In the first settlement of a national investigation, HealthEast Care System agreed in May to pay the federal government $2.28 million to settle allegations that 3 of its hospitals overbilled Medicare for kyphoplasties.

Some 100 hospitals are under investigation, according to the legal expert who represented HealthEast. The investigation is being led by the US Attorney for the Western District of New York in Buffalo.

The settlement involves kyphoplasties performed from 2002 through 2007 at St Paul, Minnesota-based HealthEast’s St Joseph’s Hospital, St John’s Hospital, and Woodwinds Hospital.

The investigation stems from a whistleblower lawsuit filed in 2006 by 2 former employees of Kyphon, Inc, the company that developed balloon kyphoplasty.

Kyphoplasty, a treatment for spinal fractures caused by osteoporosis or cancer, involves using a balloon catheter to create a cavity in the fractured bone and filling the cavity with bone cement.

The suit alleged that Kyphon conducted a fraudulent marketing campaign that induced hospitals to bill Medicare for kyphoplasty as an inpatient procedure even though the procedure can be performed safely as an outpatient procedure.

“By keeping patients overnight, hospitals could seek greater reimbursement from Medicare and make much larger profits on kyphoplasty,” said Kathleen Mehltretter, acting US Attorney in Buffalo.

HealthEast says it “cooperated fully” with the investigation, and no penalties are involved.

In 2008, the government reached a $75 million settlement with Medtronic Spine LLC, which acquired Kyphon in 2007. The company did not admit wrongdoing.

Whistleblower allegations
The whistleblowers’ original complaint, filed against Kyphon and a Buffalo hospital and recently unsealed, alleged Kyphon started in 1999 to develop a marketing scheme “to exploit high reimbursement under inpatient DRGs to persuade hospitals to perform kyphoplasty.”

Kyphon was highly profitable, according to the court filings, with the profit margin on its products ranging from 87% to 92%.

DRGs that Kyphon recommended paid hospitals about $6,000 to $10,000 depending on the area of the country. That compared with outpatient reimbursement of about $2,000 in 2005, according to the court filing.

Billings for unnecessary inpatient admissions are considered false claims, which are illegal under the federal False Claims Act (sidebar).

Among allegations are that Kyphon representatives met with coders and
medical record departments to explain how to code and bill the charges to ensure payment under the DRGs.

Court documents also say sales reps would be present in the OR during kyphoplasty and were taught to ask the OR nurses whether the patient had been admitted for an inpatient stay. If not, the sales rep allegedly would arrange for the physician to sign orders for inpatient admission in the OR.

Also part of the allegedly fraudulent scheme was to market an instrument for performing bone biopsies during kyphoplasties. The company, according to the whistleblower suit, advised physicians they had to perform bone biopsies on every patient regardless of medical history or condition.

**Only the beginning**

The HealthEast settlement is only the beginning, says Ronald H. Clark, PhD, JD, the legal consultant who represented HealthEast and an expert on the False Claims Act.

“Basically, every hospital performing kyphoplasty could potentially be a subject of this investigation,” he says.

He says HealthEast ran into problems despite having what he calls “the best compliance plan I have ever seen in a hospital. This shows you no compliance plan will catch everything.”

The settlement holds lessons for hospitals and OR leaders, not only on billing for kyphoplasty but for any new technology introduced in a hospital.

The immediate lesson—if the US Attorney comes calling, cooperate, Clark advises. Kyphoplasty billing problems are easy to uncover, says Clark, who was formerly a senior counsel in the Civil Fraud Division of the US Department of Justice. Investigators can simply run a computer report on a hospital’s claims. If most kyphoplasties come up as inpatient, that’s a red flag.

He says HealthEast came out reasonably well because it cooperated fully with the US Attorney.

Clark outlines the approach hospitals should take in his blog at http://fcaexpert.blogspot.com/2009/02/new-national-kyphonplasty-enforcement.html

For those who don’t cooperate, he says penalties can be much more severe. The government can assess $5,500 to $11,000 per each piece of paper associated with a false claim plus treble damages.

**Best defense**

Clark says a hospital’s best defense is to invest in a “top-notch compliance plan.

“Have your plan reviewed. Make sure it is effective, supported with adequate resources and that you have a good compliance officer,” he advises managers.

The settlement holds other lessons. Be sure the hospital has a policy stating that contact between employees and outside vendors and independent physician groups must be authorized, he advises. Compliance officers need to be aware of whom employees have contact with because under the law, the hospital will be treated as though it was fully aware of what was going on.

Also, though nothing precludes a salesperson from being in the OR to make sure a device is used correctly, “the danger is that in many hospitals in which kyphoplasty was performed, sales personnel were giving billing
advice,” he says. “That can work its way into becoming a billing rule, and that becomes a problem.”

Another lesson: Include the compliance officer in the product evaluation process to make sure procedures involving new products are billed appropriately.

**Educate employees**

Employees and managers need to be educated about the compliance plan, Clark adds. They should know who the compliance officer is and feel comfortable going to the officer with any concerns. Employees who feel comfortable reporting concerns and know their concerns will be addressed are less likely to consider filing a whistleblower suit.

One way he judges if a hospital has a good compliance plan is to ask any employee, “Who’s your compliance officer?” If he gets a blank stare, he knows something is lacking.

Every employee should have easy access to pertinent parts of the compliance plan. Two ideas are to provide color-coded notebooks or post information about the plan on the hospital’s intranet.

“The consequences of not being proactive for hospital management are severe,” he says. “It can mean huge amounts of money, affect your Medicare eligibility, and if you have a building project, it can affect any bonds that require approval from HHS.”

*Ronald Clark’s website is at http://fcaexpert.com*

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**What is the False Claims Act?**

The False Claims Act and its amendments create incentives for people who know about fraud against government programs like Medicare to disclose the information by filing a whistleblower (*qui tam*) lawsuit.

Some specifics:

- Anyone who presents or causes to be presented false or fraudulent claims to the US government or makes false statements to induce the government to pay false claims is liable for a civil penalty of $5,500 to $11,000 for each claim, plus 3 times the amount of damages the government sustains.
- Anyone having information about false claims can bring an action for herself or himself and the government and share in any recovery, receiving 15% to 30% of the total amount recovered.
- The act provides protections for whistleblowers.