THE NATIONAL LAW JOURNAL | IN FOCUS | MONDAY, DECEMBER 13, 2004

BUSINESS FRAUD

ALM

Voluntary disclosure catches on

For some employers, self-reporting of employee wrongs can lessen penalties.

By David Matyas
SPECIAL TO THE NATIONAL LAW JOURNAL

WHEN AN ORGANIZATION discovers that an employee may have engaged in improper actions, its officers and directors cannot just "look the other way." But is it enough merely to discipline those who engaged in the improprieties and ensure that these activities do not continue? Or should an organization take more aggressive action by informing government agencies of the misdeeds?

In fact, organizations that submit claims to the federal government have long recognized the potential benefits of self-disclosing to government agencies and government contractors certain kinds of information about potential improper conduct. In fact, the Federal Civil False Claims Act specifically says that voluntary disclosure of potential liability can merit a reduction of damages from treble to double. Moreover, in the amendments recently adopted by the

U.S. Sentencing Commission, the Federal Sentencing Guidelines now specifically states that organizations can decrease their culpability score by not only cooperating in an ongoing government investigation but also by self-reporting potential violations of law.

Nevertheless, as government enforcement actions against health care organizations have grown exponentially over the last two decades, when a health care organization identifies that it may have engaged in an activity that is a violation of law, one of the most significant decisions that it must make is whether to disclose this activity to the federal government through the Department of Health and Human Services' office of inspector general's (OIG) "Provider Self-Disclosure Protocol."

A discussion of that protocol begins with a consideration of the 1995 pilot voluntary disclosure program. In the 1990s, the OIG launched a major anti-fraud initiative called Operation Restore Trust that targeted irregularities among a number of key health care sectors (durable medical equipment providers, and providers of home health, hospice and nursing home care) in five states: California, Florida, Illinois, New York and Texas.

As part of that effort, the OIG in 1995 created a pilot voluntary disclosure program that allowed certain types of health care providers to come forward on their own to report fraudulent conduct affecting Medicare, Medicaid and other federal health care programs.

While it was a significant first effort, the pilot program had very narrow eligibility. In addition to being open only to corporate entities doing business in the four industries in the five states covered by the Operation Restore Trust initiative, an applicant was eligible for admission to the program only if it revealed a matter not already under investigation by—or known to—a federal or state law enforcement agency.

In addition to its limited eligibility qualifications, the program also carried a major disincentive: It greatly increased the legal exposure of entities entering the program by requiring them at the outset to sign an agreement to cooperate fully and openly with authorities.

The pilot program, as limited as it

David Matyas is a member of Epstein Becker & Green's health law practice, resident in the firm's Washington, D.C. office. Matyas (dmatyas@ebglaw.com) is co-author of Legal Issues in Health Care Fraud and Abuse: Navigating the Uncertainties *(American Health Lawyers Association 1997).*

was, furnished the OIG with a solid first step in formalizing the voluntary disclosure process and in gaining experience upon which to design a permanent program. While the stringent eligibility requirements of the pilot resulted in very little participation by the time the program ended in 1997, the government nonetheless credited it with providing the OIG with "valuable insight into the variables influencing the decision to make a disclosure to the Government." See OIG Provider Self Disclosure Protocol, 63 Fed. Reg. 58,399 (Oct. 30, 1998).

1998 expansions

Using what it had learned during the pilot program, the OIG in 1998 issued a new, expanded and simplified national program called the Provider Self-Disclosure Protocol that opened the plan to all health care providers doing business with federal health care programs, and removed or moderated disincentives that had discouraged participation in the pilot program.

In addition to extending eligibility to all health care providers—including individual providers—nationwide, the new program eliminated the old program's application process, predisclosure requirements, rigid time frames for reporting and other preliminary qualifying characteristics.

Voluntary reporting

The self-disclosure protocol is the linchpin of the OIG's efforts to make it easier—and substantially less forbidding—for providers voluntarily to disclose instances of potential fraud and abuse which may have given rise to corporate liability. The OIG has used the protocol to recast voluntary reporting as an indication of corporate health and integrity rather than as a sign of vulnerability, and has been quick to sell the potential benefits of self-reporting improprieties directly to health care providers by emphasizing corrective action rather than culpability.

To make its point, the OIG itself has said that the best evidence that a provider's compliance program is operating effectively is when the provider "identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities." See, e.g., June Gibbs Brown, An Open Letter to Health Care Providers, March 9, 2000 (available at oig.hhs.gov\fraud\docs.\openletters\ openletters.htm.)

Voluntary disclosure has great appeal to the government. The OIG is more than pleased when a party or entity performs an investigation at its own expense, helps to police itself and expedites identification and resolution of potential violations.

Provider exerts a measure of control.

For the discloser, one of the keys to the attractiveness of the voluntary disclosure process is that it presents the provider with the opportunity to exert a measure of control over the subsequent investigation of the matter in question. While this gives the provider a certain amount of flexibility, the provider should exercise caution and recognize that the OIG will not continue to work with a provider that attempts to subvert or circumvent the protocol.

To self-disclose, the entity notifies the OIG of the suspected violation, conducts an internal investigation and produces a report on the findings of the investigation. The self-disclosure protocol lays out standards and outlines the specific kinds of information the OIG expects to find in a voluntary disclosure.

At the initial stage of a disclosure, the process requires only the identification of a potential violation, provision of basic information and a certification that the submission is truthful and being made in a good-faith effort to aid the OIG. More detailed information will be collected during the later internal investigation.

The disclosing entity then conducts an internal investigation and, on completing it, submits to the OIG a report containing the results of that investigation. In a typical case, after the initial disclosure of the matter, the OIG agrees—for a reasonable time—to forgo its own investigation of the matter if the provider agrees to conduct its own review in accordance with the protocol.

The disclosing party's report must address two key issues: It must describe the "nature and extent" of the matter, and it must detail how the disclosing party discovered and responded to it.

To detail the nature and extent of the infraction to the satisfaction of the OIG, the discloser must examine the potential causes of the illegal practice, establish over what period the matter occurred, determine who was involved and affected, and identify possible risks to health, safety and quality of care. The "discovery and response" aspect of the report must document the matter dating from its discovery through the completion of the investigation.

The disclosing party also must estimate the monetary impact of the matter in question. That means that the party either must review all of the claims affected during the relevant time period, or—if the potential matter affects a very large number of claims—prepare a statistically valid sample of the claims that can be projected to all of those that are affected.

Once an entity completes its investigation and report and has provided the OIG with a completed self-disclosure submission, the OIG begins to verify the information

contained in it. Because the extent of the OIG's verification process depends heavily on the quality and thoroughness of the entity's internal investigation and reporting, it is important for the discloser to have done a complete and well-documented examination of the issue in question. The OIG also requires the entity to provide total access to any audit materials and other supporting documents "without the assertion of privileges or limitations on the information produced." See OIG Provider Self Disclosure Protocol, 63 Fed. Reg. 58,399 (Oct. 30, 1998).

Downsides

While the self-disclosure process is not exactly the equivalent of throwing oneself "upon the mercy of the court," the protocol does carry a number of potential risks. Not the least of these is the potential discovery of new information during the process that may be treated by the OIG as a new matter that is separate from the protocol and disclosure. Moreover, although the implication is that openness and honesty will merit better treatment from the government, the OIG does not guarantee that the provider will be protected against civil or criminal liability resulting from the disclosure.

There are a number of other potential drawbacks, as well. For example, an employee may learn about the matter as a result of the internal investigation and become a qui tam relator and provide testimony for the government—an option that became even more attractive after a 1986 amendment to the False Claims Act increased the whistleblower's share of any award.

Entities also must realize that anything less than full disclosure or disclosure based on inadequate or incomplete facts may be worse than no disclosure at all. A less than complete disclosure actually may damage a health care provider's credibility and increase suspicion at the OIG.

Additionally, although under normal circumstances the OIG will not request attorney-client communications or materials covered by the work-product doctrine, the risk does exist that materials developed as part of the discloser's internal investigation and government disclosure may no longer be privileged documents.

Risks and benefits

There are very substantial benefits to properly executed and submitted self-disclosure. Perhaps foremost is that self-disclosure allows a health care provider to choose and control the time, place and manner of disclosure—thus minimizing the cost and disruption incurred by a formal investigation. And significantly, by maintaining a higher degree of control over disclosure situations, voluntary disclosure also can lower the need for a health care provider to conduct extensive damage control in the wake of adverse publicity that would more likely result if an investigation were initiated by the OIG.

As mentioned above, an internal investigation always carries the risk of inspiring an employee to bring a qui tam action. But conversely, a party's voluntary disclosure to the government also may benefit the company by pre-empting an employee from initiating that action.

One of the OIG's primary goals in encouraging self-disclosure is to "promote a higher level of ethical and lawful conduct throughout the health care industry." By demonstrating an earnest attempt to exhibit that conduct through voluntary disclosure, a self-disclosing health care provider can gain early credibility with the OIG that may produce substantial benefits later in the process.

The government itself has acknowledged that it will make efforts when possible to reward a discloser's cooperation by granting it affirmative "credit" in the form of reduced fines and penalties—as well as possible avoidance of exclusion from federal health care programs.

But perhaps one of the greatest potential benefits of self-disclosure is that a health care provider—by demonstrating that it has established an effective corporate compliance program—may be able to alter drastically the conditions contained in any subsequent Corporate Integrity Agreement (CIA), and may be able o sidestep the imposition of a CIA altogether.

The OIG in 2001 confirmed that significant modifications in fact had been made to agreements with health care providers that had self-disclosed misconduct to the government. Those modifications included not only limiting the scope of a CIA through a shortened term or less onerous auditing requirements—but even forgoing the imposition of a CIA entirely.

Early success

As of March 31, the OIG had received more than 200 submissions under the self-disclosure protocol from a variety of health care providers including hospitals, home health agencies, laboratories and medical practices. Of these submissions, self-disclosure cases had resulted in 42 recoveries and 30 settlements, totaling more than $74 million.

Taken altogether, carefully considered and managed self-disclosure can be an extremely valuable legal tool in helping providers address matters of potential liability in their dealings with federal health care programs. The OIG Provider Self-Disclosure Protocol provides a relatively open methodology for pre-emptively tackling situations which, if left unaddressed, can later become increasingly complicated, expensive and problematic. NLJ