CCH Healthcare Compliance LETTER

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Letters to the Editor

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Bill introduced to STOHP final Privacy Rule

by Gordon R. Shea, J.D.

Representative Edward J. Markey (D.–Mass.) has introduced a bill in the United States House of Representatives to repeal the recently finalized version of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). The bill would take the Rule back to one of its earlier incarnations that was set to go into effect during the last days of the Clinton administration.

"No force or effect." Markey's bill – titled STOHP, an acronym for "Stop Taking Our Health Privacy" – would take "modifications made to" the Rule this August and deem that, in the two key areas of consent (for uses or disclosures to carry out treatment, payment or healthcare operations) and marketing, those modifications "shall have no force or effect."

If enacted, the Markey legislation would return the Privacy Rule to how the Rule stood when its December, 2000 changes were ready to take hold. The practical effect would be as follows:

Marketing. The STOHP Act would redefine (or, perhaps stated more properly, *re*-redefine) marketing as the making of a communication about a product or service when the purpose of such communication is to encourage recipients to purchase or use the product or service.

This definition would be subject to certain narrow exceptions for communications made verbally and communications made without connection to any remuneration from a third party. To use an example employed by the Department of Health and Human Services (HHS), these exceptions would mean that it would not be marketing for a pharmacy to call a patient about the need to refill a prescription, even if that refill reminder was subsidized by a third party. It would, however, be marketing if that same subsidized reminder was sent to a patient in the mail.

If a given communication was considered marketing, the covered entity making the communication would usually be required to obtain the recipient's authorization to use or disclose any protected health information related to it.

Consent. Many or most providers would be required under the STOHP Act to obtain patients' written consent prior to using or disclosing protected health information. Consent could, however, be done as a one-time, general permission from the individual, which the individual would have the right to revoke. Unlike under the final, Bush administration version of the Privacy Rule, providers would be allowed to condition a patient's treatment on whether or not they received the patient's consent.

STOHP would not, however, reinstate the consent provisions of the December, 2000 Privacy Rule wholesale. It would instead mandate that the Privacy Rule's con-

sent provisions "be construed and applied" so as to allow "a health care provider to use or disclose an individual's protected health information without obtaining the prior consent of the individual" in some situations.

The largest of these exceptions would allow providers to temporarily forego consent when the provider "determines, in the exercise of professional judgment, that the individual's consent is clearly inferred from the circumstances" and obtaining consent "would be impracticable." STOHP would also explicitly rule out any need for up-front consent to "fill or dispense a prescription, search for drug interactions related to that prescription, and determine eligibility and obtain authorization for payment regarding that prescription." Under all of these situations, however, consent would still need to be obtained at some point.

STOHP is co-sponsored by four other Democratic representatives: Michael E. Capuano of Massachusetts, Howard L. Berman and Henry Waxman of California, and John Dingell of Michigan. There are currently no Republican co-sponsors of the bill, the text of which includes Congressional "findings" that the "Bush administration undermined medical privacy protections" with the finalization of this year's changes to the Privacy Rule. The bill also includes a finding that the Bush administration's finalized Rule "significantly weakened medical privacy protections" that were set to go into effect after December, 2000.

"Age-old principles"? According to Representative Markey, his bill takes "steps to apply age-old principles of medical privacy to the realities of the information age."

"This bill is necessary to restore Federal medical privacy protections that were taken away by the Bush Administration," co-sponsor Waxman said in a statement supporting the bill. Waxman also indicated that he considered a return to the December, 2000 version of the Privacy Rule a minimal first step toward strengthening medical privacy protections. He said such protections should ultimately include "protections against discrimination by employers and health insurers based on an individual's genetic" data.

The text of the STOHP bill is available from the Government Printing Office website at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_bills&docid=f:h5646ih.txt.pdf. ■

CCH Chicago Bureau, Oct. 29, 2002

CMS proposes to PAD HIPAA-related records

by Gordon R. Shea, J.D.

The Centers for Medicare and Medicaid Services (CMS) has proposed a new system, to be called the Privacy Accountability Database (PAD), that will aid the agency in reporting, tracking, and accounting for disclosures made pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act of 1974. CMS's Federal Register announcement of PAD notes that CMS "possesses the nation's largest collection of health care data (consisting of over 60 systems of records), with information on over 74 million Americans," thus making implementation of the new PAD system of obvious interest to anyone who interacts with the nation's Medicare or Medicaid systems.

The PAD database, says CMS, will include information on disclosures that the agency makes to various other entities such as to members of Congress, courts and other similar bodies, and to outside contractors or consultants hired by CMS itself.

According to CMS, HIPAA already permits the agency to give such entities the kind of data that the PAD will track, and the PAD program will simply give CMS the accounting and reporting capabilities it will need to track disclosures of such data. Nevertheless, CMS will also take the opportunity of PAD implementation to tighten up its privacy policies. For example, CMS says that it will begin barring non-routine disclosures of even non-identifiable information in situations such as those in which the agency releases small samples of data. In barring such disclosures, the agency hopes to reduce the possibility that the small sample size itself could be used to deduce individuals' identities even though the data released may be impersonal. In addition, CMS plans to bring PAD program information fully into line with HIPAA's "minimum necessary" standards, disclosing only the smallest amounts of information needed to achieve the purposes of any necessary disclosures.

Announced in the Federal Register in early October, PAD will be implemented

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in stages beginning on April 14, 2003 – the date that the government has mandated for HIPAA Privacy Rule compliance. The first stage will encompass CMS's Medicare Beneficiary Database and its National Claims History National Medicare Utilization Database, which CMS says are "the source for the most frequently disclosed information" that the agency holds.

Interested parties have until December 7, 2002, to submit comments on the proposal to the government. ■

Proposed Rule, 67 FR 62482, Oct. 7, 2002, ¶100,917

CMS is new transaction/ code set enforcer

by Gordon R. Shea, J.D.

Department of Health and Human Services (HHS) Secretary Tommy Thompson has announced that the Centers for Medicare and Medicaid Services (CMS) will enforce the transaction and code set standards of the Health Insurance Portability and Accountability Act (HIPAA). CMS also plans to create a new office to centralize oversight of its HIPAA responsibilities.

CMS "best able." While HHS's Office of Civil Rights enforces HIPAA's recently-finalized privacy mandates, and while CMS has long been in charge of enforcing HIPAA's insurance portability requirements, it had previously been unclear what government agency would take charge of the transaction and code set administrative provisions. Now that CMS has been given that responsibility, HHS said in a press release, the agency will focus its enforcement efforts "on obtaining voluntary compliance" with pertinent rules, mostly "through technical assistance."

HHS Secretary Tommy Thompson said that "CMS is the agency best able to" accomplish code set and transaction enforcement, which Thompson deemed necessary "to streamline and standardize the electronic filing and processing of health insurance claims, save money, and provide better service for providers, insurers, and patients."

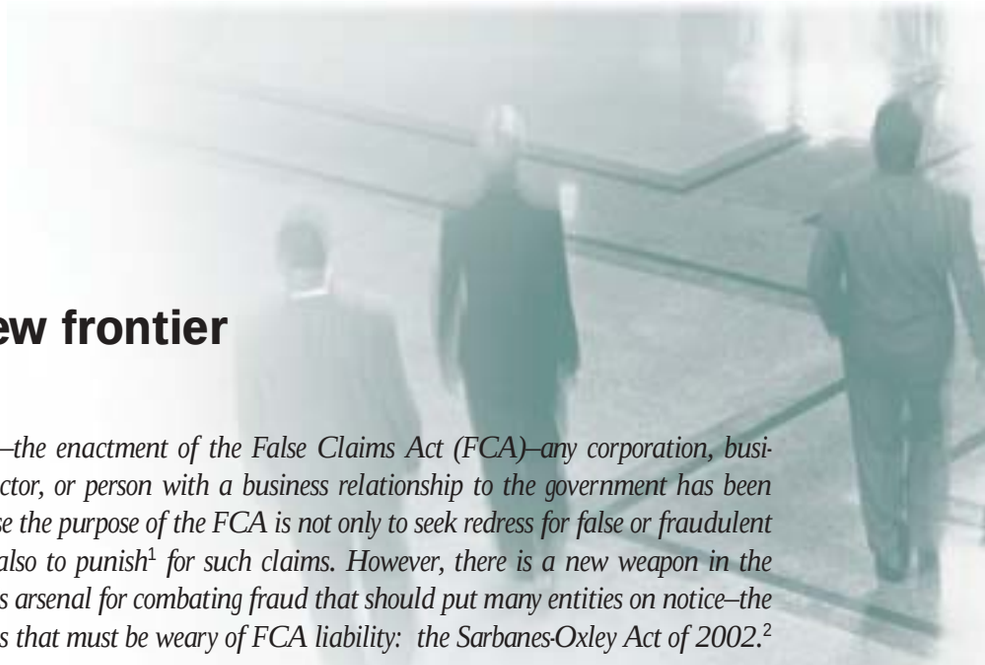
The transactions and code set provisions set standards for electronic data exchanges among different actors in the healthcare field. At the time the rules on transactions and code sets were promulgated, there were hundreds of different electronic formats being used for health claim information across the country. The hope was (and continues to be) that substantial efficiencies and cost savings could be realized by standardizing such matters. Towards this end, the transactions and code set provisions of HIPAA were finalized in 2002. Their effective date was set at October 16th of this year, though many HIPAA covered entities have filed for a one-year extension under which they need not comply with the rules until October 16, 2003.

New CMS office. Meanwhile, CMS deputy administrator Rueben King-Shaw, Jr., commented that CMS's new initiative to centralize the agency's growing list of HIPAA enforcement duties under a single new office will give the agency "the most efficient operation possible, while providing strong support for all our partners in the health care community." According to HHS's press release on the matter, the new office (as yet unnamed) will not only set up and run processes for CMS's HIPAA-related responsibilities, but will also help develop regulations for all HIPAA administrative standards that come under the agency's purview. A significant part of this effort, HHS said, will be conducting outreach activities.

HHS indicated that CMS's enforcement efforts will be largely driven by complaints received by the agency, with progressive-style enforcement being the rule. Under this system, the agency said, HIPAA covered entities that run afoul of HIPAA regulations will be given multiple opportunities to show their efforts toward HIPAA compliance and to help design their own proposed corrective action plans.

HHS's press release on the matter is available at http://www.hhs.gov/news/press/2002pres/20021015a.html. ■

CCH Chicago Bureau, Oct. 22, 2002



On The Front Lines

Sarbanes-Oxley: The new frontier

by Raio G. Krishnayya, J.D.

Since 1863–the enactment of the False Claims Act (FCA)–any corporation, business, contractor, or person with a business relationship to the government has been wary because the purpose of the FCA is not only to seek redress for false or fraudulent claims but also to punish[1] *for such claims. However, there is a new weapon in the government's arsenal for combating fraud that should put many entities on notice–the same entities that must be weary of FCA liability: the Sarbanes-Oxley Act of 2002.*[2]

This is especially true of for-profit healthcare entities. While the legal landscape with regard to the Sarbanes-Oxley Act is currently hazy, for-profit healthcare entities should consider the ramifications of this Act on their business operations. Furthermore, there are a few striking similarities between the FCA and the Sarbanes-Oxley Act that can provide some guidance on how the latter statute may operate. This is especially important given that there is little prosecutorial history in this area.

Much of the hype associated with Sarbanes-Oxley has been focused on the notion of corporate corruption. The nexus between corporate executives being hauled away in handcuffs and the movement of safeguarding our economy seems to be the Sarbanes-Oxley Act. Not surprisingly, for-profit healthcare entities must not only consider FCA ramifications in their compliance programs but also Sarbanes-Oxley problems. Why? First, the language of Sarbanes-Oxley is broad enough to tie some of the same conduct that implicates FCA violations into Sarbanes-Oxley violations. Second, there may be a common misconception that governmental investigators are only concerned with the Enrons and Worldcoms of the business world. Not so.

For example, in August, the *Wall Street Journal* reported that HealthSouth Corporation was being investigated by the Securities and Exchange Commission (SEC) as a result of HealthSouth's changes in Medicare billing for outpatient physical therapy services. This may seem odd since Medicare billing is governed by the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services. However, the SEC's involvement occurred because the billing changes would allegedly affect HealthSouth's earnings by $175 million.[3]

Therefore, in conjunction with broader powers afforded by Sarbanes-Oxley, the SEC would have latitude to track routine billing practices (and not just Medicare and Medicaid practices) to determine if such changes affect corporate earnings. Healthcare entities that presume that they are only subject to FCA problems may be surprised to find the SEC conducting a joint investigation with the HHS Office of Inspector General.

Key provisions

Legislative bill H.R. 3763 (the Sarbanes-Oxley Act) was signed into law in July of this year. Probably the most widely noted provision of this statute is Title III, or the Corporate Responsibilities provision, which required the heads of the largest U.S.-based companies to file sworn statements attesting to the truth and accuracy of their financial data.[4] However, Title VIII, Corporate and Criminal Fraud Accountability, has expanded the government's reach into combating fraud and abuse. Consider some of the provisions that could conceivably affect for-profit corporate healthcare entities and note the comparisons and distinctions to FCA liability.

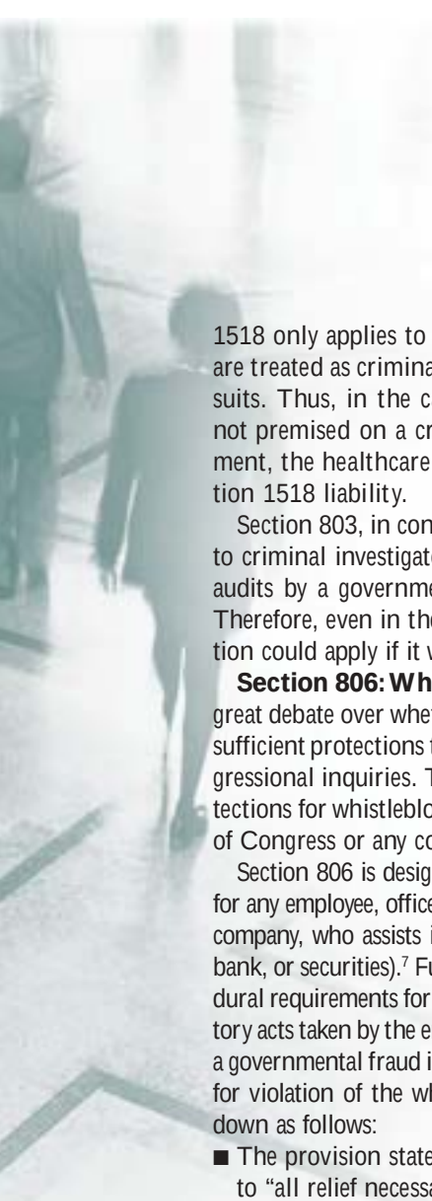
Section 803: Obstruction. This section was drafted to amend the federal crime of Obstruction of Justice under Title 18, Chapter 73.[5] Section 803 reads:

> Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States or any case filed under title 11, or in relation to or contemplation of any such matter or case, shall be fined under this title, imprisoned not more than 20 years, or both.

Interestingly, Title 18, Section 1518 includes an Obstruction of Justice provision exclusively for healthcare-related offenses.[6] Section 1518 reads:

> Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years, or both. (b) As used in this section the term "criminal investigator'' means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.

The inclusion of Section 803 begs the question of why a healthcare entity would be concerned about Section 803 when Section 1518 expressly addresses obstruction in healthcare fraud cases. The answer is that Section 1518 has a narrower application. Section 1518 only imputes culpability when a healthcare entity willfully obstructs the investigation of any *criminal investigator*. This implies that Section



1518 only applies to healthcare fraud and abuse cases that are treated as criminal prosecutions, not as civil false claims suits. Thus, in the case of any governmental audit that is not premised on a criminal investigation leading to indictment, the healthcare entity would be free and clear of Section 1518 liability.

Section 803, in contrast, is broader. Its focus is not limited to criminal investigators but rather *any matter;* even routine audits by a government agency could impose 803 liability. Therefore, even in the case of a civil audit, criminal obstruction could apply if it was done knowingly.

Section 806: Whistleblower protections. There was great debate over whether the language of 806 would provide sufficient protections to whistleblowers who cooperate in congressional inquiries. The debate resulted in inclusion of protections for whistleblowers who report fraud to "any Member of Congress or any committee of Congress."

Section 806 is designed to afford protection from retaliation for any employee, officer, contractor, subcontractor or agent of a company, who assists in the investigation of fraud (mail, wire, bank, or securities).[7] Furthermore, the section details the procedural requirements for employees seeking redress for anti-retaliatory acts taken by the employer in conjunction with assistance in a governmental fraud investigation. As a final point, the remedy for violation of the whistleblower protection provision breaks down as follows:

- The provision states that a prevailing employee is entitled to "all relief necessary to make the employee whole."
- Compensatory damages to include reinstatement at the same seniority level, back pay with interest, special damages, litigation costs, expert witness costs, and reasonable attorney fees.

Section 1107: Informant protections. This provision was drafted to be an addendum to the statute pertaining to the protection of informants who cooperate in criminal investigations.

At first read, the language of Section 1107 and 806 seem identical. However there are several key distinctions that impact a governmental investigation into fraud. On the one hand, Section 1107 carries criminal penalties, which means that a person who is an informant but not an employee does not necessarily have a civil remedy for interference with his or her lawful employment. On the other hand, Section 806 remedies are primarily administrative and civil. Second, and highly significant, especially when compared with the FCA, is the fact that Section 806 is narrowly applied only to *employees* of "publicly traded companies." Section 1107, however, applies to *any person*.

The significance of this distinction for a healthcare entity is that someone covered under Section 806 could also be covered under Section 1107. Thus, a whistleblower reporting Medicare and Medicaid fraud who is also an employee or former employee (as is often the case in FCA cases) could conceivably be protected by both 806 and 1107 as well as under the FCA whistleblower provisions.

Sarbanes-Oxley vs. False Claims: burning both ends of the candle

Section 803 and the FCA. Section 806 seems to read like any garden-variety criminal statute. In the healthcare context, however, a provider facing a FCA lawsuit could find a concurrent action under Section 803. Recall the basic language of the FCA: "any person who knowingly presents or causes to be presented," to the United States, "a false or fraudulent claim for payment or approval is liable...." Section 803 has similar language in that anyone who "knowingly" falsifies or covers up *any* record (such as a claim for reimbursement—part of the SEC investigation into HealthSouth Corp.) that falls within the jurisdiction of "*any department or agency*" may face fines or incarceration for up to 20 years. The fact that the statute includes the broad sweeping language "any department or agency" conceivably allows a FCA investigation to expand into a Section 803 investigation and possible prosecution.

There are, however, several counterpoints to the notion of a potential concurrent Section 803 prosecution.

First, it is important to realize that Section 803 is a criminal statute, which raises certain issues that distinguish the procedural requirements from a FCA claim. Clearly, the government must prove a Section 803 violation *beyond a reasonable doubt*, which is different from a FCA claim—which need only be proved by *a preponderance of the evidence*.

Second, a government investigation into possible Section 803 violations would probably take precedence over a FCA claim. However, depending on how egregious the violation, there is likelihood that the government could pursue both claims. The Section 803 claim would be designed to punish the criminal act, and the FCA claim would be designed to recover significant damages as a result of the fraud. It is important to realize that the fines incurred under 803 would be insignificant as compared to those in a FCA claim.

Third, Section 803 prosecutions could arise from FCA investigations. In cases where the government subpoenaed the reimbursement records of a provider, if the provider knowingly falsified the records or withheld discoverable information, then the government would be entitled to pursue a Section 803 claim. This emphasizes the previous point about the distinction between Section 1519 suits and Section 803 suits. In theory, the government could not prosecute violations of the FCA under Section 1519 but could under Section 803.

Whistleblower protections. Both the FCA and the Sarbanes-Oxley Act allow employees who have assisted in a government investigation to recoup in situations where the targeted employer has discriminated against the whistleblower for his or her assistance. However, differences between these two statutes are worth noting in part because of the potential criminal liability associated with Section 1107 enforcement.

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Questionably experienced lawyer awarded cut legal fees

by Gordon R. Shea, J.D.

An attorney of questionable experience who handled a client's False Claims Act (FCA) *qui tam* action was entitled to substantial fees and costs for his work, though only in an amount that was less than half of what he claimed, a Massachusetts federal court has held.

The case, *U.S. ex rel. Averback v. Pastor Medical Associates P.C.*, is a notable and practical reminder of the workings of FCA's oft-overlooked Fee Shifting provisions, contained in 31 U.S.C. §3730(d). Under those provisions, unique in the legal cannon, a defendant who loses an FCA lawsuit must pay the plaintiff relator's attorney fees – even when a case settles rather than going to trial.

Attorney claims settlement fees. A settlement, in fact, formed the basis of the fee shifting dispute in *Averback*. The relator in the case, Dr. R. J. Averback, initiated legal action when the controlling doctor in her medical practice, Pastor Medical Associates (PMA), sold the business. Unlike most other doctors who worked at the practice, Averback was cut out of most benefits of the sale.

The case was initially a complex one involving state and federal laws of both a civil and criminal nature. Eventually, however, the case came to focus on allegations of Stark II and FCA violations. It was eventually settled, with PMA paying the government $230,000 ($41,400 of which went to Averback) but admitting no wrongdoing. In fact, PMA's legal team later estimated that about 80 percent of Averback's original claims were unsuccessful.

That did not stop Averback's attorney Max Borten, however, from claiming that he and co-counsel Sidney Gorovitz were entitled to $177,439.35 in legal fees and costs. Borten, who had extensive medical training in addition to his law license, based this fee on a claimed 348 hours of "core" legal work on the case and 16 hours of "non-core" work such as filing and making phone calls.

"Woefully short," but.... Predictably, PMA chafed at paying Borten's bills. Relying on hourly billing records as evidence, PMA argued that much of Borten's work on the case centered on Averback's state law claims, which were unrelated to the ultimate FCA action. In addition, Borten's records indicated that he had spent over 60 hours in what PMA characterized as getting up to speed in "basic health care statutes."

More disturbing to the court, however, was Borten's own lack of proof that he deserved his billed rate of $325 per hour. The court said that Borten had "come up woefully short" in making such a showing; in fact, the court noted, "Borten's resume shows a decided lack of actual legal experience" applicable to the case. For his part, Gorovitz gave the court "no materials at all" to show his qualifications.

Nevertheless, the court found that Borten's medical training proved highly valuable to Averback. On that basis, the court ultimately awarded the Borten team an hourly rate of $175 per hour, for a total of about $62,000 in fees and costs.

The "purpose of the False Claims Act, as the government's 'primary litigative tool for combating fraud,'" Chief Judge William G. Young wrote for the court, "is to encourage individuals aware of government fraud to produce that information, by increasing monetary incentives and providing whistle-blower protection." This purpose, the judge said, would not be served by second-guessing legal bills, "pars[ing] out complaints and attorney billing records to such a point where any hours researching claims found somehow 'unsuccessful' or 'unrelated' to the final settlement in a case that was never litigated in open court would be deducted from the total hours claimed" by an attorney. ■

U.S. ex rel. Averback, D.Mass., Civil Action No. 99-11124-WGY, Sept. 27, 2002, ¶305,260

On the Front Lines

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The inclusion of the informant protection under Section 1107 potentially makes any retaliatory act by an employer a criminal offense under 1107. Realizing that a whistleblower who conforms to the Section 806 criteria could be covered under 1107 means that the government would be able to attach an additional charge. Therefore, while retaliation against a FCA whistleblower could only lead to recompensation, retaliation against a Sarbanes-Oxley whistleblower could lead to criminal charges as well as recompensation. The worst-case scenario is that the FCA whistleblower is in a position to have knowledge about how the false or fraudulent claims affected corporate earnings leading to dual liability under the FCA and the Sarbanes-Oxley Act.

Conclusion. Although the Sarbanes-Oxley Act is a new weapon in the government war against fraud, there is no need to advocate that a compliance program be entirely reworked to cover such violations. Instead, much of a current compliance program can be tailored to protect from such issues based on FCA similarities. The similarities allow compliance officers to simply tweak reimbursement policies as well as employer-employee conduct policies to both Sarbanes Oxley and FCA violations as well as to prevent anti-retaliation claims by both types of whistleblower. ■

Raio G. Krishnayya is an Attorney Analyst and Writer for the CCH Healthcare Compliance Portfolio. Please direct questions or comments about this article to krishnar@cch.com.

1 31 U.S.C. § 3729(a) allows for treble the damages that occurred to the government arising from the false or fraudulent claim.

2 Pub. Law 107-204.

3 Ann Carrns, *Worried HealthSouth Holders To Meet at Behest of Activist*, Wall Street Journal Online, Sept. 30, 2002, http://www.wsj.com.

4 *See SEC Staff Completes Processing of CEO, CFO Statements*, No. 2002-125, Aug. 20, 2002; http://www.sec.gov/news/press/2002-125.htm.

5 18 U.S.C. §1519.

6 18 U.S.C. §1518.

7 Submissions to the government for false or fraudulent Medicare reimbursement claims may be subject to prosecution under these sections.

Medication copayment-funding plan nixed

by Geraldine S. Stroka, J.D., R.N.

A pharmaceutical manufacturer cannot establish and support a nonprofit foundation to subsidize the copayment amounts incurred by financially needy patients when they utilized one of its drugs. The Office of Inspector General (OIG) determined that the proposed plan subsidizing patients' cost-sharing amounts "clearly implicated" the anti-kickback statute and that administrative sanctions could be incurred.

Drug copayment plan. The plan involved the payment of patients' cost-sharing amounts for a medication that treats the anemia of chronic renal disease and requires monthly administration in a physician's office. The pharmaceutical manufacturer proposed to establish and fund a nonprofit, tax-exempt foundation, earmarking all of its contributions to the foundation for the proposed cost-sharing arrangement. No employee of the manufacturer would serve as a board member, and no foundation employee would have any financial relationship with the manufacturer. The program would be advertised to physicians who could prescribe or influence the prescription of this specific drug.

Foundation's role. The foundation would determine the patients selected for the program. The manufacturer would have no role in patient selection, nor would it receive any patient or physician information generated by the program.

Only patient applicants currently using or intending to use the drug would be considered for the subsidy. The foundation would review the patient's medical condition, verify the necessity of the drug with the patient's physician, and confirm private insurance status. A financial review, following established standards, would follow to determine eligibility and the amount of the subsidy, partial or full, towards the patient's cost-sharing amount. Then the foundation, acting through a distributor, would authorize a purchase credit to the patient's physician for the drug in the amount of the patient's subsidy.

Anti-kickback statute implicated. The OIG considered the foundation's "grants" to be payments by the drug manufacturer because nothing insulated the foundation's subsidy from its source, the drug manufacturer. The real issue was whether a manufacturer of a drug or device, covered under a federal healthcare program, should be permitted to subsidize needy patients' copayments incurred by the use of its product.

Analysis. The OIG determined that the proposed plan implicated the anti-kickback statute and posed a substantial risk of program and patient fraud and abuse. The OIG reasoned that:

- the statute squarely prohibited the proposed arrangement because the subsidy shifts all or part of the cost to Medicare;
- the proposed arrangement posed all the usual risks of fraud and abuse associated with kickbacks;
- patient assistance programs that subsidize Medicare cost-sharing can be very profitable to manufacturers; and
- other alternatives existed, such as assistance programs that provide free drugs to patients, without any payment by Medicare, or other indirect vehicles including an independent foundation, established by multiple drug manufacturers, that awarded grants based on need with no ties to the contributing drug manufacturers. ■

OIG Advisory Opinion 02-13, Oct. 4, 2002, ¶150,194

Fire District's proposed billing arrangement okayed

by Sharon Sofinski

In a recent advisory opinion, the Office of Inspector General (OIG) considered whether a Fire District's proposal to treat revenue from local real estate taxes as payment of copayments and deductibles due from residents for emergency medical services (EMS) would violate the Anti-Kickback Statute.

The Fire District, owns and operates an ambulance service and is the exclusive provider of EMS for its residents. Currently, the funds for its services come primarily from real estate taxes. The Fire District is considering adopting an ordinance under which it would bill residents or their insurers (including Medicare and Medicaid) for EMS, but only to the extent of their insurance coverage. That is, residents would not incur out-of-pocket costs for the services. The Fire District would instead treat the revenues received from local taxes as payment of any otherwise applicable copayments and deductibles due from the residents ("insurance only" billing).

The Fire District asked the OIG whether the proposed billing arrangement would constitute grounds for the imposition of sanctions under the exclusion authority under section 1128(b) (7) of the Social Security Act, under the civil money penalties provision at section 1128B(b) of the Act, or under the civil monetary penalties provision for illegal remuneration to beneficiaries at section 1128A(a)(5) of the Act.

The OIG stated that the "insurance only" billing under the proposed arrangement may implicate the Anti-Kickback Statute to the extent that it constitutes a limited waiver of copayment and deductible amounts.

However, the OIG noted that there is a special rule for providers owned and operated by a state or a political subdivision of a state, such as a municipality or fire district. The Centers for Medicare and Medicaid Services (CMS) Carrier Manual states that such a provider "which ... charges patients only to the extent of their Medicare and other health insurance coverage" is not "furnishing free services." It is important to note that this provision applies only where the municipality is the ambulance supplier; it does not apply to contracts with outside ambulance suppliers.

Since Medicare does not require the Fire District to collect copayments or deductibles from residents, the OIG would not impose sanctions under the Anti-Kickback Statute where the waiver is implemented by the Fire District for bona fide residents of the Fire District.

The OIG would not impose administrative sanctions on the Fire District under sections 1128(b)(7), 1128A(a)(7), or 1128A(a)(5) of the Act in connection with the proposed billing arrangement. ■

OIG Advisory Opinion No. 02-15, Sept. 30, 2002, ¶150,196

HIPAA still #1 issue for compliance officers

by Geraldine S. Stroka, R.N., J.D.

The results of the fifth annual survey of healthcare compliance professionals are now available. It will come as no surprise to those working in the industry that the professionals surveyed rated compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulations as their number one issue. The survey, designed and conducted by the Health Care Compliance Association (HCCA) and Walker Information, gives a national perspective on the issues, goals and compensation of compliance officers, and on compliance departments' budgets and staffs.

Survey design. The questionnaires were sent to a randomized group of 3500 healthcare compliance professionals, both members and nonmembers of HCCA. There were 700 responses, a 20 percent response rate. Survey respondents were from all parts of the country and represented all types of healthcare organizations, including 27 percent from health systems and 27 percent from hospitals.

HIPAA. Of the professionals who responded, 68 percent stated that compliance with HIPAA Privacy Regulations is the largest problem they face (see graph below). In addition, 89 percent of the respondents listed HIPAA compliance as one of their top goals.

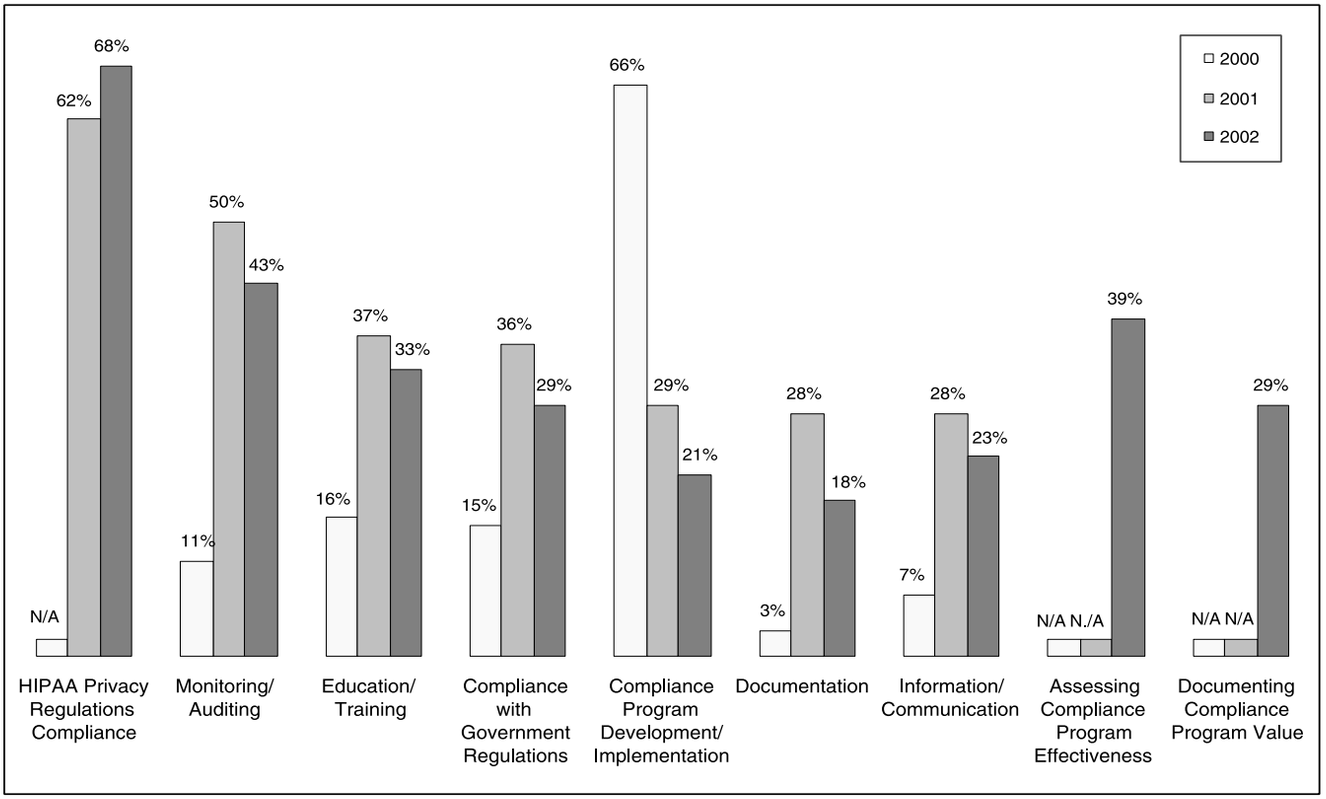
Other issues. Other issues of concern were monitoring and auditing (43 percent), assessing compliance program effectiveness (39 percent), and education and training (33 percent). The issues corresponded with the compliance professionals' goals for the upcoming years; monitoring and auditing (82 percent), education and training (72 percent), and conducting effectiveness evaluations (65 percent) were identified as the most prominent compliance program goals.

Compliance careers. The survey highlights many areas of concern to healthcare compliance professionals, including department staffing and budget. It also highlights areas of personal interest, namely, career advancement and salary. For the first time, the compensation for the chief compliance officer, responsible for the entire compliance program, was listed as well as that of the corporate compliance officer, responsible for the day-to-day operations of the program. These salaries were reported by employer type, size of organization, educational level, and region.

Survey's importance. The survey is well worth reading in its entirety; it is a comprehensive review of the "state of healthcare compliance officers in the United States." A vast amount of yearly comparative information is presented. The survey is available on the HCCA Web site at http://www.hcca-info.org/documents/HCCAsurvey9_02.pdf. ■

Fifth Annual Survey, 2002 Profile of Health Care Compliance Officers, Oct. 1, 2002, HCCA and Walker Information

What would you say is the single biggest issue facing your organization's Compliance Program today?



Note: Results add to more than 100% because some respondents mentioned more than one issue.

Source: 5th Annual Survey, 2002 Profile of Health Care Compliance Officers, the Health Care Compliance Association (HCCA) and Walker Information. From an unrestricted educational grant from PricewaterhouseCoopers.