revenues have begun to produce revenue. That has led to an increase in business-to-business applications where vendors deal with hospitals or physicians, as well as business-to-consumer applications where vendors deal with patients or health care organizations.

Many of these arrangements raise concerns about patient privacy, according to Collier. He notes that the California Health Foundation studied the 21 most heavily trafficked health care consumer Web sites and found that while 19% had privacy statements, those statements were largely inadequate and not adhered to.

Another 18% utilized cookies to track consumer activity on the Internet. Moreover, most of the 21 sites surveyed shared information with third parties.

Regardless of whether the privacy regulations required by the Health Insurance Portability and Accountability Act of 1996 are released this year, he says providers must be aware of state laws and aggressive enforcement of those laws. ■

CIA complexity

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requirement to conduct education.

More recent CIAs also include expanded requirements for filing reports, notes Bacon. "That is another example of where I have seen astronomical changes in the last five years," he asserts.

Bacon says he is also concerned that providers will have to file an audit report along with the management report. That puts the onus on organizations to report additional information that the CIA did not require, but that now potentially becomes part of public records under the Freedom of Information Act. "I am very concerned in this area," he says.

Bacon also cautions that all entities under

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CIAs should be familiar with SOP 99-1, which is the American Institute of Certified Public Accountants' guidance to practitioners in conducting and reporting on CIAs, introduced last year. "This is a document that certainly concerns me," says Bacon. He says that is because the testing procedures go above and beyond anything that was required in many of the earlier CIAs.

For example, SOP 99-1 includes requirements for testing audit records against payroll records. "None of this is required in many existing CIAs, but it is clearly mentioned in the agreed-upon procedures," he reports.

Bacon also predicts that specific references to SOP 99-1 will be included in future settlements. "However, if you are not required to do that level of testing on your current agreement, the cost of bringing in that external auditor to follow those procedures is significant," he asserts.

Patrick Marion, president of Compliance Concepts in Philadelphia, reports that for most of the CIAs that have come out over the last year, the independent review organization (IRO) is instructed to review the implementation of the CIA as well as the detailed claim review.

Marion, formerly a member of the OIG, says that gets back to the negotiation of the CIA. He points to one institution where the CIA audit requirement was not to audit the claims submission but rather the internal audits that it had conducted.

"That is much different than having an independent firm take a sample of claims, replicate an audit, and come up with an overpayment as opposed to evaluating whether the audits were timely and thorough." That change probably saved the organization $100,000, he adds.

Marion says one important area to examine with an external review organization is its track record and experience in dealing with the federal government in areas such as auditing procedures.

"If you are going to bring somebody in to look at physician claims, you don't want somebody who has worked on 25 lab settlements," he warns. "You need that specific level of expertise on the issues they are dealing with."

Marion says one of the specific issues an IRO must be familiar with is the OIG's statistical program. He notes that the OIG's audit division has very specific rules on how it performs statistical sampling and what it must report. However, the investigative arm of the OIG is not obligated to follow those rules. "If you can bring to the table your knowledge of those rules, the difference on the same errors can be literally millions of dollars," he says.

According to Bacon, deciding whether to involve a specialist requires looking at the subject matter. That might mean attorneys for interpretation of specific regulations, medical specialists, or board certified physicians.

Bacon cites one audit dealing with urological procedures that used both internal- and external-board certified urologists to help overturn the audit. Likewise, he says cost-reporting issues may require accountants with specific expertise in those issues.

Marion adds that while organizations may engage clinical experts, somebody must be responsible for managing the entire process. "You may have multiple clinical specialties involved, and you need a person who is going to be able pull all of those independent pieces together and put them in a package to present to the government," he explains.

According to Bacon, once the shadow audit is completed and a CIA has been reached, the need to perform continued shadow audits is often redundant.

But he says there needs to be an assembled team that will investigate any unfavorable variances. IRO findings can be wrong, he warns. For example, records may have been overlooked or the interpretation of a physician's shorthand may be subject to interpretation. "If you go through those unfavorable findings, you should be able to reduce any liability attributable to the error rates," he says. ■

OIG gets mixed reviews on CIA requirement update

The Department of Health and Human Services Office of Inspector General (OIG) has posted 23 new answers to questions frequently asked by providers under a corporate integrity agreement (CIA) about reporting overpayments, the selection

and independence of an independent review organizations (IRO) as well as material violations. But health care attorneys say the new guidance is a double-edged sword.

Mike Kendall, a health care attorney with McDermott, Will & Emory in Boston, says the OIG's latest notice demonstrates both the best and worst features of the OIG's approach to CIAs.

On one hand, he says there is some very precise information regarding auditing, sampling, and other tasks that providers will find very helpful. Also, the OIG makes a significant effort at industry education by offering carefully thought-out recommendations and standards.

But Kendall says there is a flip side to that coin. "Some of the standards included in the notice are ambiguous enough that providers should be concerned," he warns.

The most recurrent problem, he says, is the definition of a material violation (which is what a reasonable person would consider a potential violation of a criminal, civil, or administrative law). "That is a very broad and ambiguous definition and to put that onus on providers without any precise definition of how to deal with that threat is troubling," he asserts.

Moreover, Kendall says the OIG's notice is part of a process the OIG is using to make CIAs far more pervasive and far more burdensome.

He notes that these agreements are not mandated by Congress and are not part of any Health Care Financing Administration program initiative. "They are an invention of the OIG to expand its day-to-day control over providers in a way that is not provided by statute," Kendall argues.

Tom Jeffries, a health care attorney with the Seattle-based Davis, Wright Tremain, says it is clear from this release as well as earlier OIG guidance that the OIG is attempting to bootstrap items included in recent CIAs to older agreements. He also agrees that the OIG fails to provide any "bright lines" in terms of dollar amounts or other thresholds that would explain what constitutes a material violation, particularly for purposes of reporting an overpayment.

To view the OIG's entire document, go to *www.dhhs.gov/progorg/oig/new.html.* ■

Nursing homes

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Attorney **David Hoffman**.

Similar to earlier agreements, the remedy imposed on Ashton Hall includes monitoring and fines. However, the facility also was required to create a minimum $100,000 fund over the next two years devoted to improving quality of life and environmental factors at the facility. Hoffman says his office will have input into how that money is spent.

The quality-of-care threat facing nursing homes is by no means limited to the Eastern District of Pennsylvania. While that U.S. attorney's office has spearheaded this concept, Hoffman predicts that similar cases will emerge in a number of other districts.

"The whole quality-of-care issue as far as the False Claims Act is concerned is continuing to gather steam," warns health care attorney **Marie Infante** of the Washington, DC, office of Mintz Levin. According to Infante, Medicaid fraud units and attorneys general are also beginning to look at this issue.

Quality of care isn't the only threat looming for nursing homes, however. In a report released last week, the Department of Health and Human Services Office of Inspector General (OIG) recommended that the Health Care Financing Administration (HCFA) make sure that adequate medical reviews of Part B therapy in nursing facilities are conducted and that therapy providers understand billing procedures and medical necessity guidelines.

While the report was mandated by Congress, Infante says nursing homes should take note. "If I was a nursing home, I would assume that all Part B therapy is going to be scrutinized very carefully," she says. "The OIG has a history of being deeply suspicious of therapy in nursing homes."

The OIG points out that implementation of monetary caps on therapy services in skilled nursing facilities (SNFs) coincided with a dramatic decrease in Part B therapy charges last year. But the OIG says that preliminary reports indicate that a rebound in SNF Part B therapy charges should be expected over the next two years.

It attributes part of that increase to inadequate contractor oversight of billing practices and medical necessity of Part B therapy. ■