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OIG warns of expanded administrative sanctions

Senior counsel discounts contention that agency is criminalizing honest mistakes

The HHS Office of Inspector General (OIG) plans to increase the use of administrative sanctions — including the civil monetary penalty and exclusion authorities — "where the evidence warrants," says **Mac Thornton**, the OIG's senior counselor.

For the first time, a practicing health care lawyer is Inspector General, and that has brought a new perspective to the OIG, Thornton told attendees at the American Health Lawyers' conference in Baltimore April 3. On one hand, that means cooperation with health care providers. "But make no mistake, the OIG is still expanding in staff and in geographical reach," he warns. According to Thornton, the OIG's Office of Investigations will reach all 50 states with resident offices this year.

Thornton also discounts contentions that the OIG is criminalizing honest mistakes and innocent errors. In fact, he says unwarranted fear is driving some physicians from the Medicare program. It also is leading to a failure to report overpayments and, in some cases, deliberate undercoding. To combat those fears, Thornton points out that, over the last three years, fewer than 50 physicians a year have received a criminal conviction or civil sanction by the OIG.

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Stark case deals setback to government prosecutors

In one of the few reported cases applying the Stark self-referral law, a federal district court in Michigan last month ruled against the government, reports health care attorney **Linda Baumann** of Reed Smith in Washington, DC.

In the government's suit against McLaren Regional Medical Center in Lansing, MI, the court found that a leasing arrangement did not violate either Stark or the anti-kickback statute because the payments were part of an arm's-length transaction, were set at fair-market value, and did not reflect the volume or value of the physicians' referrals, she explains.

*See **Stark case**, page 3*

Creative FCA cases seen replacing national initiatives

The good news for hospitals is that no sweeping new enforcement initiative is looming on the national horizon. The bad news is that the government continues to find creative ways to employ the False Claims Act.

The government's enforcement agenda increasingly is being taken over by whistleblowers, says **Craig Holden**, a health care attorney with Ober Kaler in Baltimore. "We are seeing more and more relators who are repeat relators," he reports. "They made millions of dollars in big cases, and they come back and file new cases against others."

Holden says one new trend may be the use of the False Claims Act to prosecute Stark II violations. "The government is clearly setting up a record to enforce Stark through the False Claims Act," he says. Holden points to the Department of Justice's (DOJ) contention that Stark II offers "a

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OIG initiatives

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According to Thornton, the OIG believes two important infrastructure components require attention. One is the system for assessing overpayment collections and the Medicare appeals process. The contractor claims-processing procedures for overpayment collections could be substantially standardized across the country, and methods for determining overpayments also should be standardized, he argues.

The same holds for differences among contractors regarding coverage and payment policies, which could be made more consistent, Thornton says. Medical reviews also should be more standardized and predictable, he adds.

"All of these steps are important in view of the fact that many health care enterprises now provide services in more than one jurisdiction of carriers or intermediaries," says Thornton.

The current framework for conducting Medicare appeals is "ineffective, untimely, and confusing for everybody," Thornton concedes. He adds that while fundamental reform is pending in Congress, many improvements could be made immediately through regulatory action.

Among the OIG's suggestions for improvement are the establishment of an administrative appeals process dedicated to Medicare, ensuring adequate resources for each level of appeal, and providing for Centers for Medicare & Medicaid Services (CMS) representation at the higher levels of appeal.

In addition, he says that reviewers at different levels use different standards. "A lot of improvements could be made," he argues.

"The IG can make a difference at the margins, but with respect to grand shifts in policy, that's up to Congress," argues former HHS Principal Deputy General Counsel Robert Charrow. "The IG can steer a ship a few degrees to the right or left, but only Congress can turn the ship around."

Fixing the outdated enforcement that now governs health care fraud enforcement must be a top priority, says Charrow, of the law firm Crowell Moring in Washington, DC. According to Charrow, the most needed reform is the ability of providers to sue CMS. "The ability to have meaningful judicial review of CMS and OIG actions would be first on my priority list," he says.

"The real question you have to ask yourself is, 'Why should CMS be less accountable than any other federal agency?'" he says. "One could argue they should be more accountable — not less — because they affect the lives of more people." Agencies that are not subject to judicial review tend to become "cavalier" and "arrogant," and that is unhealthy, he adds.

Legislation is pending that would amend the appeal process and make certain regulatory changes. However, Charrow argues those bills would do little more than codify existing court decisions.

Charrow also contends that the anti-kickback laws governing federal health care programs vest "extraordinary discretion" in the OIG and HHS and are so expansive that they prohibit conduct that is perfectly legitimate in other settings, he says. ■

OIG clarifies EMTALA reg

HHS Office of Inspector General (OIG) Chief Counsel Mac Thornton says there has been some confusion about a regulation issued in mid-February that involves the penalty amount in patient-dumping actions. According to Thornton, hospitals with only one EMTALA violation often argued that, if no pattern of patient dumping

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existed, a certain degree of leniency was warranted. "We agree that makes sense," he says.

The new rule seeks to differentiate between hospitals that have engaged in a pattern of practice and those that have engaged in an isolated incident. But Thornton says it only applies during the final stage of a litigated case before an administrative law judge, after liability has been determined.

Thornton also points out that since 1988 when EMTALA enforcement started, only six of the 268 EMTALA cases concluded by the OIG have been litigated. "In other words, 98% of patient-dumping cases are settled," he says. The rule that was recently promulgated concerns only litigated cases, he emphasizes. ■

FCA cases

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straightforward framework" for identifying false claims. (DOJ used those words in a fall 2000 memo to Congressman Pete Stark [D-CA].)

"I would submit that Stark II is the antithesis of 'a straightforward framework,'" Holden counters. Nevertheless, he notes that several cases recently have been prosecuted on this basis. **(See related story, page 1.)**

Ed Rauzi, a health care attorney with Davis Wright in Seattle, says the newest use of the False Claims Act is in the area of pharmaceuticals — for example, claiming that the information given to the parties that calculate average wholesale prices for Medicare and Medicaid was somehow false. "I think that is the newest development," he says. Rauzi says one major reason for this is the increasing amount of money being spent on pharmaceuticals.

According to Holden, the recent Columbia HCA settlement can be used almost as a roadmap by health care providers because of the range of issues it includes, such as lab unbundling, DRG upcoding, community educators (claiming costs for people doing marketing in home health), cost-report issues, home health management fees, and medical necessity issues with respect to hospital-based home health agencies.

Holden also notes a recent *qui tam* case that was settled for a modest $1.5 million. The case was premised on the health system's failure to report and repay a known $794,000 overpayment. Notably, he says the relator was a former employee of a consultant the hospital had hired to scrutinize cost reports. The government now is investigating the consultant and all its clients.

"The interesting point raised by this is the extent to which providers have a duty to repay overpayments," says Holden. He notes a provision in the Medicare statute that that if a provider is aware of an event that affects its right to have received money and fails to repay it with the intent to convert it unlawfully, that is a crime.

According to Holden, it is a "strangely worded" statute the government may never have used before. But he warns that a proposed regulation published in January would give providers 60 days to notify the carrier or intermediary once an overpayment is identified and to repay it. It is silent on the sanction for not doing so, and remains a proposed regulation. But hospitals should keep an eye on this, he cautions.

Rauzi also warns that while major national initiatives may appear to be waning, there still are numerous areas of payment that can spell trouble for providers. Rauzi says he has never seen a payment methodology that was not seriously flawed under the surface. "I would say there is nothing more irretrievably broken than the outpatient prospective payment system," he warns. ■

Stark case

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The government had intervened in a *qui tam* case that had been brought under the False Claims Act, alleging that McLaren had entered into an improper arrangement to rent space from a company owned by several physicians.

According to the complaint, false claims were submitted because McLaren was paying the physicians an excessive amount of rent to compensate physicians for referrals to McLaren in violation of the Stark law and the anti-kickback statute.

The court dismissed the case with an opinion that is notable for several reasons, according to Baumann. "First, the court took a very pragmatic approach, focusing on whether the remuneration

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at issue constituted 'fair-market value' payments for the space being leased, rather than undertaking a broader, legal analysis," she says.

In addition, Baumann says the methodology the court used to determine what constituted fair market value should provide helpful guidance to parties attempting to structure their relationships in compliance with the federal fraud and abuse laws.

Finally, Baumann says the case demonstrates the importance of reviewing the government's allegations and documentation very carefully. "McLaren is yet another example of a case where providers have prevailed by challenging the deficiencies in the data presented by the government," she argues.

In recent months, Centers for Medicare & Medicaid Services Administrator Tom Scully repeatedly has promised modifications to Stark. Earlier this month, he responded to an inquiry by the Chicago-based American Hospital Association (AHA) that addressed several outstanding questions. One area AHA asked for guidance on was a provision that says hospitals can pay physicians for things unrelated to the provision of designated health services.

Scully's letter says that hospitals may base their activities on "any reasonable interpretation" of the statute. But **Craig Holden**, a health care attorney with Ober Kaler in Baltimore, says it is unclear if that means anything a hospital pays is acceptable. "Does it mean that, since a hospital provides nothing but designated health services, nothing is protected?" he asks. ■

HHS updates timetable for components of HIPAA

The recent extension for the transaction and code sets required by the Health Insurance Portability and Accountability Act (HIPAA) is just one change health care providers must be aware of, says Department of Health and Human Services (HHS) undersecretary **Donna Eden**.

For starters, the first set of modifications and changes to the original transactions rule, which were developed with substantial of input from affected providers, suppliers, and health plans, now are sitting at the Office of Management and Budget waiting for clearance, she says.

The proposed changes can be viewed at the HHS web site, www.hhs.gov, she adds. "There are no secrets, no surprises, no standard rule making," says Eden. "These are all responses to requests from the industry." She says time timeframe for release is "very soon."

In addition, Eden says there is finally movement in other areas as well. "It is very hard to finish construction of a new system if you only have the blueprint for parts of it," Eden concedes. "We are trying very hard to get these next pieces out the door."

The National Provider Identifier should be available very soon, she says. That will be a final rule to give the criterion the standards to replace the current multiple sets of identifiers. "We have seven sets of institutional numbering systems, which will be collapsed to one uniform set."

The employer identifier, which Eden says has not been the subject of any controversy since it originally was proposed in 1998, also is close to completion. "That is nothing more or less than the tax employer identifier number," she says.

The security portion has gone through several rounds of revision in order to make sure that it comports with the new privacy rules as well the proposed changes to privacy, says Eden. She offered no specific timeframe, however.

The electronic signature is on hold because Congress has, in the intervening time from enacting HIPAA, enacted two subsequent electronic signature pieces of legislation that must be reconciled, says Eden.

In addition, she says the health care industry has been telling HHS that there is not yet an industry standard ready for adoption. "There are several major electronic signature standards available," she explains.

"But they don't talk to each other, and the interoperability issues have not yet been satisfactorily resolved to the level where a national standard can be promulgated."

"Don't hold your breath looking for a national electronic signature standard until some of those issues have been resolved by the standard-setting organizations that are working on this issue," adds Eden. ■