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New administration pledges zealous enforcement of FCA

Health care providers' pleas for relaxation of Stark II and HIPAA privacy rules may go unanswered

Health care providers hoping for a reprieve in the enforcement of the False Claims Act (FCA) under the Bush administration shouldn't hold their breath. In fact, newly appointed U.S. Attorney General John Ashcroft already has pledged vigorous FCA protection at the same time that as many as a dozen states are now testing their own recently passed FCA statutes.

Former Department of Justice (DOJ) attorney and FCA expert **John Boese** of Fried, Frank in Washington, DC, says that what effect the incoming Bush administration would have on FCA enforcement efforts may already have been answered.

In a Jan. 31 letter, Ashcroft told Sen. Charles Grassley (R-IA), author of the 1986 amendments that resurrected the Act, that he plans not only vigorous enforcement of the FCA, but active defense of its constitutionality and opposition to any efforts to weaken it.

Under the Clinton administration, DOJ became an avid and vocal advocate of *qui tam* constitutionality, notes Boese. In fact, Assistant U.S. Attorney General David Ogden personally argued in the Fifth Circuit on the constitutionality of the statute.

Health care attorney **William Saraille** of the Washington, DC-based Arent Fox agrees that the DOJ is by and large extremely supportive of whistle-blowers and the whistle-blower provi-

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HCFA bid to clarify EMTALA stymied by regulatory freeze

A tightly held regulation clarifying important portions of the Emergency Medical Treatment and Active Labor Act (EMTALA) was expected to be published in the *Federal Register* last month, but was pulled at the last minute. The proposed rule already had cleared the Office of Management and Budget but fell victim to the Bush administration's 60-day freeze on all new regulations.

"There are differing opinions on how EMTALA applies, and the rule was intended to provide greater consistency," reports **Ellen Griffith**, a spokeswoman with the Health Care Financing

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State false claims statutes begin to claim victims

Two employees of Orange, CA-based Bergen Brunswig Corp. who reported the company was allegedly recycling and reselling pills will receive $750,000 as their cut of a $4 million payment made by Bergen to the state of Hawaii last month. The case marks the first settlement under the Hawaii False Claims Act (FCA), but **Thomas Grandy**, an attorney for the whistle-blowers, predicts it won't be the last.

In fact, Grandy, of Davis Levin in Honolulu, forecasts that similar suits filed under state FCA statutes in at least a dozen other states are likely to grow exponentially in the next few years. The Hawaii FCA statute was passed by the Hawaii state legislature last year.

The two women who filed suit were pharmacy technicians. "They were told to reuse old drugs — take blister packs of drugs that were returned, remove the drugs, and then repackage them," Grandy says.

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sions simply because they bring cases. "More and more, we are seeing the health care agenda set not so much by DOJ, but by the whistle-blowers that come to DOJ," he asserts. "That is a fundamental change in the landscape over the last two years."

On the brighter side, Saraille says that at least certain elements of the Bush administration may be somewhat more sympathetic to claims by providers that they have been misled by incorrect or missing guidance either by the Health Care Financing Administration (HCFA) or its contractors.

In fact, Saraille predicts that both the Bush administration and Congress will take a hard look at HCFA's management of both Medicare and Medicaid. "That criticism could draw attention to the administrative handling of certain issues that may give either OIG or DOJ some pause," he predicts. While that will not mean a sea of change in terms of the overall level of enforcement activity, it could have an impact in discreet areas where there are well-publicized complaints, he adds.

But the good news may stop there. Saraille says the Bush administration's recent 60-day freeze on new regulations issued under the Clinton administration is not likely to translate into further revisions of the final Stark II regulations released last month. In fact, he predicts only marginal changes, if any.

"HCFA saw the writing on the wall and decided to do itself what it would have been forced to do if it failed to take action," asserts Saraille. He says that silenced the outcry that marked the response to the proposed rules and probably avoided a reform bill from Congress. "That means that compensation arrangements will stay in the Stark law," he predicts.

The Health Care Portability and Accountability Act (HIPAA) of 1996 may be a different story, however. The American Hospital Association's executive vice president Rick Pollack urged the Department of Health and Human Services Secretary Tommy Thompson to reopen for comment certain portions of the new privacy rules that are scheduled to go into effect Feb. 26. "The cost and scheduled implementation date for the new privacy rules are overwhelming," Pollack asserted Jan. 31. "Adherence to that compliance schedule will be unattainable for many hospitals given the extensive changes in overall operations the new privacy rules will require and their high cost."

There is some question about whether or not the 60-day pause affects the HIPAA regulations because those regulations were passed pursuant to a congressional deadline. "Whether or not the 60-day hold applies in that context is an open question," says Saraille. ■

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Grandy says the Bergen case, settled last month, is the largest ever obtained in Hawaii by either the federal or state government. It was spearheaded by the Hawaii Medicaid Fraud Unit. Grandy expects to see that trend repeated in other states as well.

So does health care attorney **William Saraille** of Arent Fox in Washington, DC, who says that it is now much more common to find joint investigations between state and federal investigators. "There is a more significant, and in some cases, a leading role played by a state investigator or state Attorney General," he reports. As successful as the federal government has been with the FCA, there are many states that want to make their mark as well, he argues.

John Boese of Fried, Frank in Washington, DC says he expects state FCAs to become a significant, but not overwhelming issue. "I think more and more states are going to pass FCA statutes, and I think there is going to be more and more

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activity," he asserts. But state FCA statutes will never rival the impact of the federal FCA either in monetary terms or importance, he predicts.

"Even in a large state like California, you are still only dealing with one state," he explains. "The big numbers are with the nationwide companies where you have nationwide offices and alleged false

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Administration (HCFA). That leaves the complex proposed regulation in the hands of the White House for the time being, she says.

Steve Lipton, a health care attorney with Davis Wright in Seattle who specializes in this area, says there is no shortage of interpretations when it comes to EMTALA. "It is not uncommon to see the OIG [Office of Inspector General] take a position on EMTALA that seems to be at odds with HCFA."

The courts also have interpretations that are at odds with HCFA and the OIG, and on top of that, the courts often disagree among themselves, adds Lipton. For example, he notes that the First and the Sixth circuits have held that EMTALA applies to inpatient, while the Fourth and the Ninth have generally held that EMTALA does not apply to inpatient.

On top of all that, it is not uncommon to see differences of interpretation between the regional offices of HCFA or those offices and the courts. One recent EMTALA decision handed down by the Ninth Circuit Jan. 23 is a case in point. In that case, *Arrington vs. Wong,* an ambulance was en route to a hospital when the emergency physician told the ambulance to take the patient to another hospital. The patient died before the ambulance reached the hospital.

The patient's family sued under EMTALA, and the circuit court overturned a lower court ruling in favor of the plaintiffs. The court argued that it was following the Department of Health and Human Services' regulation that a hospital may divert an ambulance that has contacted its emergency room and is on its way to that hospital only if the hospital is in diversionary status.

"That is a bit of a stretch under EMTALA," asserts Lipton. He says the regulations make it quite clear that EMTALA does not apply unless the patient is on hospital property or in a hospital-owned ambulance. Health care attorney Lowell Brown of Foley & Lardner in Los Angeles goes even further. "This decision is out there in left field," he asserts.

Moreover, Brown reports that a representative from HCFA's Region IX office already has indicated that HCFA does not plan to follow the ruling. "For whatever reason, HCFA historically has ignored court decisions involving private plaintiff cases."

While that discounts the importance of the decision in terms of administrative sanction, it does nothing to diminish its importance from possible patient action against hospitals in that region. "It is still the law of the Ninth Circuit, which covers almost all the western states as well as Alaska and Hawaii," Lipton asserts.

According to Brown, most of the EMTALA case law now matters where private plaintiffs sue a hospital in federal court. "It is almost like a brand-new personal injury cause of action that the law has created," he explains. "Plaintiff lawyers are increasingly discovering it."

"It is a very strange situation," Brown asserts. "Even though HCFA is not going to go after hospitals, private plaintiffs can." That leaves hospitals without any clear guidance, he says.

An upcoming issue of Compliance Hotline *will offer advice on how to comply with EMTALA's growing threat under HCFA's hospital outpatient prospective payment regulation*. ■

GAO cites HIPAA problems, offers few solutions

The General Accounting Office (GAO) handed the Senate Committee on Health, Education, and Labor a 14-page report last week that sizes up the practical difficulties health care providers will face in implementing the privacy regulations required by the Health Care Portability and Accountability Act (HIPAA) of 1996. But while the report outlines many of the challenges providers face, it offers few prescriptions for solving them.

Aronovitz told the committee that most providers believe the Department of Health and Human Services (HHS) addressed many of their concerns in the final draft but still view the regulation as impractical. Even the flexibility offered in

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the final regulation is seen as creating more ambiguity, according to the GAO.

Chief among the complaints were the requirement to obtain patient consent or authorization prior to using or disclosing personal health information. Also high on the list of concerns is how regulated entities will apply the privacy provisions to their business associates and the fact that more stringent state requirements will continue to pre-empt the federal regulation.

The Chicago-based American Hospital Association recently lobbied HHS to reopen for comment certain portions of the new privacy rules that are scheduled to go into effect Feb. 26.

"The cost and scheduled implementation date for the new privacy rules are overwhelming," Pollack asserted Jan. 31. "Adherence to that compliance schedule will be unattainable for many hospitals, given the extensive changes in overall operations the new privacy rules will require and their high cost."

Those concerns did not fall on deaf ears. Sen. Pat Roberts (R-KS) has called the regulation impractical, but admitted he saw no simple remedies. ■

HCFA expands home health 'homebound' definition

The Health Care Financing Administration (HCFA) last week issued instructions to its fiscal intermediaries that clarify the definition of "homebound" under the Medicare home health benefit. But the revision, which is effective immediately, threatens to trip up home health agencies (HHAs) that don't carefully study the new changes, warns **Bill Dombi**, vice president of law at the National Association for Home Care in Washington, DC.

Under the revised policy, "an absence from the home related to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment, in an adult day program that is licensed or certified by the state or otherwise accredited" will not automatically disqualify a patient from being considered "confined to his home" and eligible for Medicare reimbursement.

Dombi says the policy requires further clarification from HCFA. "There are a number of issues HHAs and patients in adult day centers want to see addressed before they step into this area."

He notes that this policy revision changes only the portion of the homebound requirement that deals with absences from the home. "The patient still must demonstrate that it is a considerable and taxing effort to leave the home," he cautions.

From a compliance perspective, if HHAs have patients that have been referred to them who are going to an adult day center, they must first be careful not to deny Medicare coverage in the home setting, warns Dombi.

In addition, if HHAs try to use this change in policy as a method of expanding their market, they must be certain that the activities of the adult day center are part of the plan of care prescribed by the physician. There also must be a reasonable basis for claiming that those activities are either psychosocial or therapeutic.

Dombi says therapeutic and psychosocial necessity often are more difficult to qualify than medical necessity. That means HHAs must be certain they have some supporting documentation. "If they have that, their chances of having it covered are extremely high," he says. ■