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One-day stay investigation may herald next federal initiative

Federal health care investigators also continue work on pneumonia upcoding, PATH initiatives

Health care attorneys say an ongoing investigation by the U.S. Department of Justice into one-day stays at numerous New Jersey hospitals is showing signs of becoming the government's next major national initiative in health care fraud enforcement. The government is attempting to identify patients who are admitted and discharged the same day, yet are billed as inpatients, they say.

"The government will get a printout that identifies all of the individuals admitted and discharged on the same day and send that out to various hospitals to say these were inappropriately billed as inpatients," says **Robert Salcido**, a former trial attorney with the civil division of the U.S. Department of Justice.

"The theory is that those people should have been billed as outpatients because they did not stay overnight," says Salcido, now a partner with Akin Gump in Washington, DC.

Based on the government's pattern of taking an investigation in one locality and spreading it across the country, he says this could turn out to be the next national initiative. If that happens, it would be consistent with the Department of Health and Human Services' Office of Inspector General's Work Plan for FY 2002, which focuses heavily in

*See **One-day stays**, page 2*

How to guard against kickback charges

Kickback suits against hospitals are on the rise. Unfortunately, there are no bright lines in this area, and it is very difficult for compliance officers to get that through to their staff, warns health care attorney **Donna Thiel** of Morgan Lewis in Washington, DC. "They have to rely on inferences that are raised based on money or benefit," she says. "That has to be justified on a rational basis that isn't just the volume or value of referrals."

According to Thiel, compliance officers should begin by educating their staff about the basics of the anti-kickback statute. She says compliance officers then can use a four-part analysis that looks at

*See **Kickback defense**, page 3*

Circuits limit scope of FCA in quality-of-care cases

Two recent circuit court decisions may stem the growing effort to use the False Claims Act (FCA) as a weapon in quality-of-care cases. Just before Christmas, the Second Circuit Court of Appeals issued a lengthy opinion that severely limits any quality-of-care case that can be brought under the False Claims Act by the government or a *qui tam* relator. That follows a similar ruling by the Sixth Circuit Court of Appeals that the FCA does not apply to "those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions."

"This is very important," says FCA expert **John Boese**. The Second Circuit, which Boese says may be the second most influential circuit court in the country, rendered its decision in the face of staunch opposition by the U.S. Department of Justice (DOJ) and several private parties that filed briefs with the court.

*See **FCA cases**, page 2*

One-day stays

Continued from page 1

the area of patient transfers and discharges.

Even as these new investigations emerge, the government still is working on several existing national initiatives, such as pneumonia upcoding and physicians at teaching hospitals, better known as PATH. According to **Dan Anderson**, an attorney in the civil division at the U.S. Department of Justice, the government still is working on roughly 90 pneumonia upcoding cases nationwide.

Anderson says there have been roughly 25 successful prosecutions to date, mostly in the form of settlements. The common theme in all these cases is the existence of a system that is designed to guarantee the enhancement of revenue rather then the accuracy of codes, he says.

"That is not the end of the investigation by any stretch of the imagination," says Anderson. But he says successful cases tend to share common themes, such as coders with bonuses based on their enhancing revenue, penalties for coders who complain about coding procedures, and instructions to coders that fly in the face of established coding rules.

According to Salcido, the most fruitful tactic for hospitals targeted by these investigations is to hire a clinician and determine their error rate, then look at the hospital's specific circumstances to determine why a particular code was used. Hospitals then can use that to make a presentation to the Department of Justice that, even if there is an overpayment issue, there is no False Claims Act issue.

Negligence alone cannot create False Claims Act liability, Salcido notes. If the error rate is low, the argument can be made that at worst the conduct was negligent rather than reckless.

Salcido says another defense is the so-called "government-knowledge defense." When there is a continuing dialogue with the government regarding a particular practice, it is difficult for the government to come back and say that it was deceived. "If there is a dialogue taking place with the fiscal intermediary or peer-review organization, that makes the government's case much more difficult," he explains.

A third defense is that the regulatory guidance is inherently ambiguous or that the party acted with a reasonable interpretation. "In the pneumonia context or DRG creep, you must look at the underlying regulatory guidance and instructions related to those codes and ascertain whether you were appropriately coding," he says. ■

FCA cases

Continued from page 1

In making its decision, the Second Circuit joined four other circuits in limiting FCA enforcement of regulatory violations. "The Second Circuit is now actually the sixth appellate court to reach this holding," says Boese, of the law firm Fried Frank in Washington, DC.

In the Sixth Circuit, the court affirmed a district court decision granting summary judgment to FCA defendants who were alleged to have billed the Medicare program for medical tests on equipment that was not properly calibrated. The district court had ruled that a "claim" submitted to the government for services that did not meet a particular standard of care did not make the claim "false or fraudulent" under the FCA.

Quality-of-care issues have been rising on the government's radar screen ever since the Health and Human Services' Office of Inspector General (OIG) included this area in its compliance guidance for nursing homes two years ago. Since that time, the U.S. Attorneys office in Philadelphia has

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successfully prosecuted several quality-of-care cases against nursing homes.

Dan Anderson, an attorney in the civil division at the DOJ, says the DOJ has tried to be very careful in its use of the FCA in this area. "We are not alleging medical malpractice," he says. "I don't think any DOJ lawyer thinks we are in business to say that other doctors would have done it differently or other providers would have done it differently."

Rather, he says, the department has sought to establish a minimum threshold under which no provider should fall and still be reimbursed for those services.

"Nursing homes are not out of the woods yet," says health care attorney **Marie Infante** of Mintz Levin in Washington, DC. These decisions make the court's position more explicit, she says. But if services are so substandard that it can effectively be argued that no services were provided at all, these decisions may not offer protection.

Infante adds that the decisions likely will have a more direct impact on Medicare Part B services than on Medicare Part A, which includes nursing homes, where it still will be possible to make the so-called failure of care argument.

Anderson says the FCA isn't the only enforcement tool being used in this area. He reports that the DOJ has established a loose working group that has brought together the OIG, U.S. Attorneys, nursing home ombudsmen, and state enforcement officials to address quality-of-care issues in nursing homes and devise ways to address the problem.

The FCA remains the biggest tool in the DOJ's chest, and it is not likely to lay down that weapon based on those decisions alone, Infante says. She also points out that the OIG's Work Plan makes it clear that the government is moving ahead with its agenda in the area of quality of care beyond just nursing homes. In effect, she says, DOJ and the OIG often are letting the state Medicaid Fraud Units act as fact finders.

"Most states have certain state law analogues," she says. In the area of long-term care, that can be the False Claims Act, but more likely is related to criminal charges associated with elder abuse or neglect. ■

Kickback defense

Continued from page 1

referrals of Medicare-covered goods or services, remuneration (either direct or indirect, in cash or in kind), intent to induce referrals, and safe harbors.

In analyzing referrals, Thiel says it is important for staff to understand that not only physicians, but hospitals, home health agencies, and others can make referrals. "They should also know that the statute prohibits not only direct referrals but payments to anyone who will recommend the leasing, purchasing, or ordering of any goods, facility, item, or service," she says.

Former Assistant U.S. Attorney **Michael Kendall** of McDermott Will in Boston argues that the safest route to guarding against kickback charges is simply to discount the price of the product or service and record this on the invoice. "If you can just get the best, lowest price for the product at issue, it is a far better way to do it," he says. If that route isn't taken, he says, the details of all agreements must be scrutinized closely.

For example, one case was brought against a company offering free phlebotomists to urology offices to perform certain tests. If the company is drawing blood and the physician is not getting the $5 charge for the blood draw, the government may not be alarmed, says Kendall. But if the physician is billing for the blood draw and an outside lab company is supplying the employee to perform the service, that will catch the government's attention, he warns.

Likewise, if the outside company is taking weights and temperatures and helping to prepare the patient for the exam, that also is likely to draw attention, he says.

Analyzing remuneration is extremely difficult, warns Kendall. On its face, he says, remuneration is merely anything of value that is given in order to illegally influence a decision. "It's a bribe," he says. "You pay somebody to do something they should not do. That is fairly straightforward." But many deals are far more nuanced, he cautions.

Kendall says that when looking at remuneration, it is important to determine who is getting the benefit. "If it is going to a person for personal use and to influence a purchasing decision, it is almost certainly illegal, unless it is of *de minimus*

value," he warns.

Then there is the issue of indirect payments, which virtually always go to the health care institution. "Indirect payments are a huge problem," he warns. "The government has scratched the surface in some areas, and in other areas, it has no idea what is going on."

Indirect payments are the most subtle and complicated issues for kickback analysis, Kendall says. For example, if a hospital is renting space to a physician practice, determining whether the practice is paying fair-market value isn't easy.

"There is no perfect answer," says Kendall. "But there are good-faith responses." If providers document what they are doing and there is sound business analysis and it is not trying to influence a referral, he says it probably can be justified.

Likewise, there is no general rule to follow where "free goods" are concerned. For example, free stands sometimes are given along with IV solution. But that may simply represent a discount off the price of the bags that could be accounted for on the invoice.

Kendall says hospitals must scrutinize all these areas, even though that means wrestling with both the business and the medical side of the organization. But physicians may not want to give up free services, especially if their own budget will not reflect a straight discount, he warns.

"That is a huge problem for compliance officers," says Kendall. "You simply say, 'Take $100 off the price of the good,' but that does not benefit the individual doctor who made the purchasing decision, who may want the free chair or exam table instead."

Here are some of the other questions compliance officers must confront:

- **Can a small gift or premium result in liability for kickbacks?** According to Kendall, there is both a legal and a practical answer to this question. For example, pharmaceutical companies may offer a free meal at a hospital. But even a small gift that is *de minimus* may create an appearance problem regardless of its value. "The real issue is intent," says Kendall.
- **How do you decide what is acceptable?** Compliance officers probably should have legal counsel to make this decision because of the complexity of safe harbors and other considerations.

"Begin with common-sense items," he says. "Anything that goes to you personally is obviously suspect, and anything that is hidden is very suspect." For example, if a group-purchasing organization (GPO) tells a client they want two fees — the typical 3% GPO fee for anything the hospital buys as well as a 2% marketing fee on top of the 3%, the government may say it is a problem if the GPO does not disclose both fees to its members.

Kendall says he finds hidden marketing fees, hidden charges, and hidden costs that are disguised in the paperwork. "I always tell clients, 'You are not a criminal, so don't act like one,'" he says. "If what you are doing can not be openly disclosed to the payer or the participants, then there could be a real problem."

- **Are holiday parties an inducement for referrals?** Again, there is no simple answer here. Sponsoring a hole at a golf course is one thing, but if an ambulance company spends $10,000 on the party, that's another matter.

"Maybe you can accept it, but it is a question of how you handle it," he explains. If a pharmaceutical company wants to give the hospital a holiday party, that may not be a problem as long as it goes on the cost report as well as the invoices of the purchases from the drug company. ■

Allina settles false claims case for $16 million

Allina Health System will pay the government $16 million to resolve allegations that the Minneapolis-based company overbilled Medicare, Medicaid, and TRICARE/CHAMPUS, the U.S. Justice Department announced Jan. 15.

The settlement resolves the government's contention that between 1994 and 2001, Allina's hospitals and clinics used a variety of improper billing methods, such as duplicate billing and upcoding.

The settlement also resolves three *qui tam* suits that alleged Allina knowingly retained overpayments even after the company's own audits demonstrated that it had submitted erroneous claims. Although Allina repaid the specific claims identified as erroneous in the audits, the suits alleged that it did nothing to ensure that other false claims were repaid. ■