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Government says number of *qui tam* relators is ebbing

Health care attorneys say whistle-blowers are losing ground

Make no mistake, the False Claims Act still is the 800-pound gorilla of health care anti-fraud efforts. Judgements and settlements in health care fraud cases exceeded $1.2 billion in 2001 and amount to more than $850 million so far this year.

Nevertheless, the number of *qui tam* relators is dwindling steadily, and some in the health care community maintain whistle-blowers actually are losing ground.

"While the number of annual *qui tam* filings remains significant, we are seeing a plateau in the number filed each year," says **Robert McCallum**, assistant attorney general in the civil division of the U.S. Department of Justice (DOJ).

He says the boom in the filing of new *qui tam* cases peaked in the late 1990s and continues to taper off.

In fact, the total number has declined steadily from a high of 533 in 1997 to 300 last year, which may reflect the impact of compliance programs, he adds.

"I don't really know how to explain the downturn," McCallum recently told a joint American Health Lawyers Association/Health Care Compliance Association conference in Washington, DC.

He points out that many of the cases filed last

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CMS targets nursing home quality

Nursing home enforcement remains "an enormous issue," Centers for Medicare & Medicaid Services (CMS) Administrator **Tom Scully** warned health care providers earlier this month. He added that quality of nursing homes is now one of the agency's highest priorities. The U.S. Department of Health and Human Services' Office of Inspector General (OIG) listed nursing homes as one its top priorities in its Work Plan for FY 2003.

As a result of collaboration among federal agencies, Scully says several major cases are "close to resolution." However, several veteran health care attorneys say CMS is mixing apples

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Six keys to successful investigative interviews

Internal compliance investigations often begin with interviews. In this case, the first step may be the most difficult component of an internal investigation strategy to master, warns **Steven Ortquist**, chief compliance officer at Banner Health System in Phoenix. "The investigative interview is as much art as it is science," he says.

Here are six interviewing techniques that Ortquist says will allow even a novice compliance investigator to conduct an effective compliance investigation interview:

I. Two are better than one. As a general rule, Ortquist says it makes sense to conduct investigative interviews in tandem. For one thing, a second set of ears provides the interviewer with a witness to what is said in the interview and significantly reduces the ability of the interviewee to change his or her story at a later time, he says.

As witnesses and subjects of an investigation begin to understand the significance of the

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Qui tam relators

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year still are under investigation and says it is too early to determine whether the decline indicates greater care by relators' counsel in choosing which cases to bring.

If that is the case, McCallum says this could result in the government's intervention in a higher percentage of cases. He notes that while the government has intervened in roughly 20% of cases, very few of the 80% that are declined produce large settlements.

"The vast majority yield modest or no recoveries at all," says McCallum, "and the merits of many of those declined cases has been questionable."

Health care attorney **Karen Guarino** of King and Spaulding in Atlanta contends that whistleblowers are, in fact, losing ground. She says the fact that the government is moving to more creative theories to bring False Claims Act cases supports what she has heard from FBI agents and DOJ that the "low-hanging fruit" has all been picked.

"The obvious fraud cases have been brought," asserts Guarino. "The very high-dollar cases have been settled." She says the cases she now sees come down to either very sophisticated fraud theories or "meritless cases brought by opportunistic whistle-blowers apparently viewing the False Claims Act as a lottery game."

"Not only has the low-hanging fruit been picked," argues health care fraud and abuse attorney **Robert Griffith** of Boston, "the next level of fruit is more than likely beyond the grasp of the False Claims statute. Most of the statutes addressing health care fraud and abuse do not reach the alleged fruit in the top branches."

Griffith says the government's efforts to eliminate waste should focus on a full review of existing policies with an eye toward increasing the clarity of existing regulatory language.

"For too long, the government has been a shepherd of the Medicare flock who left all the work to the sheep dogs or carriers," he maintains. "It is time for the government to examine its own complicity in a system that is more rampant with waste and lack of oversight than actual fraud," he adds. "*Qui tam* relators cannot help in that arena."

McCallum agrees that the government is witnessing an increasing complexity in the types of cases filed. For example, he says the government is deeply involved in complex areas including cost report fraud, drug pricing issues, and Medicare carrier fraud.

"We continue to investigate pharmaceutical companies for violations of the Medicare rebate statute," he reports. "We are also dedicated to pursuing allegations of fraud by the Medicare program's carriers and fiscal intermediaries that contract with HHS to process and audit Medicare claims."

McCallum says DOJ is fully also committed to working with HHS on failure of care cases, especially those that result in death or injury of nursing home patients. **(See related story, page 1.)**

According to McCallum, the bottom line is that the information received from *qui tam* relators is critical to rooting out fraud. He says their unique position often makes them an invaluable resource. As the government addresses more complex fraud theories, this is certain to continue, he maintains.

"The False Claims Act is still the 800-pound gorilla, but it is climbing down out of the tree more selectively," says *qui tam* attorney **Mark Kleiman** in Los Angeles.

"There are a number of [U.S. Attorneys] offices that have upfront economic criteria," he explains. "They are not going to look at a case where you don't have a fairly significant amount of single damages." ■

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Investigative interviews

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investigation, Ortquist says their willingness to disclose what they know may diminish. "Sometimes their recollections of what occurred are even altered by fear of the coming outcome of the investigation," he adds.

According to Ortquist, a second set of ears also assures a more comprehensive grasp of what the interviewee says, because interviewers often hear and focus on different things. Finally, he points out that a second interviewer who mainly is an observer will be able to focus more fully on answers to questions and may be able to take more comprehensive notes.

II. Put interviewees at ease. Being called into an investigative interview by the compliance officer rarely is a welcome process. Ortquist says this is especially true for lower-level employees who may have less trust in the protections that exist for those who disclose the improprieties of other employees.

According to Ortquist, investigators may be able to put the interviewee at ease by first discussing your organization's nonretaliation policy and answering any questions about the policy or its operations. It also may help to relieve some anxiety by taking a few minutes up front to talk about something other than the problem at hand, he adds.

III. Ask open-ended questions. When conducting an investigative interview, Ortquist says it is important to ask questions that will draw the interviewee out.

Often when interviewees are encouraged to reflect on what they know about a situation, the investigators will learn new and unexpected facts that may assist in the investigation, he explains.

Ortquist says investigators should avoid questions that require only yes/no answers, or questions that appear to lead a person to a particular answer.

For example, he says "describe the billing process in your department, focusing on places where you believe there is a lack of controls" is more likely to provide information useful to the investigation than is the question, "are you comfortable with the controls built into the billing process in your department?"

IV. Ask specific questions to develop problems the interviewee identifies. When the interview identifies a weakness or problem that needs further development, interviewers should ask more focused questions, Ortquist suggests. "It will often happen that an interviewee will make assumptions about what you know," he explains.

To avoid that, he says investigators should encourage them to explain a situation fully, as if they were explaining it to someone who had no knowledge of health care or the particular facts and circumstances involved in an alleged violation.

V. Allow people to answer fully. Just as it is possible for interviewees to assume that an interviewer understands certain aspects of a problem, interviewers can find themselves making the same assumptions, warns Ortquist.

"The investigative interview is not about what you know or assume you know about the operations of a particular area or the character of people who may be subjects of the investigation," he asserts. "It is not about what you have seen in your review of documentary evidence or heard from other interviewees in the investigation."

Rather, he says it is about finding out what the interviewee knows about the facts and circumstances that may be involved in the suspected impropriety. "Allow people to answer your questions fully," he says. "Don't allow discomfort with silence while the interviewee considers his answer to cut short the answer that may be about to emerge."

VI. Take thorough notes — don't rely on your memory. According to Ortquist, the significance of something said in a compliance investigative interview may not immediately be obvious.

"Take thorough notes of your conversations with interviewees," he says. "Write things down even if they don't make sense at the time that they are said.

"Your memory may fade, and you may become confused about who said what, as one interview turns into several with other subjects or witnesses," Ortquist adds. "The more complete your notes of the conversations, the more correct will be your conclusions when the investigation nears its end." ■

Nursing home quality

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and oranges by tying its quality and enforcement efforts too closely.

In the past few years, Scully says CMS has imposed more than 13,000 remedies on non-compliant nursing homes, including more than 6,000 civil monetary penalties, he told the joint American Health Lawyers Association/Health Care Compliance Association conference in Washington, DC.

He added that setting standards and measuring those standards against what is needed to improve quality of care in nursing homes is one of the agency's major initiatives.

Health care attorney **Joe Bianculli** in Arlington, VA, says there is no question CMS and the OIG have a legitimate role to play in enforcing nursing home compliance and quality, but he questions their approach.

"It would be useful for CMS and the OIG to get on the same page," argues Bianculli. In the last several years, he says they have taken different approaches to both compliance and quality. "CMS is tied down with an incredibly bureaucratic, incredibly coercive, incredibly penalty-oriented enforcement process," he asserts. "In my view, if it has any connection with quality at all, that connection is purely coincidental."

Bianculli contends the OIG has taken a much more useful approach by defining what it considers to be the most significant indicators of quality and correlating those indicators directly with resident outcomes at specific facilities. He credits that approach with the size of the OIG's settlements in this area, because in most instances he says the cases brought by the OIG are beyond dispute.

CMS is another story, according to Bianculli. "There is really no philosophical or theoretical underpinning for CMS' enforcement activity, other than simple punishment," he asserts. "The agency persists in the notion that retrospective punishment is likely to promote quality."

According to Bianculli, CMS often takes a statement of deficiencies from a variety of surveyors of "wildly different" skills and training and imposes penalties based only on that paper record. "CMS does very few surveys itself," he says. "There is very little firsthand information about what is actually going on in facilities." As a result, he says the hearing process frequently is jammed with appeals of surveys that facilities believe are not well founded.

Marie Infante of the Washington, DC, office of Mintz Levin, takes a similar view. She says CMS is mistakenly looking at the problems of enforcement and quality as "parallel tracks." While CMS' publication of quality information is a positive step, she says the agency's own enforcement efforts are driving things exactly in the other direction.

"The adversarial and arbitrary survey process is a contributor to driving good staff away and having good facilities drop their participation in the Medicare and Medicaid programs," she argues.

Infante contends that a more logical approach to addressing significantly deficient practices would be to take the money and reinvest it back in the facility in areas that directly benefit residents and staff and can be directly monitored. ■

DOJ settles seven cardiac *qui tam* suits

The U.S. Department of Justice (DOJ) announced Oct. 17 that it settled for a total of more than $5.4 million with seven hospitals alleged to have improperly billed Medicare for medical procedures involving experimental cardiac devices, bringing to more than $40 million the total settlements collected in the nationwide cardiac devices false-claims litigation.

DOJ also announced that the government has intervened and filed complaints against four other hospital defendants.

The suits allege that between 1986 and 1995, the hospitals unlawfully charged federal health care programs for medical procedures using experimental cardiac devices that had not been proven safe and effective by the Food and Drug Administration in violation of the False Claims Act.

The case originally was brought by whistleblower Kevin Cosens, a former medical device salesman, against more than 100 hospital defendants. Cosens will receive more than $1 million of the latest settlements. ■