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OIG softens its stance on corporate integrity agreements

Existing compliance plans may eliminate the need for CIAs or shorten their duration

The Health and Human Services Office of Inspector General (OIG) revealed May 23 that it will consider foregoing corporate integrity agreements (CIAs) as part of settlements when there is adequate evidence of an effective compliance program.

"This marks a retreat from the position that all cases require CIAs, and that is very beneficial," says **Ted Acosta**, a senior manager at Ernst & Young in New York City, who recently completed a four-year stint as senior attorney at the OIG.

According to health care attorney **Tom Crane** of Mint Levin in Boston, never before has the OIG publicly stated that it might waive the need for a CIA entirely when the case does not involve a voluntary disclosure. "That part is new and represents a step forward." He notes that the OIG's "Open Letter to Providers" in March 2000 indicated these measures would be possible only if the matter involved a voluntary disclosure.

Acosta says the OIG's update on CIAs has an important dual purpose. First, it publicizes the benefits of prompt and diligent self-disclosures. But he says it also illustrates that the OIG is open to alternative ways of working with providers to achieve compliance by giving them significant credit for what they already have accomplished.

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DCIS pursues aggressive *qui tam* program

The Department of Defense Criminal Investigative Service (DCIS), which helps oversee more than $5 billion in spending for 8.2 million active duty and retired military personnel and their dependents through TRICARE, is shaping up as the new health care enforcer on the block.

DCIS already has an aggressive *qui tam* program, and last year the agency opened 55 cases based on referrals, according to **Joseph McMillan**, special agent in charge of the DCIS Mid-Atlantic field office based in Arlington, VA. He says DCIS currently is investigating 529 health

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How you can negotiate a manageable CIA

When the Health and Human Services (HHS) Office of Inspector General (OIG) investigates a provider, it always asks three questions, says **Joe Russo**, president of HP3 Healthcare Concepts in Bethlehem, PA:

1. Is there a compliance plan in place?
2. Is that plan effective?
3. Was that plan in place when the alleged wrongdoing occurred?

If you can answer "yes" to each of those questions, you will have dramatically improved your chances of negotiating a manageable corporate integrity agreement (CIA), Russo argues.

"A CIA is not a boilerplate document to be presented to you for your execution," asserts **Michael Kline** of Fox Rothschild in Lawrenceville, NJ. He says getting outside counsel involved early is an important part of the process that can take a variety of forms. That is because outside

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Integrity agreements

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That said, Acosta notes there are some instances where providers still ended up with a CIA, even though they came forward voluntarily. "It is very hard to judge from the outside without knowing all of the facts," he adds. "The OIG may have had other reasons."

Acosta also warns that it can be dangerous to read too much into CIAs as an indicator of where the OIG or the Department of Justice is zeroing in. He points out that CIAs follow investigations, and the majority of those investigations stem from *qui tam* suits. "The government does not have any control over the kinds of *qui tams* that are filed," he says.

In the area of sampling, that is not the case, however. "The OIG has really changed the landscape in this area," Acosta contends. He adds CIAs offer significant insight into OIG's own policies and practices. "The CIA provisions almost set a minimum standard for the industry," he explains.

The OIG reports that its informal review of the results of recent negotiations shows that "significant" and "appropriate" modifications are being made to CIAs with providers that have established compliance programs and make disclosures of misconduct.

The OIG also indicated that it will consider reducing the term of CIAs from the usual five years to three years and scale back the role of the independent review organization if providers can show they have an established system of internal audits.

While CIAs usually include the seven basic elements included in the Federal Sentencing Guidelines, the specific terms of a provider's CIA are subject to negotiations. Notably, the OIG offers "real-life" examples of how its stated policy is working in practice:

♦ A rural hospital in the Southeast self-reported that it had submitted claims with information that was falsified to support reimbursement. The hospital agreed to resolve its financial and exclusion liability. However, the OIG did not impose a CIA because the misconduct was committed by the former management and the new management disclosed its findings as part of a pre-existing compliance program.

♦ A northeastern hospital system identified during the course of an internal audit that one of its teaching hospitals had submitted improper claims. The hospital system agreed to resolve its False Claims Act liability, but the OIG did not impose a CIA because the hospital system disclosed the misconduct to the government, and the system had a comprehensive pre-existing compliance program.

♦ A hospital in the Southwest identified that it had improperly coded claims for mammography services. The hospital uncovered the false claims during the course of an internal audit and agreed to resolve its liability. However, the OIG did not impose a CIA because the misconduct was "isolated and distinct," the hospital disclosed its findings, the damages were relatively small, and the hospital had a comprehensive pre-existing compliance program. ■

Negotiating tips

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counsel may or may not initially have a good sense of a provider's operations, depending on how long they have served and how they have historically interacted with the compliance department or in-house counsel on reimbursement issues.

Early involvement allows the outside counsel to work with the provider and its compliance officer

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to identify important operational and other issues for the negotiation process.

"If you do things right, you can also retain a potential scintilla of attorney/client privilege," adds Kline. He points out that audits and other information required under a CIA lack attorney/client privilege with respect to the OIG because the agreement stipulates that everything will be disclosed.

But the fact that information must be disclosed to the OIG does not mean providers are prohibited from asserting under the Freedom of Information Act (FOIA) that certain proprietary, financial, or other exclusionary material cannot be obtained from the OIG.

In other words, just because providers must make complete disclosure to the OIG does not mean they are required to disclose the same information to competitors and third-party payers. For example, some insurance companies now routinely seek FOIA disclosures following OIG settlements to determine whether copayments and deductibles should be returned to them.

An effective response asserting attorney-client privilege and other proprietary rights of a provider usually can thwart or slow those attempts, he maintains.

Gil Stone, chief compliance officer at The Medical Center at Princeton (NJ), says that one of the mistakes made by his facility, which now is operating under a five-year CIA, was not heeding the advice of Horizon Blue Cross's Medicare bulletin regarding outpatient billing regulations. "We put a lot of reliance in our relationship with Horizon, as our fiscal intermediary, believing they would act as a monitor for us if we had any Medicare billing overpayments," he explains. Instead, Horizon passed certain information to the OIG.

Stone says Princeton, which lacked a compliance plan at the time, realized its error and immediately settled with the government. That helped to avoid treble damages. But when it came to negotiating the CIA, Princeton was not in a hurry. Those negotiations started off without outside counsel and took more than a year to complete, he reports.

Princeton started with the standard CIA but then successfully negotiated with the OIG to have its own internal review group. It also added the option of having an independent review organization (IRO) review the results of its compliance and billing practices. "I would not have done it without having an IRO available," says Stone. While most providers will have a difficult time understanding the OIG's sampling and auditing procedures, known as RAT-STATS, IROs are experts in that area, he points out.

In addition, when the CIA implementation report was ready to be submitted, "the IRO's independent review of our compliance program proved helpful," Stone reports. As a result, Princeton received no exceptions in the implementation report of its compliance program.

Russo says that ongoing internal monitoring and external nonstatistical random reviews are critical for providers, even those not under a CIA. He says that should include education in the health information management field.

While the medical record function is critical to the financial viability of the organization as well as False Claims Act exposure, many providers are reluctant to spend money on credentialed certified expert coders. "That's a mistake," he says. ■

HealthSouth settles with government for $7.9 million

HealthSouth Corporation, the country's largest provider of outpatient surgery, diagnostic imaging, and rehabilitative health care services, agreed to pay $7.9 million to settle allegations of health care fraud, the U.S. Department of Justice announced May 23.

The settlement resolves allegations that the Birmingham, Alabama-based company overcharged Medicare and the TRICARE program for equipment and supplies purchased from G.G. Enterprises, a corporation owned by the parents of HealthSouth's CEO. The government alleged that HealthSouth improperly billed these items at a price above G.G. Enterprises' costs.

The settlement also resolves allegations that HealthSouth overbilled the health care programs for rental payments and the costs of an abandoned computer system. The investigation was triggered by Greg Madrid, a billing clerk formerly employed by HealthSouth, who will receive $1.48 million. ■

DCIS enforcement

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care fraud matters ranging from upcoding and overbilling to quality of care.

McMillen says DCIS will continue to emphasize the investigation of health care fraud as it involves TRICARE and federal health insurance programs impacting the Department of Defense. DCIS reported approximately $626 million in recoveries last year.

According to McMillen, DCIS also is forging relationships at TRICARE and with other law enforcement agencies to establish data-mining capability for health care investigations and has participated in more than 70 nationwide task forces. DCIS is participating with the Department of Justice, the Department of Health and Human Services' Inspector General, and other agencies to develop ways to share open and closed health care information.

This summary information would be entered in a secure centralized database system, reports McMillen. Agencies then could conduct queries to determine if the same target was being investigated by multiple agencies. He says DCIS also is monitoring medical privacy guidelines to assess their impact on federal law enforcement and investigations.

The role of DCIS also is likely to grow along with the size of TRICARE, which last month started offering 1.4 million Medicare-eligible uniformed services beneficiaries age 65 and older new pharmacy benefits using retail and mail-order outlets. McMillen says that DCIS already is working to identify potential areas of fraud in this new system. ■

Advisory opinion: OIG approves EMS arrangement

The Health and Human Services' Office of Inspector General (OIG) last week approved the proposed lease of cardiac diagnostic equipment to emergency medical services (EMS) providers. As with several other advisory opinions on ambulance restocking, the OIG blessed the proposed arrangement because it said appropriate safeguards were in place.

"This opinion does not stretch any boundaries," says **Joe Lynch**, a health care attorney with Vinson Elkins in Washington, DC. "EMS is already a highly regulated area." On its face, Lynch says the program outlined in the opinion clearly presents the types of things the letter of the anti-kickback statute prohibits. "I think this is a case where the OIG takes a practical 'real-world' perspective in interpreting the statute," he says.

Not only did the proposed arrangement not threaten to increase costs to the Medicare program or steer patients to a particular hospital, it was likely to have a positive impact on the quality of patient care by permitting earlier and more accurate pre-hospital screening, the OIG claimed.

Health care attorneys say that most recent OIG advisory opinions have clarified existing practices rather than breaking any new ground. But they say that should not be surprising. "The whole nature of the process does not lend itself to a lot of groundbreaking," says Lynch. For one thing, opinion requesters often are reluctant to invite scrutiny. In addition, the OIG is very precise in terms of what it will approve.

Health care attorney **Bruce Shih** of Latham and Watkins in Los Angeles notes several common themes among advisory opinions. First, to the extent the proposed arrangement does not meet a safe harbor, a favorable advisory opinion provides protection that the OIG will not prosecute.

Second, to the extent the proposed arrangement does not meet a safe harbor and technically violates the anti-kickback statute, a favorable advisory opinion is absolutely necessary, and the OIG has demonstrated its willingness to grant favorable opinions for such technical violations in certain cases, says Shih. He says a good example is small percentage commissions to independent contractors to accommodate a real-world approach to practices.

Finally, a requesting party may seek reassurance from the OIG that a proposed arrangement meets a safe harbor. That was the case in the OIG's latest opinion, in which it determined that payments by vendors to a group-purchasing organization (GPO) owned by entities affiliated with various health care providers that purchase items covered by the GPO's vendor contracts would fall within the GPO's safe harbor. ■