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Corporate integrity agreements undergo new changes

Department of Justice increases its flexibility in negotiating new agreements, experts say

Hospitals that are in the process of negotiating a corporate integrity agreement (CIA) or operating under an existing agreement should be aware that both the negotiation of these agreements and their enforcement continue to undergo important changes. "It is not business as usual with respect to CIAs," warns **Brent Saunders**, director at PriceWaterhouseCoopers in Washington, DC.

Former U.S. Department of Justice attorney **John Bentivoglio** says the good news is that the Department of Health and Human Services' Office of Inspector General (OIG) has added substantial resources to the units responsible for negotiating and overseeing compliance of CIAs. "That should be good news because it will likely increase their flexibility and willingness to tailor agreements to meet unique circumstances," he explains.

Charles Murdter, a health care attorney in Davis Wright Tremain's San Francisco office, says he is seeing this new attitude already. "The current posture of the general counsel's office at the OIG is tough but fair," Murdter asserts. "I am seeing a little more flexibility from the OIG in trying to craft the terms of an integrity agreement to match the capacity and the needs of a particular provider."

Bentivoglio says the bad news is that the OIG now is making good on its plans to carefully monitor compliance with corporate integrity agreement.

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How to limit your facility's EMTALA liability

The Emergency Medical Treatment and Active Labor Act (EMTALA) remains a major challenge to hospitals because the regulation is so broad and often has multiple interpretations in the way the Health Care Financing Administration (HCFA) interprets it, experts contend. In addition, the Department of Health and Human Services' Office of Inspector General (OIG) has discretion in how it assesses financial penalties and the courts often interpret EMTALA different ways.

"There are many gray areas, and providers trying to deliver care in their emergency department must understand that there is often much confusion,"

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HHS extends comment period for privacy regs

The health care industry is hoping that the 30-day extension to the public comment period for the final privacy regulations, just announced by the Department of Health and Human Services, results not only in a relaxation of some of the most onerous measures but also a delay in the regs' effective date, now two years away. However, senior agency officials responsible for crafting the mammoth final rule released Dec. 20, refuse to speculate on how the final rule may change, and seasoned observers say that's because nobody knows right now.

HHS Secretary **Tommy Thompson** told hospital executives at the Health Care Compliance Association's privacy conference (HCCA) in Washington, DC, on Feb. 27 that while the agency wants a thorough review to examine the potential for unintended consequences, it remains committed to implementing the rule mandated by the Health Insurance Portability and

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CIA changes

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"The level of scrutiny that providers can expect will increase, and the likely consequences for violating their corporate integrity could be quite severe since they will be repeat offenders in the eyes of the OIG," he asserts.

Saunders says he already is seeing that. Not long ago, he says, annual reports required under a CIA would be submitted to the OIG, and no response would even be generated. "It was like sending it into the black hole," he asserts. "That is not the case today."

Today, he says, the OIG is not only reading these reports but responding to them. "I have several clients that have had spot checks and audits done randomly and unannounced with very little notice," he reports. "The government is taking them much more seriously and holding providers to the terms of the agreement."

Ed Rauzi, a health care attorney in the Seattle office of Davis Wright Tremain, says the OIG's increased attention makes the negotiation of CIAs critically important.

Rauzi says much of the documentation and many of the provisions for CIAs remain similar across the board. But he adds there are typical and atypical agreements, and hospitals in the process of negotiating should examine the CIAs for Columbia/HCA and the second agreement for the University of Chicago as examples.

"The reason those [agreements] are very interesting is that they recognize that absolute perfection is not attainable," says Rauzi. The second University of Chicago settlement is a case in point, he says. The issue there is evaluation and management codes, which physicians use to describe office visits. "There is just total confusion about how those things should be coded, and you can never get it completely right," he explains.

Another trend that Murdter reports is what he calls individual integrity agreements. "The whole fraud and abuse enforcement effort is now filtering down to the individual provider level," he says. In some instances, that means that individual providers are now signing those agreements.

Murdter says those agreements tend to be modeled after the compliance plan promulgated last summer for physicians and small group practices. On the whole, these agreements are not as burdensome as typical CIAs.

Others say the best CIA is no CIA at all, and sometimes that it is achievable. According to **Chris Ideker**, a partner with Ernst & Young in Atlanta, a case in point is the University of California, which recently settled a Physicians at Teaching Hospitals (PATH) investigation for $21 million with no CIA. "I question after this California settlement whether a PATH settlement will ever have a CIA again," he asserts. "I would think any attorney negotiating on behalf of an institution is going to try to avoid one."

He says taking this route raises the question of whether the institution is going to give up its waiver of permissive exclusion. But he predicts many academic institutions will take that risk, believing there is little chance the OIG is going to exclude them anyway.

But even as some areas such as PATH investigations recede in importance, others are receiving more scrutiny. **Gregory Warner**, director of compliance at the Mayo Foundation in Rochester, MN, says one such area is quality of care.

Some recent CIAs have included quality issues, he notes. "It will be interesting to see how much more that happens," he adds. "That will be another new and interesting twist to the expanding role of a compliance officer."

Bentivoglio warns quality-of-care cases often merit more novel provisions that achieve patient protection goals than a straightforward financial fraud case. "At the end of the day, you have to make the substantive case about why it is appropriate from a law enforcement program integrity and patient perspective," he says. ■

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Privacy regs

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Accountability Act of 1996.

According to **Kristin Welsh**, senior associate director for policy development at the American Hospital Association in Washington, DC, the association has three primary concerns — the patient consent process, requirements surrounding relationships with business associates, and current minimum necessary requirements. Those concerns track closely with the priorities outlined by **Allysa Fox**, executive director at the Blue Cross/Blue Shield Association in Washington, DC.

Here is a rundown of key areas in which health care representatives are seeking changes:

♦ **The consent process.** Welsh says AHA is concerned about the consent process required by the final regulation. "The whole process of providing notice and getting consent from patients is dramatically different from the proposed rule to the final rule," she explains. As it stands, hospitals and other providers are likely to waste a lot of energy figuring out how to implement this process. "We need to do more research through our own membership and then educate the administration about how it would actually work in practical terms," she says.

♦ **Business associates.** Fox says even covered entities will have to comply with a whole tangle of rules surrounding business associates. While improved from the proposed rule, Welsh agrees they still have troubling implications for hospitals that work with state data collection agencies and state associations that collect information through research activities. "We are not exactly sure at this point what we can continue doing with or without a business associate agreement," she asserts.

♦ **Minimum necessary requirements.** Fox says the minimum necessary requirements included in the final rule will add significant cost and have the potential to impede providing care. "If you constantly have to look for the least amount of information you can use or disclose when caring for a patient, you are just not going to get the best care for the patient," she says.

Meanwhile, Congress last week rescinded the Occupational Safety and Health Administration's (OSHA) ergonomics standards, which were designed to reduce the incidence of repetitive motion injuries. Critics argued the regulations would have been extremely costly for providers to implement. According to OSHA, home health providers would have been the hardest hit with an estimated annual cost of $43 million to comply with the regulation. But hospitals, physicians, and all other providers that move patients also would have been significantly affected.

Congress used the Congressional Review Act, which permits Congress to reject regulations within 60 days of the effective date with a majority vote. President Bush now has the option to veto the resolution, but has already announced he will not do so. ■

EMTALA liability

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warns **Charlotte Yeh**, MD, FACEP, medical director for Medicare policy at the National Heritage Insurance Co. in Hingham, MA. In fact, Yeh says court systems are taking on a whole new interpretation of EMTALA, and interpretations can vary among federal district courts.

Yeh says that makes it extremely important going forward that every hospital has at least one individual who is very knowledgeable about EMTALA, regarding both regulations and case law, particularly for decisions that apply to their particular region.

Yeh says there are several other measures hospitals can take to limit there risk in this area. For example, she says it also is important to be aware of new advisories and new regulations that may be issued periodically. She points to an OIG survey issued in November 1999 that showed that many hospitals were unaware of the special advisory on EMTALA.

In addition, Yeh says it is critical that each hospital develop its policies and procedures very carefully. She warns that hospitals typically are held accountable for following their own rules. "Make sure that your policies and procedures are written with enough instruction to your staff but also written with a fair degree of flexibility, because not every circumstance can be anticipated."

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Third, hospitals must ensure patients understand the EMTALA requirements. In short, she says hospitals must understand the risk of a patient filing a complaint.

On a more positive note, Yeh points out that most courts generally have decided EMTALA should not be a forum for federal malpractice claims, but that it should stay within the state court system.

"Most of the federal courts tend to look at whether or not disparate or discriminatory treatment occurred and whether a hospital failed to follow its own rules," she asserts.

Finally, she notes that the General Accounting Office (GAO) has initiated a study of EMTALA that is due out in late spring or early summer. She says it will offer an important opportunity for the provider community to provide feedback on what their experiences under EMTALA have been.

She also recommends that hospitals talk to the American Hospital Association, state hospital associations and specialty societies such as the American College of Emergency Physicians about experiences that can be transmitted to the GAO. ■

EMTALA teleconference offers advanced solutions

On Thursday, March 29, the publisher of *Compliance Hotline* will offer the teleconference *Advanced EMTALA: Solutions to Today's Toughest Compliance Dilemmas*.

This advanced teleconference will bring you detailed answers you won't find anywhere else about the "patient-dumping" regulations. Speakers will discuss the role of nonphysicians in medical screening examinations and clarify complex challenges.

You may invite as many participants as you wish to listen to the teleconference for the low fee of $199 for subscribers to one of American Health Consultants' publications, and $249 for nonsubscribers. Registrants to the *Expanding Scope of EMTALA* teleconference, held in November 2000, will receive a special discount.

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Assisted living comes under fire in the states

Hospitals thinking about branching out into the assisted living environment — or that already have a foothold there — can take comfort that Congress still is taking a hands-off regulatory approach to this rapidly growing area. But they also should closely scrutinize a wave of activity under way at the state level, experts warn.

"Fraud and abuse is going to be a huge issue in assisted living in the years to come," warns **Ken Burgess**, a partner with Hooper, Lundy and general counsel to the Assisted Living Federation of America (ALFA) in Fairfax, VA.

According to Burgess, the root of the problem lies in the relationship these facilities have with outside vendors such as pharmacy, nursing, therapy, and durable medical equipment.

Facilities often contract with outside entities for these services. "The whole issue of how facilities screen them and choose them and supervise them is going to be a large and difficult issue," he asserts.

The reason is that to date only a handful of states offer Medicaid funding for assisted living, and there is no Medicare reimbursement at all. "It is still largely a private-pay market or commercial market, and because of that you do not have the hook into the fraud and abuse laws," explains Burgess.

But when outside vendors sell their goods and services in a facility, assisted living providers are sometimes seen as enabling those vendors to commit fraud.

ALFA spokeswoman **Whitney Redding** says the assisted living industry is not opposed to regulation, but wants to be certain that it takes place at the state level rather than the federal level. "Some people would address concern over quality of care by taking us down the same road as nursing homes," she warns.

Indeed, some states simply have adopted existing nursing home regulations already on the books for assisted living. That isn't happening everywhere, Burgess says, but in the area of transfer or discharge and resident assessment, state legislators often lift the nursing home regulation almost verbatim. ■