

Health Insurance Portability and Accountability Act

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HIPAA Ten Years Later: A New Initiative for Expanding Enforcement

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I. Executive summary

As we commemorate ten remarkably successful years of the Department of Justice's (Department) implementation of the Health Care Fraud and Abuse Control program included in the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, the Department is launching a renewed commitment to its critical health care anti-fraud effort. Over the course of the past fifteen months, the leadership of the Department has been focused on aggressively pursuing new sources of funding for our health care fraud and pharmaceutical fraud enforcement efforts. This memorandum will outline the results of those efforts and chart the course for the reinvigoration and expansion of our work in this important area of law enforcement.

We will provide funding for thirteen civil litigators for U.S. Attorneys' offices, seven civil litigators for the Civil Division, and up to three civil litigators for the Office of Consumer Litigation. The addition of these new civil litigators will help our districts and divisions address and resolve pending False Claims Act (FCA) and other civil health care and pharmaceutical fraud cases. We are also setting aside separate additional funding for civil health care fraud litigation support expenses for all U.S. Attorneys' offices and the Civil Division.

On the criminal front, we will provide additional funding for criminal health care fraud litigation support expenses for all U.S. Attorneys' offices. We will also provide funding for the Criminal Division and U.S. Attorneys' offices involved in the three Strike Force districts: South Florida, Los Angeles, and Houston. The Strike Forces will target areas of the country experiencing high levels of health care fraud, including durable medical equipment suppliers engaged in fraud and home health care providers

engaged in fraud. The Office of Consumer Litigation will also receive two additional criminal prosecutors to work on pending Food and Drug Administration cases and other pharmaceutical fraud matters.

We will provide funding for the Civil Rights Division to continue its monitoring and enforcement work involving publicly run nursing homes and hospitals. We will also continue our support for the Elder Justice and Nursing Home Initiative by funding nurse consultants to support our failure-of-care cases and funding ongoing research projects that are making important contributions to the field of elder abuse. Finally, the Federal Bureau of Investigation (FBI) will receive new funding and resources for their health care fraud investigations.

By giving the districts and our components an immediate infusion of new funding and resources, we will build on our past accomplishments and continue to grow our efforts to protect the financial integrity of our publicly funded health care programs and continue to ensure the safety of the medical products and services we receive.

II. Ten years of accomplishments

The HIPAA established the Health Care Fraud and Abuse Control Program (HCFAC), a comprehensive program to combat fraud and abuse in health care. The Program was designed to be jointly administered by the Attorney General and the Secretary of the Department of Health and Human Services (HHS) to ensure the agencies coordinate their efforts in fighting fraud. HIPAA annually appropriates monies from the Medicare Trust Fund to an expenditure account, called the HCFAC account, for use in HHS and Department anti-fraud efforts. Before the funds are disbursed, the Attorney General and the HHS Secretary must jointly certify that the funds are being distributed and used in a manner consistent with the intent and purposes of HIPAA. What was revolutionary about HIPAA from an enforcement perspective was that it established mandatory funding streams for the Department and the FBI to support dedicated prosecutors, litigators, and investigators pursuing health care fraud cases. HIPAA provided

the appropriated funds which would grow each year until 2003. This meant that, until 2003, the Department could count on increasing resources to pursue health care fraud and pharmaceutical fraud cases and keeping expanding its enforcement efforts.

The growth the Department experienced in health care fraud work since 1997 is remarkable. Over the last ten years since the HCFAC program was created, the Department has significantly increased the number of civil and criminal matters it is pursuing. In FY 2006, the Department convicted 547 defendants of health care fraud offenses, the highest number to date. This represents about a 50% increase in convictions since the start of the HCFAC program in 1997. See Figure 1, page 7.

On the civil side, last year the Department filed or intervened in 217 new civil health care fraud cases, which represents an increase of about 155% since the program started in 1997. Last year was also a record year for civil recoveries. The U.S. Attorneys' offices and the Civil Division obtained judgments and settlements totaling over \$3.2 billion in fraud recoveries. Of that amount, \$2.2 billion came from health care fraud cases. In the past seven years, attorneys from the Civil Division and the U.S. Attorneys' offices recovered over \$5 billion in pharmaceutical matters, including over \$1.2 billion in fiscal year 2006 alone. This included \$704 million obtained from the Swiss biotechnical corporation, Serono, S.A., in a series of cases involving off-label marketing and kickbacks. The Department also obtained \$435 million to resolve similar off-label claims with Schering-Plough. Health Care continues to be the chief area of the Department's qui tam litigation under the FCA, accounting for more than 53% of the 5,643 qui tam cases filed since 1986 overall. In the past three years, health care recoveries have averaged 74% of the total FCA recoveries the Department sees each year. See Figure 2, page 7.

III. The importance of our health care fraud work

Health care fraud remains one of the Department's broadest and most comprehensive areas of law enforcement, involving each of its ninety-four U.S. Attorneys' offices, the Criminal Division Fraud Section, the Civil Division, the Civil Rights Division, and the FBI. Our efforts are essential to preserving the financial integrity of our nation's health care system and deterring fraud

schemes that put the health of our citizens in jeopardy. This work requires close cooperation with our partners at the Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services.

The kinds of cases the Department has pursued over the last year alone reflect the breadth of law enforcement work the Department routinely undertakes. We are prosecuting individuals operating sham durable medical equipment companies that are literally stealing money from the Medicare program—money that could otherwise be spent on providing health care for our elders. We are keeping pharmaceutical companies accountable by ensuring that they follow the law in the way they market and distribute their drugs and refrain from paying kickbacks to doctors in exchange for writing prescriptions. We are keeping hospitals accountable by ensuring that they do not fraudulently submit inflated bills to the Medicare program through upcoding or by requesting outlier payments (special payments intended to defray the expense of the most costly cases) for all their patients. We are investigating nursing homes where residents are dying from malnutrition and infected bedsores, and we are prosecuting the nursing home owners who fail to provide adequate care for the residents.

In every case, our paramount concern is patient harm. Many of the fraud schemes we see are being perpetrated by people who have no regard for the health of the beneficiaries and are willing to put lives at risk in order to line their pockets. We saw this with the doctor who was diluting chemotherapy drugs being administered to cancer patients. We saw this with the infusion therapy scams where HIV-positive patients were being given diluted medication or no medication at all. These unscrupulous people mar what is otherwise an honorable and needed service—caring for the elderly and sick.

Finally, health care fraud is still perceived as a low risk/high reward crime. Playing the odds, the worst that most people defrauding the system believe can happen to them is they get their provider number taken away or they have to pay back the money they stole as an "overpayment." The bottom line is criminals will continue to test the system and try to find vulnerabilities to exploit unless there is a real threat of criminal prosecution.

IV. HCFAC's proven rate of return

Since 1998, health care fraud-related collections, returns, and transfers to the Medicare Trust Fund generally have increased during most years along with HIPAA annual dedicated appropriations for federal law enforcement efforts. In other words, as our funding increased, our recoveries for the Medicare program increased as well. The "return on investment" or "recovery rate" to the Medicare Trust Fund for every dollar of HCFAC funding allocated for federal law enforcement has increased from less than \$2 in 1998 to nearly \$5 today. This rate of return does not even take into account the money saved from the deterrent effect of our criminal prosecutions. See Figures 3 and 4, pages 8 and 9.

V. The problem

The Department's negotiated share of HCFAC program funds increased annually since 1997 and peaked at \$55.2 million in 2002. Since 2003, when HCFAC program funds reached their statutory cap, the Department has received \$49.415 million annually from the program. Similarly, HIPAA provided annual increases in health care fraud enforcement funding for the FBI, which peaked at a statutory maximum of \$114 million in 2003.

We understand that the funding cap created new challenges for the U.S. Attorneys' offices and Department litigating components. In order to maintain a constant level of personnel in the field, EOUSA began to use litigation support funds to pay for attorney and staff salaries. As a result, fewer HCFAC funds were available to pay for the consultants, document management, and other litigation support costs these often complex cases require, making it more difficult to push these cases forward.

Other components had similar problems. The Civil Division is facing an increasing case load of pending qui tam and pharmaceutical fraud investigations and active cases. As of today, 243 pharmaceutical matters have been opened or filed under the False Claims Act alleging various types of fraud in the pricing and sale of pharmaceutical products paid by federal health care programs. Approximately 146 of these are still under investigation. Many of these matters concern allegations of both criminal and civil wrongdoing. While we have had record recoveries in the last year, there is a sense we could be moving cases

forward to resolution more quickly with the proper amount of resources, including personnel and litigation support funding.

The Civil Rights Division is investigating many Civil Rights of Institutionalized Persons Act (CRIPA) cases where they obtain court enforceable agreements requiring publicly-funded institutions to correct deficient conditions. The monitors for these cases involve significant expenses, and the Division has had difficulty supporting these costs.

The Criminal Division is also in the midst of launching an ambitious initiative aimed at targeting three areas in the country with a high concentration of health care fraud: South Florida, Houston, and Los Angeles. In the five months following the launch of the initiative in South Florida, the Strike Force and U.S. Attorney's Office in the Southern District of Florida have indicted over fifty-three defendants for health care fraud—a number equivalent to 10% of our annual health care fraud filings. We must support the U.S. Attorneys' offices and the Strike Forces in the districts affected by rampant health care fraud.

VI. The solutions

A. Inflationary cap lifted until 2010

The first success in securing new funding we had this year was in removing the statutory cap to the HCFAC account and obtaining some much-needed inflationary relief. The "Tax Relief and Health Care Act of 2006," signed by President Bush in December 2006, provides for annual inflation adjustments to the maximum amounts available from the HCFAC account for the Department and for the FBI beginning in 2007 for each fiscal year through 2010. This law will allow the Department to maintain its current level of law enforcement efforts, and has helped to alleviate some of the inflationary erosion we have seen since the cap in 2003.

B. Department to receive increased HCFAC account allocations

In addition to the inflationary increases provided by the new law, the Department reached an agreement with HHS over the allocation of the HCFAC account that will provide the Department with some additional funding above the Department share of the inflationary adjustment. Therefore, we now have an additional \$2.378 million in HCFAC funding to allocate between

our components in the last quarter of FY 2007. In October, we will have an additional \$4 million in HCFAC funding to distribute among components above the level we started with in FY 2007 (assuming 2% inflation in FY 2008).

C. Three percent fund will make our HCFAC funding go further

We recognized that we would need additional resources beyond the new HCFAC funding to support our initiative. The 21st Century Department of Justice Appropriations Authorization Act (P.L. 107-273; 28 U.S.C. 527 note) provides the Department authority to credit to its Working Capital Fund with up to three percent of all amounts collected pursuant to civil debt collection litigation activities. This fund is also known as the Three Percent Fund, and is managed by the Collections Resource Allocation Board.

The Three Percent Fund can only be used for civil debt collection activities, such as in FCA cases, including pharmaceutical and other health care fraud cases. The Board, in concert with the Office of the Deputy Attorney General and the Office of the Solicitor General, has approved for the next twelve months, additional funding to jump start the civil enforcement portion of our initiative. The Board will continue to seek ways to support this initiative as long as Three Percent Funds are available. This may not be a long term solution because the availability of funds depends on the amount the Department collects through its enforcement activities, and these amounts vary from year to year. The Board and the Department's leadership will monitor the use of the funds closely and keep the districts and components using these funds informed if there will be a need to find alternatives to the Three Percent Fund to support the new personnel and litigation expenses we are going to start funding now.

D. President's FY 2008 budget request

The Administration recognizes the work we do in this area is an essential part of basic, good government work. The President's 2008 budget includes a \$17.5 million increase for the Department as part of an overall \$183 million discretionary cap adjustment for HHS program integrity work. We are working to provide informational briefings to members of Congress on the importance of the increase in funding to the

Department's law enforcement efforts and to the integrity of the Medicare and Medicaid programs.

As you can see, we are working on several different approaches to address our resource needs. Our plan is to use the funds we have obtained this year to chart a course for sustainable growth of our health care fraud and pharmaceutical fraud program.

VII. The Health Care Fraud and Pharmaceutical Fraud Initiative

What follows is a discussion of the main elements of the new initiative. These elements were put together in conjunction with the different Department components involved.

A. Funding for twenty-three new civil litigators and litigation support needs

Our civil enforcement litigation in health care fraud has not been able to grow in recent years due to the statutory funding caps. The program has also been plagued by rising demands in litigation support expenses (such as consultants, document management capabilities, and travel expenses). By providing an infusion of new personnel and litigation support funding into this area, we will accomplish two key objectives: 1) an immediate increase in the speed at which we push cases towards trial or settlement, and 2) a reduction in the number of pending cases and the amount of time it takes for cases to be resolved. Recoveries will be expedited, and may be expanded, if more government litigators and other professionals are deployed to work on the current inventory of cases.

We will provide funding for thirteen new civil litigators in the U.S. Attorneys' offices to pursue health care fraud and pharmaceutical fraud cases. The new civil litigators and litigation support expenses will be paid for in the first twelve months through the Three Percent Fund. In addition, we will open a litigation support fund specifically for all United States Attorneys' offices civil health care fraud cases to ensure that our litigators have the resources they need to pursue their cases, which are often against very well-funded corporations. We will send funding for new civil litigators to the districts that presently have cases they need to immediately push forward and require the additional attorney or two to get the job done. The Executive Office for United States Attorneys (EOUSA) will be working with the districts to identify the places

with the most pressing needs. EOUSA will also be responsible for administering and overseeing the new civil litigation support funds. Districts needing civil litigation support funding for health care fraud or pharmaceutical fraud matters should work through EOUSA to receive the funds. As used in this section, all references to a "litigation support fund" indicate that a line item or set aside will be created within the Three Percent Fund for Civil Division and U.S. Attorneys' offices litigation support expenses in connection with this initiative.

We will also provide funding for ten new civil litigators in the Department's Civil Division. Seven of those litigators will be for the civil fraud section to work on pending health care fraud qui tams and pharmaceutical cases and up to three of those new civil litigators will be for the Office of Consumer Litigation to work on pending pharmaceutical and FDA cases. The Civil Division will also have its own dedicated litigation support fund, which will be managed by the Division with oversight from the Associate Attorney General's Office. It is our intent that a shortfall in litigation support funding will no longer be an impediment to cases moving forward. In addition, we will provide funding for two new criminal prosecutors for the Office of Consumer Litigation.

B. Funding for the Criminal Division

The Criminal Division will receive sufficient funding from the HCFAC program to support Strike Forces in South Florida, Houston, and Los Angeles for the next two years. The Strike Forces will also be working in support of the recently-announced "demonstration projects" initiated by the Centers for Medicare and Medicaid Services (CMS) in each of these areas. The demonstration projects will be targeting fraudulent durable medical equipment providers and home health care fraud. The CMS initiative will require all providers to register, undergo background checks, and be subject to unannounced inspections by CMS personnel. By supporting these prosecutorial efforts with CMS, we will ensure the administrative fixes are backed by the deterrence of criminal prosecutions.

C. Funding for the U.S. Attorneys' offices

In addition to providing thirteen new civil litigators for U.S. Attorneys' offices and ensuring that there are always sufficient litigation support funds available for civil cases, we will also ensure

that our criminal efforts are fully supported and expanded. We will create a separate criminal litigation support fund for criminal health care fraud cases. This fund will be managed by EOUSA, and districts needing the funds to support their cases should submit their requests to EOUSA. We will support funding for additional Assistant U.S. Attorney criminal prosecutors in each of the Strike Force districts, including South Florida, Houston, and Los Angeles. In addition, over the course of the next year we will review the needs of other districts, particularly districts that have not received much HCFAC funding in the past but are prosecuting significant numbers of cases.

D. Funding for the Civil Rights Division

We will provide sufficient funding for the Civil Rights Division to fully support its investigation and monitoring expenses in the important CRIPA cases it is undertaking. We would like to encourage the Division to continue to expand its efforts in this area to ensure that deplorable conditions contributing to suffering and deaths in nursing homes, hospitals, facilities for persons with developmental disabilities, and other publicly-funded institutions are corrected.

E. Funding for the Elder Justice and Nursing Home Initiative

We are also fully supportive to the additional needs of our Elder Justice and Nursing Home Initiative. It provides a valuable service in supporting our prosecutors and litigators in failure-of-care cases at nursing homes and long-term care facilities. It has also been funding cutting-edge forensic research in areas such as bruising in elders, which will help further develop the field and experts we need to pursue these cases.

F. Federal Bureau of Investigation

The FBI accounts for over 50% of our health care fraud investigations and referrals and is an integral part of this initiative. With the lifting of the inflationary cap in the HCFAC program this year, the FBI will receive an additional \$4.218 million in FY 2007. We will be working closely with the FBI to ensure that our agents are in place in the districts that are seeing high concentrations of health care fraud or that have trends showing increasing amounts of fraud.

VIII. Accountability, oversight, and results

Our expectation is the districts and components receiving the new initiative funds will be able to demonstrate that the funds they receive are used to augment, not in place of, their current health care fraud and pharmaceutical fraud enforcement efforts. Renewal of these funds each year will require a showing that the funds were used for additional health care or pharmaceutical litigation or prosecutions and the funds generated actual results. Over the course of the next year we will be looking at all aspects of our health care fraud and pharmaceutical fraud program across districts and components and evaluating how effective we are being with the funding we have. We will also be working closely with the FBI and HHS-OIG to determine where the new fraud schemes are emerging to ensure that districts experiencing increased fraud will have the agents and resources to bring the cases to them.

IX. Conclusion

This is the first part of what we hope will be a controlled expansion of the health care fraud and pharmaceutical fraud work of the Department. We will be managing this growth carefully to make sure we are using our resources wisely and having the greatest impact in the field. We commend you for your hard work in preserving the integrity of our publicly-funded health care programs, and in particular, for your dedication to ensuring the health and safety of medical services for our nation. ♦

ABOUT THE AUTHORS

□ **Paul J. McNulty** was sworn in as Deputy Attorney General of the United States on March 17, 2006. Prior to his confirmation by the Senate, Mr. McNulty had served as Acting Deputy Attorney General since November 1, 2005. Mr. McNulty has spent nearly his entire career in public service, with more than two decades of experience in federal and state government. He served as the United States Attorney for the Eastern District of Virginia. Under his leadership, the U.S. Attorney's Office in Eastern Virginia grew more than 20 percent. Before becoming U.S. Attorney, Mr. McNulty directed President Bush's transition team for the Department of Justice and then served as Principal Associate Deputy

Attorney General. In the prior Bush Administration, Mr. McNulty was the Justice Department's director of policy and its chief spokesman. He was Chief Counsel and Director of Legislative Operations for the Majority Leader of the U.S. House of Representatives. He was also Chief Counsel to the House Subcommittee on Crime where he served for eight years. During those years he was a principal draftsman of many anti-terrorism, drug control, firearms and anti-fraud statutes.

□ **William W. Mercer** has been Acting Associate Attorney General (AAG) since September 6, 2006 and also served as the United States Attorney for the District of Montana. Mr. Mercer was Principal Associate Deputy Attorney General for one year. He was Counselor to the Assistant Attorney General and Senior Policy Analyst in the Office of Policy Development. Mr. Mercer was a member of the Attorney General's Advisory Committee (AGAC), and was appointed Chairman in May 2004. He served in this position until he was appointed Principal Associate Deputy Attorney General. AAG Mercer serves on the Advisory Committee on Appellate Rules for the U.S. Court of Appeals for the Ninth Circuit. ☒

We would also like to recognize and thank the following individuals for their tireless efforts on behalf of the Department in putting this initiative together: Daniel S. Fridman, Senior Counsel to the Deputy Attorney General and Special Counsel for Health Care Fraud; William Moschella, the Principal Deputy Attorney General; Lee Lofthus, the Assistant Attorney General for Administration; Mark D. Epley, Senior Counsel to the Deputy Attorney General; and Steven G. Shandy, Senior Program Analyst in the Fraud Section of the Criminal Division.

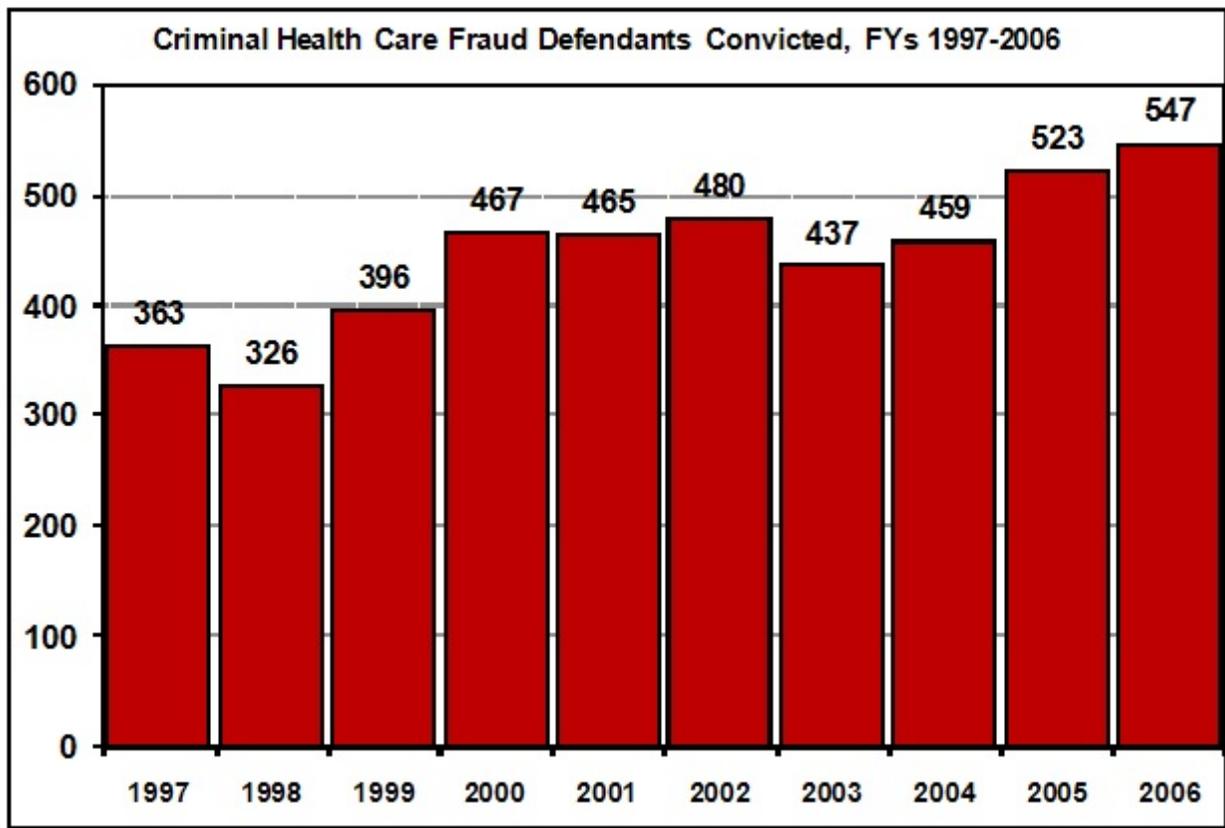


Figure 1

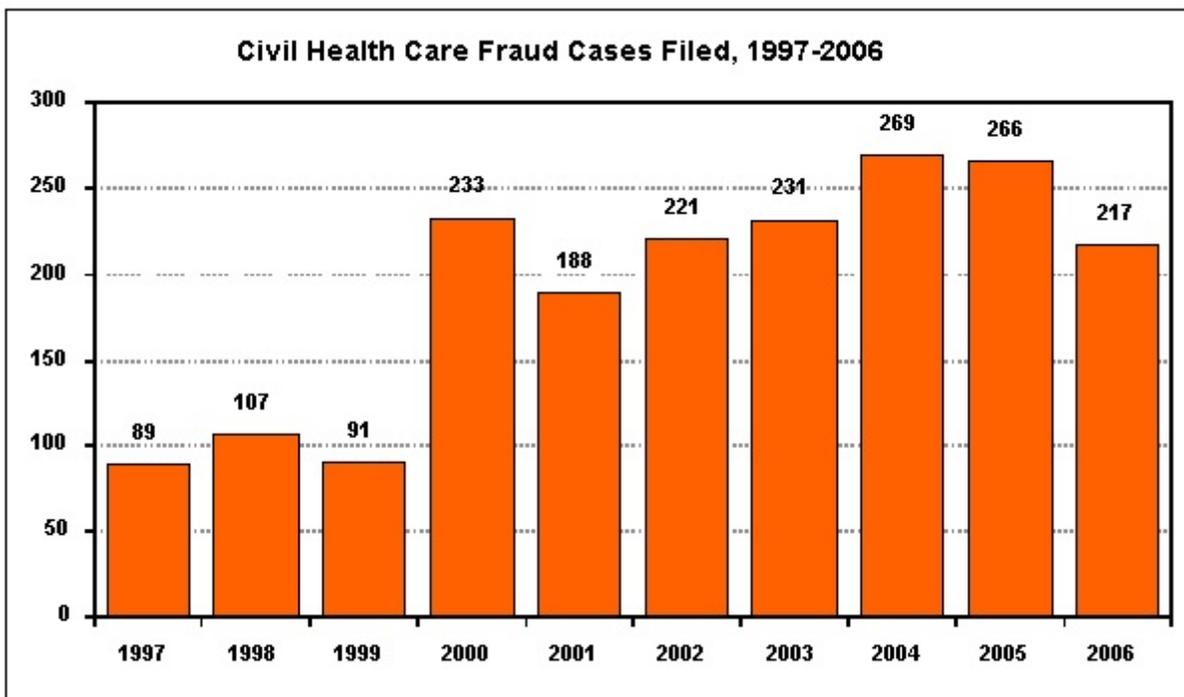


Figure 2

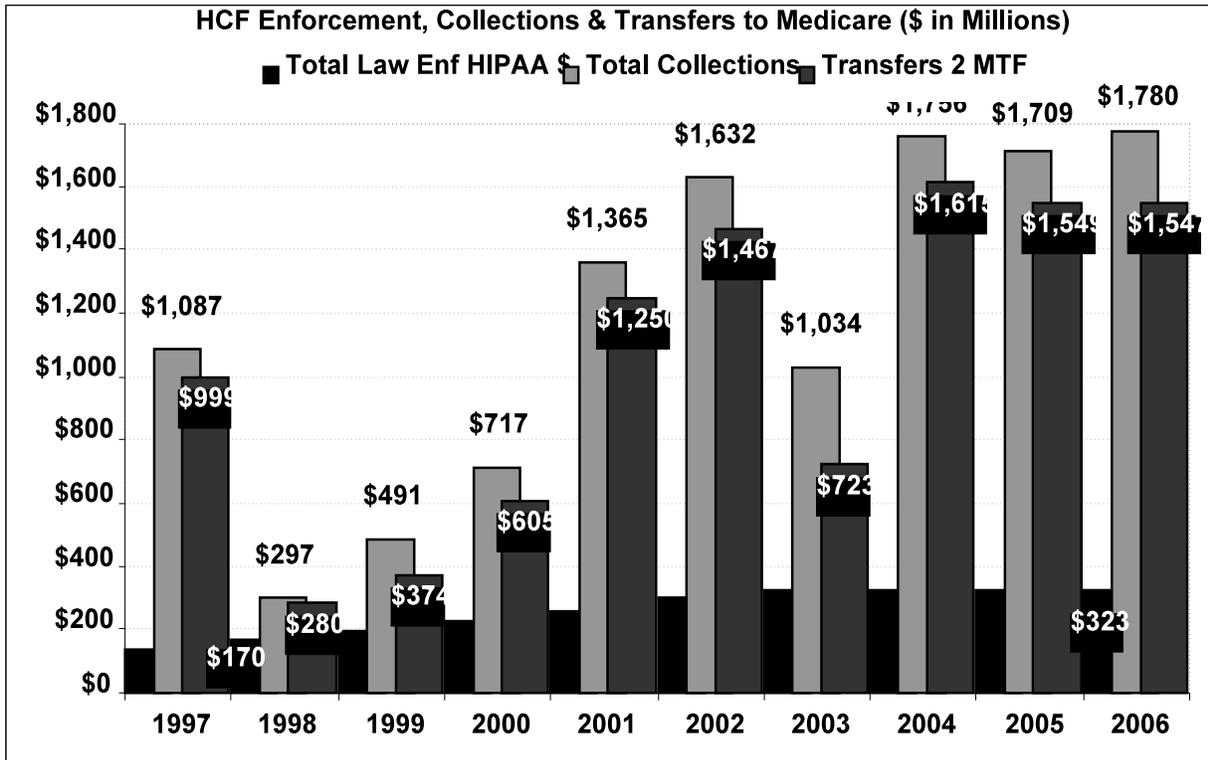


Figure 3

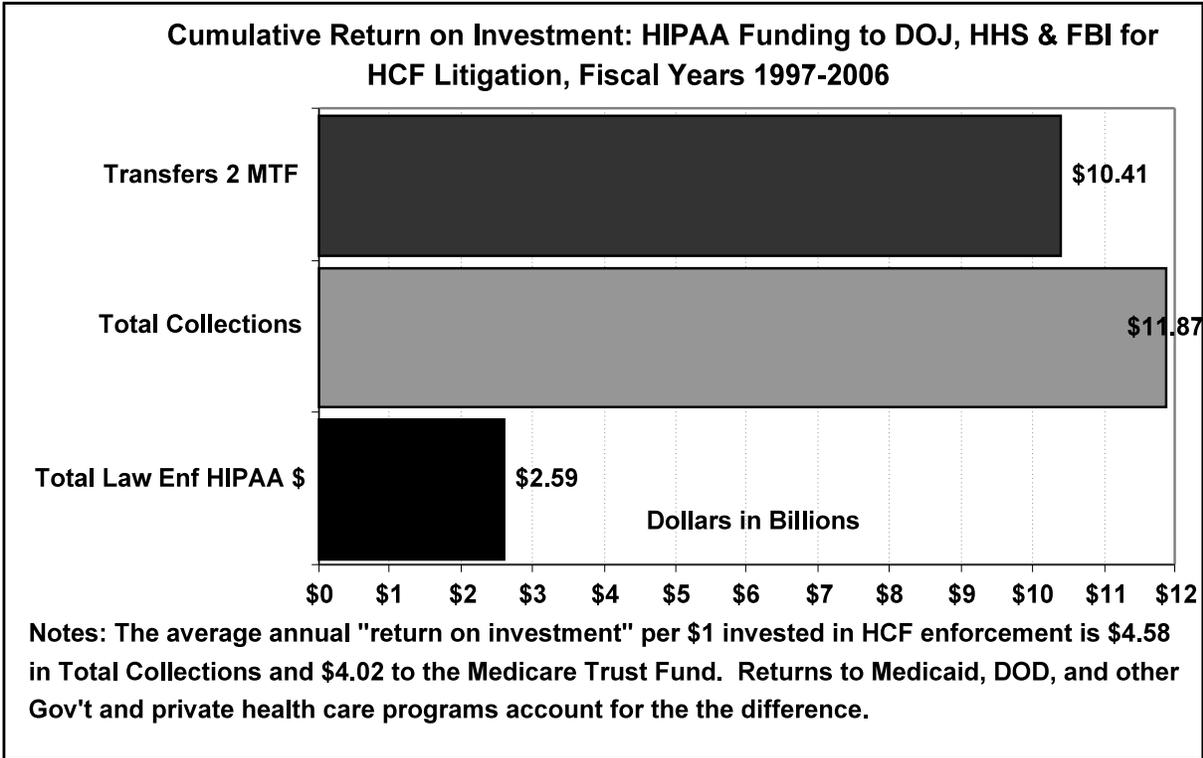


Figure 4

Successfully Prosecuting Health Insurance Portability and Accountability Act Medical Privacy Violations Against Noncovered Entities

Ian C. Smith DeWaal
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Criminal Division
Fraud Section

I. Introduction

What links the following cases?

- A hospice worker who appropriated the identity and credit information of a terminally-ill patient, which he then used to obtain credit cards and run up extensive debt in the name of the dying patient.
- An employee in a doctor's office, which provided medical and rehabilitation services to FBI patients, who disclosed the name and identity of a patient to undercover agents posing as organized crime members, in exchange for cash.
- The owner of a medical billing company who paid his cousin, who worked in a Florida medical clinic, \$5-10 each for approximately 1,130 clinic patient names and Medicare numbers, which he then used to fraudulently bill the Medicare program for \$7.5 million.

Not one of these disclosures was made by a person defined as a "covered entity" as defined by the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (HIPAA), (42 U.S.C. §1320d-1). "Any standard adopted under this part shall apply in whole or part ... to a health plan, a health care clearinghouse or a health care provider ...", yet each of these defendants was convicted of violating the HIPAA criminal medical privacy statute, 42 U.S.C. §1320d-6.

This article will discuss cases which have been brought against individuals who were not covered entities, as well as one against one HIPAA covered entity. It will also review the theory of

prosecution, and explain why these prosecutions are consistent with the June 2005 Opinion from the Office of Legal Counsel (OLC) which concluded that only limited classes of individuals and entities could be directly prosecuted for violations of § 1320d-6. Finally, it will explain why these cases stand as models for future HIPAA privacy prosecutions against individuals who do not fall within those categories.

II. Background of the HIPAA medical privacy criminal statute

The enactment of HIPAA in 1996, represented a comprehensive overhaul of our nation's approach to health care delivery and payment. Of special interest to the Department of Justice (Department) was the new initiative to combat fraud and abuse in the health care industry, which contained new health care fraud criminal statutes including administrative subpoena authority to investigate health care fraud offenses (18 U.S.C. §§ 669, 1035, 1347), and created the advisory opinion process to provide industry guidance on behaviors which would violate the Medicare and Medicaid antikickback statute (42 U.S.C. §1320a-7d). It also enacted the health care fraud and abuse control program (HIPAA § 201(a), 42 U.S.C. §§ 1320a-7c) which includes, *inter alia*, a dedicated health care fraud funding stream for the FBI and Department litigating divisions, as well as the Department of Health and Human Services (HSS) Office of Inspector General (OIG). HIPAA § 201(b), 42 U.S.C.A. §1395i.

The initiative also included the first federal effort to move the United States medical industry to electronic billing and payment transactions, which was predicated on the adoption of a comprehensive scheme to protect the confidentiality of all individually identifiable

health information (medical records in whatever form). HIPAA Sections 262 and 264; 42 U.S.C. §§ 1320d-1 to 1320d-8.

The enacted HIPAA medical privacy statutes included a civil monetary penalty statute which empowered the Secretary of HSS (the Secretary) to impose civil monetary penalties for violation of the future privacy rules by covered entities (42 U.S.C. § 1320d-5) and new criminal penalties for, among other things, the improper "disclosure" or "use" of protected health information by any person, 42 U.S.C. 1320d-6. However, missing from the enacted "penalty" statutes, was a specific substantive privacy law, whose violation would be subject to the new penalties. Congress simply ran out of time to reach a consensus on the substantive provisions of the privacy law, in its rush to enact HIPAA prior to the November 1996 Presidential and Congressional elections.

As a last minute compromise, HIPAA mandated that the Secretary provide recommendations to Congress, within twelve months of its enactment, on what provisions should be included in a comprehensive national medical privacy law. A thirty-six month window for Congress to adopt these critical missing details of the anticipated medical privacy law was also included. Fall-back authority was conferred on the Secretary to promulgate privacy regulations within an additional six months, if Congress failed to meet its self-imposed three-year deadline to enact comprehensive health privacy laws. HIPAA Section 264.

The Secretary transmitted the required recommendations to Congress in August 1997. When Congress failed to adopt a comprehensive privacy law by its self-imposed deadline of August 1999, the Secretary published a draft health care privacy rule on November 3, 1999. 64 Fed. Reg. 59918. The final health care information privacy regulation, published on December 28, 2000 (65 Fed. Reg. 82462) and amended on February 28, 2001 (66 Fed. Reg. 12738) was effective on April 14, 2001. A two year phase-in period was included before the rule becomes enforceable against most covered entities, except for small health plans which were granted a three-year phase-in window. 45 C.F.R. § 164.534.

III. Who can be prosecuted under the HIPAA medical privacy criminal statute?

Once the medical privacy rule became enforceable, the parameters of the bare-bones criminal privacy statute, 42 U.S.C. § 1320d-6, were put in place. One further issue required resolution, however: who was the "person" who could be prosecuted, as that term was used in § 1320d-6? Section 1320d-6 provides:

- (a) A person who knowingly and in violation of this part - -
 - (1) uses or causes to be used a unique health identifier;
 - (2) obtains individually identifiable health information relating to an individual; or
 - (3) discloses individually identifiable health information to another person,shall be punished as provided in subsection (b) of this section.

The question of to whom the criminal statute applied was jointly submitted by the Criminal Division and the Secretary to the Department's OLC, in its role as the arbiter of conflicts in statutory interpretation among Executive Branch agencies. The submission, in part, focused on the question of the definition of "person", as used in the context of the further language of the statute, "in violation of this part". Given the bare-bones structure of the criminal statute, could it only be used to prosecute those who were obligated to comply with the HIPAA medical privacy regulations?

OLC issued an opinion, dated June 1, 2005, which defined "person" to include only those covered entities who were bound to comply with the HIPAA medical privacy rule, namely, health care providers, health plans, or health care clearinghouses, as provided in 42 U.S.C. § 1320d-1 and 45 C.F.R. § 164.104. The opinion stated:

We conclude that health plans, health care clearinghouses, those health care providers specified in the statute, and Medicare prescription drug card sponsors may be prosecuted for violations of section 1320d-6. In addition, depending on the facts of a given case, certain directors, officers, and employees of these entities may be liable directly under section 1320d-6, in accordance

with general principles of corporate criminal liability, as these principles are developed in the course of particular prosecutions. Other persons may not be liable directly under this provision. *The liability of persons for conduct that may not be prosecuted directly under section 1320d-6 will be determined by principles of aiding and abetting liability and of conspiracy liability.*

(Emphasis added). Memorandum for Alex M. Azar II General Counsel, Department of Health and Human Services, Timothy J. Coleman, Senior Counsel to the Deputy Attorney General, *Re: Scope of Criminal Enforcement Under 42 U.S.C. §1320d-6*, available at http://www.usdoj.gov/olc/hipaa_final.htm. [Note: The temporary Medicare prescription drug discount card program, in which "prescription drug card sponsors" provided "discount cards" which allowed participants to purchase discounted prescription drugs, expired on December 31, 2005 and, therefore, is no longer an issue. 42 U.S.C.A. § 1395w-141].

The opinion's important language concerning "aiding and abetting" and "conspiracy liability" has frequently been overlooked by the casual reader.

Other conduct that may not be prosecuted under section 1320d-6 directly may be prosecuted according to principles either of aiding and abetting liability or of conspiracy liability. The aiding and abetting statute renders "punishable as a principal" anyone who "commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission" and anyone who "willfully causes an act to be done which if directly performed by him or another would be an offense against the United States." 18 U.S.C. § 2 (2000). And the conspiracy statute prescribes punishment "if two or more persons conspire ... to commit any offense against the United States ... and one or more of such persons do any act to effect the object of the conspiracy." 18 U.S.C. § 371 (2000) (footnote omitted).

Memorandum for Alex M. Azar II General Counsel, Department of Health and Human Services, Timothy J. Coleman, Senior Counsel to the Deputy Attorney General, *Re: Scope of Criminal Enforcement Under 42 U.S.C. §1320d-6*, available at http://www.usdoj.gov/olc/hipaa_final.htm.

While "conspiracy liability" is included as an alternative theory of prosecution, and included in several cases discussed below, the primary emphasis of this article is on the Section 2 liability. The recognition that persons other than covered entities could be prosecuted for violation of the HIPAA criminal statute through operation of Section 2 of Title 18, United States Code, provided the framework on which several of the HIPAA criminal cases, to date, have been constructed. In these cases, the defendant was not the "covered entity," but merely an individual who worked in the office of a covered entity, or a conspirator who conspired with a workforce member who "caused" the actual covered entity employer to commit acts which constituted a violation of the HIPAA privacy criminal statute. The importance of Section 2 is underscored by the fact that the HIPAA rule, itself, interpreted 42 U.S.C. § 1320d-5 to preclude the assessment of civil monetary penalties against workforce members. *See* 45 C.F.R. § 160.402. Only "a covered entity is liable ... for a civil monetary penalty ... violation based on the act or omission of any agent of the covered entity, including a workforce member acting within the scope of the agency ...", subject to exceptions not relevant here. 45 C.F.R. §160.402 (c).

The prosecution of individuals for HIPAA medical privacy criminal violations beyond the closed universe of covered entities was explored in this magazine two years ago by AUSA Peter Winn. *Criminal Prosecutions Under HIPAA*, 53 UNITED STATES ATTORNEYS' BULLETIN, 21 (2005).

It is possible that the principal message of the OLC opinion that only covered entities may be *directly* prosecuted for violations of the HIPAA medical privacy criminal statute continues to obscure the critical corollary finding that Section 2 (and conspiratorial liability) provides an acceptable alternative path to prosecute non-covered entities. AUSA Winn explained:

As originally enacted in 1948, 18 U.S.C. § 2(b) provided that 'whoever willfully causes an act to be done which if directly performed by him would be an offense against the United States, is punishable as a principal.' 62 Stat. 684 (1948). In 1951, Congress added the words 'or another' to the statute.

Id. at 24. The Senate Report accompanying the proposed amendment explained the purpose of the amendment as follows:

This section is intended to clarify and make certain the intent to punish aiders and abettors regardless of the fact that they may be incapable of committing the specific violation which they are charged to have aided and abetted. Some criminal statutes of title 18 are limited in terms to officers and employees of the Government, judges, judicial officers, witnesses, officers or employees or persons connected with national banks or member banks.

Section 2(b) of title 18 is limited by the phrase "which if directly performed by him would be an offense against the United States," to persons capable of committing the specific offense. . . . It has been argued that one who is not a bank officer or employee cannot be a principal offender in violation of section 656 or 657 of title 18 and that, therefore, persons not bank officers or employees cannot be prosecuted as principals under section 2(g). Criminal statutes should be definite and certain.

It thus seems clear that when it enacted the 1951 amendment to Section 2(b), Congress intended to ' . . . make certain the intent to punish (persons embraced within Section 2) . . . regardless of the fact that they may be incapable of committing the specific violation. . . if an employee of a covered entity intentionally caused a disclosure of a patient's confidential health information, which action, if directly performed by another, that is, the covered entity, would be an offense against the United States, then the employee is punishable as a principal, that is, as if the covered entity, itself, had performed the act. An employee may not be, according to the OLC Opinion, within the category of persons to whom the criminal statute directly applies. The employee could, however, be punishable as a principal under Section 2(b) if they committed an act which would be an offense *if committed directly by the covered entity*.

Criminal Prosecutions Under HIPAA, 53 UNITED STATES ATTORNEYS' BULLETIN, 24-25 (2005).

A number of appellate cases have endorsed the operation of Section 2(b) to convict individuals of crimes for which they did not have the ordinary requisite legal "status", while only a narrow limitation on the reach of this provision was imposed by one court. An early case, *United States*

v. Scannapieco, 611 F.2d 619 (5th Cir. 1980), upheld the conviction of a firearms dealer's employee under 18 U.S.C. § 2(b) for causing a violation of 18 U.S.C. § 922, which prohibits a firearms dealer from selling and delivering a firearm to a buyer who was not an authorized person under the statute. The conviction was upheld despite the fact that the dealer was not present and was in no way responsible for the illegal sale and the consequent violation of the law. Similarly, a defendant who presented false information during a gun transaction, thereby causing a gun dealer to make false entries in a required gun sales transaction log, was successfully prosecuted through operation of Section 2(b), even though this gun dealer was also innocent of any crime. *United States v. Armstrong*, 898 F.2d 734 (9th Cir. 1990).

The Seventh Circuit recently concluded, in a securities fraud case, that a "tippee" who induces an unsuspecting, and innocent insider to breach a duty of confidentiality and disclose confidential information on which the tippee intentionally trades, may be successfully prosecuted for "insider trading" through invocation of Section 2(b). *United States v. Evans*, Slip Opinion, 2007 WL 1412546 (7th Cir. May 15, 2007). Also, a defendant may be successfully prosecuted for "producing" false identification documents in violation of 18 U.S.C. §1028 (a)(1) through operation of 18 U.S.C. § 2(b), where he did not produce the records himself, but caused an innocent government clerk to unknowingly produce the false documents. *United States v. Rashwan*, 328 F.3d 160, 165 (4th Cir. 2003).

One court limited the use of Section 2(b) in a unique situation involving an Occupational Safety and Health Administration (OSHA) statute, which is distinguishable from the HIPAA medical privacy criminal statute. The court in *United States v. Shear*, 962 F.2d 448 (5th Cir. 1992), reviewed a criminal prosecution of both the employer and an employee for an OSHA violation which resulted in the death of another employee. The underlying criminal OSHA statute applied expressly only to *employers*. 29 U.S.C. § 666(e) [in contrast, the HIPAA privacy criminal statute applies to "any person." 42 U.S.C. 1320d-6]. While upholding the conviction of the employer, the court overturned the conviction of the employee, finding that the express purpose of the statute was to protect employees. The court also held that the application of the statute only to employers specifically precluded operation of

Section 2(b) to impose culpability on an employee. Fifteen years have elapsed since the *Shear* decision, and no appellate court has cited it to extend the limitation on Section 2(b) beyond the OSHA statute, lending credence to the conclusion that this limitation is unique to the OSHA setting.

IV. HIPAA medical privacy convictions and indictments against noncovered entities

The four convictions, to date, for violations of the HIPAA medical privacy criminal statute have all been against individuals who were not covered entities, but were either workforce members of a covered entity or someone who conspired with a workforce member of a covered entity to unlawfully disclose and use protected health information.

The first conviction for a violation of the HIPAA medical privacy statute came in August 2004, in the Western District of Washington, and preceded the issuance of the June 2005 OLC legal opinion. The defendant in *United States v. Gibson*, 2:04-CR-0374-RSM, 2004 WL 2188280 (W.D. Wash. Aug. 19, 2004), was employed by the Seattle Cancer Care Alliance. During his employment, he obtained personal identifying health information from the medical record of a cancer patient, and used that information to fraudulently obtain four credit cards, with which he accumulated \$9,000 in charges in the patient's name. Gibson entered a plea of guilty to a violation of 42 U.S.C. § 1320d-6 (a)(3) and (b)(3). At sentencing, U.S. District Court Judge Ricardo S. Martinez exceeded the prosecutor's recommendation of twelve months and sentenced Gibson to sixteen months. According to the press release from the United States Attorney's Office for the Western District of Washington, Judge Martinez called the identity theft a "vicious attack on someone fighting for his life." Press Release, United States Attorney's Office, Western District of Washington, Seattle Man Gets Prison Time in First Ever HIPAA Conviction (Nov. 5, 2004) (on file with author).

While this conviction preceded the opinion from the OLC, and the charging information did not explicitly incorporate 18 U.S.C. § 2(b), the defendant took no action to reopen the conviction, possibly because "whether specified or not, § 2(b) is considered embodied in full in every federal indictment." *U.S. v. Michaels*, 796 F.2d 1112, 1118 (9th Cir.1986). "All indictments must be read

in effect, then, as if the alternatives provided by 18 U.S.C. § 2 were embodied in each count thereof." *U.S. v. Howick*, 263 F.3d 1056, 1064-65 (9th Cir. 2001) (citations omitted).

The next HIPAA medical privacy conviction involved an employee of a doctor's office which was under contract to provide physicals and medical treatment to FBI agents. According to a press release from the United States Attorney's Office for the Southern District of Texas, Liz Arlene Ramirez was convicted, on March 6, 2006, of selling confidential medical information of an FBI Special Agent to a person she believed to be working for a drug trafficker. The purchaser was actually a confidential source who recorded their meetings. Defendant Ramirez pleaded guilty to Count 1 of the Indictment, which charged a violation of 42 U.S.C. § 1320d-6 (a)(2) and (b)(3), wrongfully obtaining protected health information for personal gain and to cause personal harm. She was sentenced in August 2006, to a term of imprisonment of six months. *United States v. Ramirez*, 7:05-CR-00708 (S.D. Tex. Aug. 30, 2006). News release available at <http://www.usdoj.gov/usao/txs/releases/March2006/060307-Ramirez.htm>.

This year saw the first successful HIPAA medical privacy criminal conviction after trial. This case arose in the Southern District of Florida where defendant, Fernando Ferrer Jr., obtained Medicare patient information from codefendant, Isis Machado, who was employed as the front-desk coordinator of a Florida medical clinic. *United States v. Ferrer and Machado*, 06-60761 CR (S.D. Fla. Sept. 11, 2006). Defendant Ferrer used the illegally obtained patient information to submit \$7 million in fraudulent Medicare claims. The codefendants were charged with:

A conspiracy to

- Exceed authorized access to a protected computer and by such conduct further the intended fraud by obtaining things of value exceeding \$5,000, in violation of 18 U.S.C. § 1030(a)(4) and (c)(3)(A);
- Knowingly possess and use without lawful authority, the means of identification of another person, in violation of 18 U.S.C. § 1028A (a)(1);
- Obtain individual health information relating to an individual, with the intent to sell, transfer, use and cause to be used, that

information for personal gain in violation of 42 U.S.C. § 1320d-6 (a)(2) and (b)(3); and

The defendants were also charged with seven additional substantive counts for violation of the provisions cited in the conspiracy count. The jury returned a verdict of guilty against Ferrer on January 24, 2007. Coconspirator Machado pleaded guilty to the conspiracy count and was sentenced to three years probation on April 27, 2007 and ordered to pay restitution of \$2,505,883.48.

A final case against a noncovered entity was charged against an insurance representative employed by Hospital Billing and Collection Services, Ltd. (HBCS), a health care clearinghouse for not-for-profit hospitals nationwide, who was indicted in November 2006 in the District of Delaware. The defendant in *United States v. Williams*, 1:06-CR00129-UNA, (D. Del. Nov. 16, 2006), worked on a team that primarily processed claims for Froedtert Hospital, located in Milwaukee, Wisconsin. The indictment alleged that Williams illegally accessed HBCS's computers for the purpose of stealing personal identity information of patients.

Count one of the four-count indictment charged that Williams conspired with a previously indicted coconspirator to:

- Knowingly violate HIPAA, 42 U.S.C. § 1320d-6 (a)(2) and (b)(3); and
- Knowingly and with intent to defraud exceed authorized access to a protected computer, and by such conduct further the intended fraud to obtain things of value exceeding \$5,000, in violation of 18 U.S.C. § 1030(a)(4); during and in relation to a felony in violation of 18 U.S.C. § 1030(a)(4), to knowingly possess and use, without lawful authority, means of identification of other people in violation of 18 U.S.C. § 1028A; and

Count 2 of the indictment alleged that she obtained medical records of more than 400 patients in violation of 42 U.S.C. § 1320d-6 (a)(2) and (b)(3), and 18 U.S.C. § 2.

Williams pleaded guilty on April 26, 2006 to Count 2 (HIPAA) and Count 4 (aggravated identity theft). With respect to the HIPAA count, defendant admitted to exceeding her authorized access to the HBCS computers by printing out personal identity and medical information of over 400 patients, and selling these lists to her coconspirator, who she knew intended to use the patients' personal information in an illegal activity.

As this article was being submitted for publication, William's sentencing had been scheduled for July 31, 2007. Press Release, United States Attorney's Office, Former Medical Biller Accused of Stealing Patients' Identities (Nov. 17, 2006) (on file with author).

One additional HIPAA criminal case was commenced against a covered entity and bears review. In February 2007, in the Western District of Kentucky, Paul Hollern, a licensed chiropractor, was indicted on various charges, including a HIPAA medical privacy criminal charge, for allegedly videotaping his patients unknowingly or under false pretenses as they were treated by students enrolled in his chiropractic business training program, and then disclosing these tapes to his business students upon their graduation. Count 3 of the indictment alleged that Hollern knowingly disclosed individually identifiable health information in violation of HIPAA, for commercial advantage and personal gain in violation of 18 U.S.C. § 1320d-6 and 18 U.S.C. § 2. *United States v. Hollern*, 3:06CR82-S, Superseding Indictment (W.D. Ky. Feb. 5, 2007). Patrick Howington, *Kentucky Chiropractor Sees Empire Crumble*, THE COURIER J. (Louisville), Apr. 22, 2007, at A1.

V. Conclusion

The HIPAA prosecutions discussed in this article should serve as models for utilizing 18 U.S.C. § 2 as the means by which noncovered entities may be prosecuted for causing violations of the HIPAA medical privacy criminal statute, 42 U.S.C. § 1320d-6, consistent with the June 2005 OLC opinion. While this article has focused on section 2, it is worthwhile to note that the OLC opinion also provided its imprimatur to use the conspiracy statute, 18 U.S.C. § 371 as well, to reach conspiracies between covered entities and others. In the examples discussed above, the conspiracy was often between an individual workforce member who caused the covered entity to violate HIPAA, and an outsider unrelated to the covered entity. The bottom line is that AUSAs should be increasingly comfortable investigating and prosecuting HIPAA medical privacy criminal violations by individuals who do not fall within the enumerated classes of covered entities.❖

ABOUT THE AUTHOR

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The views expressed in this article are the personal views of the author alone and should not be considered in any way to represent the views of the United States Department of Justice.

Medicaid Fraud Enforcement

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I. Introduction

In October of 2005, in the District of Massachusetts, the Swiss pharmaceutical manufacturer Serono paid \$704 million to resolve civil and criminal claims arising from the marketing of its drug, Serostim. No. 05-545:10-17-05, (D. Mass. Oct. 17, 2005). The following year, in October of 2006, a federal jury in the Northern District of Illinois found that AmeriGroup, a managed care provider, had committed systematic and extensive fraud by not enrolling pregnant women and others with expensive health conditions. The trial judge awarded the government \$334 million in damages and in penalties based on over 18,000 false claims. *United States ex rel. Tyson v. AmeriGroup*, 2007 WL 781729 (N.D. Ill. Mar. 13, 2007). In the Eastern District of North Carolina, a pharmacist was sentenced in 2005 to thirty-three months imprisonment and ordered to make restitution in excess of \$2 million after it was found that he billed the government for thousands of prescriptions for nursing home residents—prescriptions he had not dispensed. *United States v. Pierce*, No. 7:04-cr-93-1FE (E.D.

N.C. Apr. 26, 2005). In December of 2006, in the Southern District of Ohio, Angel Health Care, Inc., and its owner, were found guilty of health care fraud and making false statements after it was determined that they billed for skilled nursing services that had not been provided to homebound patients. No. CR-2-05-250 (S.D. Ohio Dec. 18, 2006).

What do these matters have in common? Unlike the great majority of health care fraud cases brought by the Department of Justice (Department) that allege fraud against the Medicare program, these cases all involved fraud against state-run Medicaid programs.

II. Medicaid Program

Many people tend to think of Medicaid as solely a *state* health care program. In fact, Medicaid is the federal government's second largest health care program—surpassed only by the Medicare program. Medicaid was established in 1965 to provide health services to individuals and families with low incomes and few resources, and is jointly funded by the states and the federal government. In fiscal year 2006, the federal government paid \$190 billion to the states and the District of Columbia to match their expenditures in providing health care services to over 60 million Americans, or 20% of the population. It's been estimated by the Congressional Budget

Office that the states and the District of Columbia expended an additional \$110 billion to fund Medicaid, for a total annual expenditure of over \$300 billion.

Each state administers its own program and, within broad national guidelines established by federal statutes, regulations, and policies, each state establishes its own eligibility standards, determines the type, amount, duration, and scope of services, and sets the rate of payment for services. The federal statute requires that state Medicaid programs offer the following, at a minimum.

- Inpatient hospital services.
- Outpatient hospital services.
- Prenatal care.
- Vaccines for children.
- Physician services.
- Nursing facility services for persons aged twenty-one or older.
- Family planning services and supplies.
- Rural health clinic services.
- Home health care for persons eligible for skilled-nursing services.
- Laboratory and x-ray services.
- Pediatric and family nurse practitioner services.
- Nurse-midwife services.
- Federally qualified health-center (FQHC) services.
- Ambulatory services of an FQHC that would be available in other settings.
- Early and periodic screening, diagnostic, and treatment (EPSDT) services for children under age twenty-one.

States are free to offer services over and above these minimum requirements.

Medicaid policies for eligibility, services, and payment, are complex and vary considerably, even among states of similar size or geographic proximity. Thus, a person who is eligible for Medicaid in one state may not be eligible in another state, and the services provided by one state may differ considerably in amount, duration, or scope, from services provided in a similar or neighboring state. In addition, state legislatures

may change Medicaid eligibility, services, and/or reimbursement, during the year.

Generally, the groups served by Medicaid are very low-income parents, children, seniors, and people with disabilities. As an example, the state of Maryland requires that a family of four, to be eligible for Medicaid benefits, must have a monthly income of less than \$475 and countable assets (excluding a home and personal property) of \$3200. Although 75% of Medicaid enrollees are children and their parents, 70% of spending for benefits goes toward care for the program's elderly and disabled enrollees.

The federal matching funds paid to finance the Medicaid program are often referred to as the "FFP"—shorthand for the "Federal Financial Participation" in each state. The FFP differs from state-to-state, and year-to-year, depending on each state's poverty level. The wealthiest states receive a federal match of only 50%, while states with lower income levels receive a larger federal match. The highest FFP paid by the federal government for fiscal year 2007 is 76% for the state of Mississippi. In other words, for every dollar spent by the state of Mississippi to reimburse health providers for services rendered to eligible Medicaid patients, the federal government will reimburse Mississippi 76 cents. The Department of Health and Human Services publishes a state-by-state, year-by-year breakdown of the FFP at <http://aspe.hhs.gov/HEALTH/FMAP.HTM>.

Despite these large federal expenditures to support the state Medicaid programs, Medicaid recoveries have represented a relatively small percentage of total health care fraud recoveries reported by the Department to Congress. For example, in fiscal year 2005, the Department returned over \$1.5 billion to the Department of Health and Human Services (HHS) as a result of the Department's health care fraud enforcement efforts. Of that amount, though, only \$63.6 million was returned to HHS as the federal portion of the Medicaid program. (The states' portion of Medicaid restitution, in the fraud cases brought by the Department, is often made by defendants directly to the affected states, and therefore are not reflected in this figure.)

Thanks in part to the efforts highlighted at the outset of this article, the Department's Medicaid recoveries will certainly increase in coming years. However, we have been criticized by some who perceive our failure to adequately address fraud

against the Medicaid programs around the country. Critics point out that while it is true that Medicare is a more costly federal program (estimated to exceed \$407 billion in FY 2007) and that one would therefore expect a larger percentage of recoveries on behalf of Medicare, the ratio of Medicare to Medicaid federal spending is only slightly more than 2:1—far less than the recovery ratios obtained in the past by the Department.

III. Enhanced Medicaid enforcement efforts

This disparity of Medicaid recoveries, when compared to Medicare, caused some in Congress to consider reforms that would enhance federal Medicaid enforcement efforts. The result was the enactment of provisions as part of the Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006) (DRA) to: (1) provide incentives to states to enact their own false claims acts (modeled on the federal law), to encourage whistleblowers to file actions based on false claims to state Medicaid programs; (2) mandate that entities receiving Medicaid money train their employees about the applicability of the federal False Claims Act to Medicaid claims; and (3) provide increased resources for the HHS to investigate and police Medicaid fraud.

A. Incentives to states

The DRA created a financial incentive for states to enact legislation imposing liability on individuals or entities that submit false or fraudulent claims to state Medicaid programs. This incentive takes the form of an increase by ten percentage points of the state's share of any amounts recovered in a state action brought under a qualifying law. 42 U. S. C. § 1396a(a)(68). In order for a state to qualify for this incentive, the state law must meet certain enumerated requirements that are set forth in the DRA, as set forth below.

- (1) The law must establish liability to the state for false or fraudulent claims, as described in the federal False Claims Act.
- (2) The law must contain provisions that are "at least as effective in rewarding and facilitating *qui tam* actions" for false or fraudulent claims as those contained in the federal False Claims Act.
- (3) The law must contain a requirement for filing an action under seal for sixty days

with review by the State Attorney General.

- (4) The law must contain a civil penalty that is not less than the amount of the civil penalty authorized under the federal False Claims Act (\$5,000 to \$10,000 per false claim).

The DRA charged the Inspector General (OIG) of the HHS to work in consultation with the Attorney General to determine whether a state statute meets these requirements and, therefore, qualifies for the enhanced Medicaid recovery in future False Claims Act settlements. To help guide the states in drafting and enacting qualifying statutes, the OIG published its *Guidelines for Evaluating State False Claims Acts*, 71 Fed. Reg. 48552 (Aug. 21, 2006), and has since assessed a dozen state statutes that have been submitted for OIG review. As of the date of this publication, five states have been found to qualify for the enhanced Medicaid recovery: Virginia, Massachusetts, Hawaii, Illinois, and Tennessee. A current count of qualifying states can be found at the OIG web page: <http://oig.hhs.gov/fraud/falseclaimsact.html>

The Congressional Budget Office has estimated that this measure will directly reduce federal Medicaid spending by \$334 million for the period 2006 through 2010.

B. Mandatory False Claims Act training

Section 6032 of the DRA mandates, in pertinent part, that

any entity that receives or makes annual payments under the State [Medicaid] plan of at least \$5,000,000, as a condition of receiving such payments, shall —

(A) establish written policies for all employees of the entity (including management) and of any contractor or agent of the entity, that provide detailed information about the False Claims Act ..., any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse...;

(B) include ... detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and

(C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

42 U.S.C. § 1396a(a)(68)(A). The Congressional Budget Office has estimated that this measure will directly reduce federal Medicaid spending by \$70 million for the period 2006 through 2010.

C. Other Medicaid enforcement efforts

Medicaid Integrity Program (MIP): The DRA mandated the establishment, by the Centers for Medicare and Medicaid Services (CMS), of a MIP, which is charged with developing a comprehensive five-year plan to combat Medicaid fraud and abuse. Specifically, CMS must engage contractors to: (a) perform reviews of providers of items or services under the Medicaid program to determine whether fraud, waste, or abuse has occurred; (b) audit Medicaid claims, including cost reports, consulting contracts, and risk contracts; (c) identify overpayments to individuals or entities receiving federal funds; and (d) educate providers and managed care entities regarding payment integrity and quality of care. 42 U.S.C. §1396u-6(b)(1).

The DRA also provided CMS with enhanced funding in order to accomplish this task: \$5 million in 2006; \$50 million in 2007 and 2008; and \$75 million per year thereafter for the operation of the MIP. 42 U.S.C. §1396u-6(e)(1). In addition, the DRA funds CMS to hire 100 additional full-time employees to support and assist the states in combating fraud and abuse in the Medicaid program. 42 U.S.C. §1396u-6(e)(3).

OIG Funding: For each of fiscal years 2006 through 2010, the DRA appropriated \$25 million for Medicaid enforcement activities of the OIG. The OIG is required to report to Congress, no later than 180 days after the end of each fiscal year, on its use and the effectiveness of this increased funding. To advance its Medicaid enforcement efforts, the Inspector General convened a training conference at the National Advocacy Center in September, 2006, that included over 125 representatives from his office, the United States Attorney community, Medicaid Fraud Control Units, CMS, FBI, and the Government Accountability Office.

Medicare-Medicaid (Medi-Medi): The DRA also has expanded the so-called "Medi-Medi" project to include all states. In 2001, CMS, the FBI, and the State of California, initiated this project in order to analyze and compare both Medicare and Medicaid data to determine fraudulent patterns—such as instances in which both programs were billed for the same service on behalf of the same beneficiary. Since 2001, another nine states have established Medi-Medi projects. These states include Florida, Illinois, Ohio, North Carolina, Washington, New Jersey, Texas, Pennsylvania, and New York. During this time, CMS reported to Congress that it had generated 335 investigations. With the enactment of the DRA, CMS will receive a steady funding stream that peaks at \$60 million annually by FY 2010 and each year thereafter, in order to expand this project to all states.

D. Applicability of the Federal False Claims Act to Medicaid fraud

Despite the states' administration of most aspects of the Medicaid program, and only partial federal funding, courts have consistently held that federal funding and the extensive federal regulation of the program are sufficient to make false claims submitted to Medicaid actionable under the False Claims Act.

The False Claims Act, was amended in 1986 to specifically define the term "claim" to include

any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c). Even before this definition of the term "claim" was added to the False Claims Act, many courts had held that the requirement that a claim be submitted to the United States was satisfied when a claim was filed with a state or local government which paid the claim with federal funds. *See, e.g., United States ex rel. Fahner v. Alaska*, 591 F. Supp. 794, 798 (N.D. Ill. 1984) (Medicaid case); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (false claim made to local authorities who paid it from a joint construction account containing both federal and

state funds actionable under the False Claims Act). The definition of a claim was added expressly for the purpose of overruling a Seventh Circuit case that upheld the dismissal of a False Claims Act claim on the grounds that there was no federal injury. *United States v. Azzarelli Construction Co.*, 647 F.2d 757 (7th Cir. 1981). S. REP. NO. 99-345 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5287.

In *United States ex rel. Totten v. Bombardier Corporation*, a divided panel of the United States Court of Appeals for the District of Columbia Circuit held that false claims submitted to a recipient of federal funds do not fall within the scope of the False Claims Act unless the federal-funding recipient, in turn, resubmits the claims to a U.S. Government officer or employee, even where it is alleged and shown that the United States would bear the loss. 380 F.3d 488 (D.C. Cir. 2004). Judge Merrick Garland wrote a lengthy dissent in *Totten*, explaining that the majority's statutory construction was inconsistent with the False Claims Act's text and legislative history, and with the statute's underlying purposes. *Id.* at 502-16.

One district court seized upon the majority's opinion in *Totten* to hold that claims submitted to a state Medicaid program were not subject to False Claims Act liability. *United States ex rel. Atkins, M.D. v. McInteer, M.D.*, 345 F.Supp.2d 1302, 1304 (N.D. Ala. 2004). However, the Department continues to assert in briefs and oral argument that this case, as well as the majority's decision in *Totten*, was wrong, for all of the reasons set forth in the Judge Garland's dissenting opinion. Even assuming that *Totten* was correctly decided, the Department maintains that *Totten* is inapplicable in Medicare or Medicaid cases for at least two reasons. First, when someone defrauds Medicare or Medicaid, there is no question that it is the taxpayers, not some private corporation, that pay the bill. Second, even though the government relies on private contractors to process Medicare and Medicaid claims, the presentation of a false claim for payment to one of these contractors by a health care provider always results in the presentment of a false or fraudulent claim for payment of the federal share of Medicaid. Even the *Totten* majority recognized that False Claims Act liability attaches when a defendant submits a false claim for payment to a federal government grantee, who then re-presents that claim to the federal government.

A handful of courts, including some since the *Totten* decision was handed down, have applied the False Claims Act to fraud committed against the Medicaid program. *See, e.g., United States ex rel. Tyson v. AmeriGroup Illinois, Inc.*, 2005 WL 2667207 (N. D. Ill., Oct. 17, 2005); *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975); *United States v. Catena*, 500 F.2d 1319, 1322 (3d Cir. 1974); *United States ex rel. Fahner v. Alaska*, 591 F.Supp. 794, 798 (N.D. Ill. 1984); *United States v. Jacobson*, 467 F.Supp. 507 (S.D.N.Y. 1979); *United States ex rel. Davis v. Long's Drug, Inc.*, 411 F.Supp. 1144, 1146-47 (S.D. Cal. 1976). It is important to note that these cases stand for the proposition that the federal False Claims Act attaches liability only to the federal portion of the Medicaid claim, and not the states' share.

IV. Conclusion

In recent years, and as illustrated by recent results, the Department has placed an increasing emphasis on detecting and prosecuting Medicaid fraud. With the enactment of state False Claims Acts, relators in *qui tam* actions can be expected to assert a variety of Medicaid fraud claims. The additional resources provided by the DRA to the OIG and to CMS to detect and police Medicaid fraud also may result in an increased number of referrals to United States Attorneys' offices of these types of matters. In sum, we can expect that fraud against the Medicaid programs across the nation will constitute an ever-increasing piece of our health care fraud workload.❖

ABOUT THE AUTHOR

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Fraudulent Health Insurer Prosecutions

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I. Introduction

It is a known fact that many Americans cannot afford health insurance for themselves and their families. Unfortunately, the dearth of affordable health insurance creates an opportunity for enterprising criminals to prey upon individuals who need insurance by selling them bogus policies. Instead of receiving the peace of mind that should accompany their purchase of health insurance, the victims of such scams not only confront staggering medical bills, but also face being stranded without needed medical treatment for ongoing illnesses.

The large economic and emotional toll these schemes exact presents a compelling reason for criminal prosecution. At the same time, these fraud cases present unique challenges to investigators and prosecutors.

II. A case study: Employers Mutual, LLC

Between November 2000 and December 2001, over 20,000 people throughout the United States signed up for health insurance coverage through a company called Employers Mutual, LLC, a company incorporated in Nevada that operated out of California (hereinafter "Employers Mutual"). Although enrollees in the Employers Mutual health insurance plan paid approximately \$13 million in premiums, an analysis performed by a company hired to process the outstanding medical claims showed that, at the time it ceased operating, Employers Mutual owed in excess of \$20 million in unpaid medical claims.

In April 2004, a grand jury in the Central District of California returned an indictment against James Graf, William Kokott, and Kari Hanson on a variety of charges relating to the Employers Mutual fraud. Hanson pled guilty pursuant to a cooperation agreement with the government and, in April 2007, received a term of

imprisonment of eighteen months. Kokott died prior to facing trial on the charges. Graf, the lead defendant, went to trial in the fall of 2005 and the jury convicted him of a variety of charges, including conspiracy and mail fraud. In February 2007, the court sentenced Graf to a term of imprisonment of twenty-five years.

A. Exploitation of the regulatory scheme

Many purchasers of the Employers Mutual plan believed it had been reviewed and regulated by a government entity. Indeed, this belief was fueled by the distribution of materials, during the operation of Employers Mutual, indicating that the plan operated in compliance with the Employee Retirement Income Security Act of 1974 (ERISA). Employee benefit plans which are subject to ERISA are generally preempted from state insurance regulation.

Many operators of fraudulent insurance schemes exploit a key difference in the regulation of insurance companies and ERISA plans. This difference works to their advantage.

Each state regulates insurance companies within its boundaries. Prior to selling insurance in a specific state, a new insurance company is subject to regulatory scrutiny. Among other things, state regulators review the backgrounds of those who will be operating the company and investigate its financial health. In short, when an insurance company fails to meet a state's criteria, it is barred from selling its products in that particular state. The public, including insurance agents, may readily ascertain whether an insurance company has a certificate of authority to operate in their particular state by contacting their state department of insurance.

Unscrupulous operators know that they cannot pass the regulatory scrutiny of state insurance departments to gain authorization to operate as an insurance company. They lack the necessary financial capital and experience to qualify. As a way to conceal these deficiencies, they falsely claim that their plans are covered by ERISA and that, therefore, state departments of insurance lack the authority to regulate them.

Health care benefits offered through ERISA plans are regulated by the United States Department of Labor. Typically, ERISA-covered plans are offered through employers or unions. Unlike insurance companies, ERISA plans need not receive any type of approval before they start operating, or file any documentation with the Department of Labor prior to providing benefits. The reporting requirements imposed on ERISA-covered plans do not mandate that a plan file documentation until after the first year of a plan's operation. Hence, it may be difficult to discern whether a particular plan is the work of an unscrupulous operator or legitimately established pursuant to ERISA's requirements, and therefore actually exempted from state insurance regulation.

In the case of Employers Mutual, Graf sold the Employers Mutual plan through hundreds of licensed insurance agents. Since the Employers Mutual plan was promoted as governed by ERISA, the insurance agents relied upon the representation that the plan was, in fact, operated in accordance with ERISA standards and not subject to state insurance regulation.

B. The utilization of materials from any civil investigation

In the case of Employers Mutual, the Employee Benefits Security Administration of the United States Department of Labor conducted a civil investigation, and ultimately filed a civil enforcement action against Employers Mutual and its operators in the United States District Court for the District of Nevada. Although a civil investigation may not be performed in every case, such investigations certainly provide a good source of potential evidence to be used in a criminal case. The civil investigation of Employers Mutual was concluded prior to the commencement of the criminal investigation. In the event that civil and criminal investigations are proceeding simultaneously, it is important to avoid any possible allegation that the civil investigation is serving as a stalking-horse for the criminal investigation. *See United States v. Stringer*, 408 F. Supp. 2d 1083 (D. Or. 2006) (court dismissed indictment because it found that criminal investigation occurred under the auspices of a civil investigation); *United States v. Scrushy*, 366 F. Supp. 2d 1134 (N.D. Ala. 2005) (court suppressed statements made during a deposition taken by the Securities and Exchange Commission because it found that the civil and criminal investigations were intertwined and not parallel).

During a civil investigation, investigators may secure documents, visit offices, and conduct interviews. Prosecutors may collect invaluable evidence, including admissions by those conducting the fraud, while reviewing these materials. In the Employers Mutual case, Department of Labor investigators discovered an important original document. As part of the promotion of the insurance plan, according to an insurance agent who testified at trial, Graf distributed a fraudulent letter claiming that a well-known insurance company was insuring the health care plan offered through Employers Mutual. This letter, which appeared to be signed by an employee of the legitimate insurance company, was actually signed by Hanson at the request of Graf, according to Hanson's trial testimony. Investigators from the Department of Labor uncovered the original version of the letter, with the ink signature, during their visit to Employers Mutual's offices. It was a significant piece of evidence in the criminal case because the fact that the original was found in this location corroborated the testimony that Graf distributed the fraudulent letter.

If the civil investigation results in a civil action being filed, the perpetrators or witnesses may have testified in an official proceeding. Such testimony may yield valuable evidence, such as admissions by the targets of the investigation.

C. The criminal investigation

By and large, a criminal investigation into a fraudulent health insurer requires no different tools or tactics than those employed in any substantial white collar criminal investigation. However, certain aspects of these types of investigations present particular challenges.

First, because these fraudulent organizations are not actual insurance companies, the issuance of a grand jury subpoena to the company for records may not yield the desired results. If circumstances permit, obtaining and executing a search warrant is the best way to obtain company records, including marketing materials, information about who has been paying premiums to the company, and claims history, both paid and unpaid.

Second, the perpetrators of these schemes seldom speak to or send written materials directly to their victims. Moreover, they do not use centralized "boiler rooms" to sell their fraudulent products. Rather, licensed insurance agents are used to market their plans. The use of these agents

serves the purpose of those operating the scheme for a number of reasons.

- Insurance agents, who have a portfolio of clients, provide the pool of victims who will purchase the fraudulent insurance. An existing pool of clients saves the criminals marketing time and expense.
- It automatically lends an air of legitimacy to the program being sold. Members of the public mistakenly believe that any product offered by a licensed insurance agent must be trustworthy and reliable.
- The use of licensed insurance agents to execute the sale of the fraudulent insurance serves as a shield designed to insulate those orchestrating the fraud from criminal liability.

To avoid the defense argument that the insurance agents contrived the fraudulent misrepresentations concerning the program, it is important, during the course of the investigation, to develop corroborating evidence of what the fraudulent operators said and did, to supplement the agents' testimony. For instance, perpetrators may have faxed or e-mailed some fraudulent marketing materials to insurance agents. It may be possible to trace these materials back to the perpetrators.

Third, calculating the loss figure in a fraudulent insurer case may present some difficulties. If, for example, a doctor submits a bill for \$1,000, even a legitimate insurance company would not pay the entire amount. Rather, the claim would be processed and paid pursuant to the terms of the insurance program.

During the course of the civil enforcement action, the court appointed an independent fiduciary to manage Employers Mutual and pay claims. As part of his duties, the independent fiduciary hired a third-party administrator to adjudicate the unpaid claims pursuant to the terms of the coverage which was offered to the victims. In a case where no such claims adjudication has been done, it is not likely that the investigating agencies will have the necessary funding to cover the costs of processing and adjudicating a large number of claims, including the elimination of any duplicate claims. As with any fraud case, in the event that no reasonable estimate of loss is possible, gain may be employed as an alternative loss figure. However, relying on the number resulting from this methodology will provide a significantly lower figure to present at trial and

sentencing, underestimating the financial impact of the fraud.

Fourth, those operating fraudulent health insurance schemes often attempt to create a veneer of legitimacy. For instance, Graf, Kokott, and Hanson did not take all the premium moneys for themselves. Rather, a small percentage of the claims were actually paid. In addition, as established by testimony at trial, Graf and Kokott, among other things, hired a third-party administrator to process claims and consulted with a number of attorneys regarding the implementation of the Employers Mutual plan. Fraudulent health insurance operators frequently consult with attorneys during the course of the fraud, and it is important, prior to bringing charges, to obtain these communications, if warranted. Often it is possible to obtain these materials during the course of the investigation by filing a motion pursuant to the crime fraud exception to the attorney-client privilege. *See Clark v. United States*, 289 U.S. 1, 14 (1933) (the attorney-client privilege does not apply "where the relation giving birth to it has been fraudulently begun or fraudulently continued"); *United States v. Laurins*, 857 F.2d 529, 540 (9th Cir. 1988) (the "attorney-client privilege does not protect communications between an attorney and client which further a crime or fraud"). It also may be possible to obtain such communications through a waiver of the corporate attorney-client privilege by a receiver or bankruptcy trustee installed to unwind the defunct company. *See Commodity Futures Trading Commission v. Weintraub*, 471 U.S. 343 (1985) (trustee of a corporation in bankruptcy has the authority to waive the corporation's attorney-client privilege with respect to communications which occurred prior to the bankruptcy).

Based on the appearance of legitimacy that may have been created during the course of the fraud, the perpetrators may attempt to present a bad business person defense. Basically, such individuals may argue that, although they were incompetent and unqualified to run an insurance company, they lacked any intent to defraud the victims. Because of the possibility of this defense being raised, presenting a case based largely on an actuarial analysis showing that the premiums paid never could have covered the claims incurred is risky. Rather, it is imperative to show that those charged with the fraud made material, fraudulent misrepresentations and omissions.

D. The charging decisions

Once the investigation is finished, the next decision concerns the appropriate charges to bring in the case. A number of charges may apply.

Mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343) are always good charges, and the law on these statutes is well-established. Usually, fraudulent health insurance schemes involve extensive use of both the wires and the mail. If nothing else, premium moneys are usually sent by mail or wired into a bank account. Evidence supporting money laundering charges (18 U.S.C. § 1956 or 18 U.S.C. § 1957) also exists in most cases, providing additional tried and true charges.

An issue to be considered in determining what charges to bring is whether criminal statutes aimed more specifically at fraud in the health care arena would be of benefit. The criminal code contains a variety of such statutes.

Certain statutes address ERISA-regulated plans and insurance plans. For instance, 18 U.S.C. § 1033 criminalizes a variety of behaviors relating to entities "engaged in the business of insurance." The statute defines the "business of insurance" as "the writing of insurance" or "the reinsuring of risks" by "an insurer." 18 U.S.C. § 1033(f)(1). The statute defines "insurer" as "any entity the business activity of which is the writing of insurance or the reinsuring of risks, and includes any person who acts as, or is, an officer, director, agent, or employee of that business." 18 U.S.C. § 1033(f)(2). With respect to ERISA-covered plans, 18 U.S.C. § 664 prohibits the embezzlement and stealing of any assets belonging to any employee welfare benefit plan. The statute defines employee welfare benefit plan as "any employee benefit plan subject to any provisions of title I of the Employee Retirement Income Security Act of 1974." 18 U.S.C. § 664.

In many instances, there is no benefit to bringing the types of charges discussed above. Any charge requiring the government to prove that the crime involved either insurance or an employee benefit plan adds an additional element of proof that must be established beyond a reasonable doubt. To establish that the crime involved insurance or an employee benefit plan governed by ERISA most likely would require the prosecution to, among other things, present expert testimony on these subjects. Such testimony may be complicated, particularly in the case of ERISA. The better choice is to avoid the unnecessary

quagmire of whether the fraud involved either insurance or an employee benefit plan and to concentrate on proving that the scheme, however classified, constituted a fraud.

A number of statutes target fraud involving health care benefit programs. Health care benefit programs are statutorily defined to include "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual." 18 U.S.C. § 24. Although there is an absence of case law analyzing whether a fraudulent health insurance provider qualifies as a health care benefit program, based on the plain reading of the statute, it appears that such entities do qualify.

There are a variety of charges relating to crimes involving such programs. These crimes include the following: 18 U.S.C. § 1347 (health care fraud); 18 U.S.C. § 669 (theft and embezzlement from a health care benefit program); and 18 U.S.C. § 1035 (false statements relating to health care matters).

E. The trial

In the *Employers Mutual* case, Graf went to trial on a variety of charges, including conspiracy (18 U.S.C. § 371), mail fraud (18 U.S.C. § 1341), theft/embezzlement from a health care benefit program (18 U.S.C. § 669), unlawful monetary transactions (18 U.S.C. § 1957), obstruction of justice (18 U.S.C. § 1503) and tax evasion (26 U.S.C. § 7201). The jury convicted Graf of conspiracy and obstruction of justice, as well as multiple counts of mail fraud, theft/embezzlement from a health care benefit program, and unlawful monetary transactions.

During the preparation for, and the course of a trial, a number of evidentiary issues may arise. For instance, the indictment may allege that the company in question did not comply with state regulatory requirements. As part of its proof at trial, the government may need to show that no state department of insurance had authorized the company to operate within its bounds. If the charging document states that this is the case, the government would need to call additional witnesses from each state in which the program was sold. These types of trials, by nature, often require several weeks of court time even without these added witnesses whose testimony would be time-consuming, tedious, and repetitive in nature. Under these circumstances, the added time and monetary commitment needed to prepare and present these witnesses would result in little or no

benefit. Clearly, finding another way to put on the proof without calling these additional witnesses would be beneficial.

The first option in this circumstance is to attempt to reach a stipulation with the defense. Given that the fact being stipulated to, that a company was not authorized to sell insurance in a particular state, is readily ascertainable, the defense may well agree to stipulate. However, in the absence of a stipulation, another option does exist. Pursuant to Federal Rule of Evidence 803(10), the absence of a public record or entry may be proven through a certification which complies with Federal Rule of Evidence 902. Instead of calling a witness for each state, a certification for each state may be admitted into evidence.

Another evidentiary challenge which may be faced in these types of cases concerns the admission of evidence regarding the amount of unpaid medical claims left behind in the wake of the fraud. Most likely, the evidence concerning the unpaid medical claims will be presented in the form of a summary of voluminous records pursuant to Federal Rule of Evidence 1006. However, the records which are the basis of such a summary must, themselves, be admissible into evidence, even though the underlying records are not being admitted. *See United States v. Janati*, 374 F.3d 263, 272 (4th Cir. 2004). Therefore, the government must show that the underlying unpaid claims are admissible under an exception to the hearsay rule, most likely the business records exception in Federal Rule of Evidence 803(6). Given that, at the time of the trial, the fraudulent entity will not be operational and the participants in the fraud will not be testifying for the government (absent a cooperation agreement), finding a witness to establish that the claims constitute business records will be important.

F. The sentencing

In light of the Supreme Court's holding in *United States v. Booker*, 543 U.S. 220 (2005), that the United States Sentencing Commission Guidelines (Guidelines) are now only advisory, prosecutors face new obstacles to securing the imposition of substantial prison terms for white collar criminals. However, even in this new era, the unique harm caused by fraudulent health insurance operators should still provide prosecutors with sufficiently compelling arguments to persuade courts to impose significant terms of imprisonment.

A number of the sentencing factors that a court imposing sentence must now consider, in addition to the applicable guideline range under the Guidelines, militate in favor of imposing significant sentences for defendants who run fraudulent health insurance companies. The sentencing factors that a court must consider include:

- (1) the nature and circumstances of the offense and the history and characteristics of the defendant;
- (2) the need for the sentence imposed-
 - (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
 - (B) to afford adequate deterrence to criminal conduct;
 - (C) to protect the public from further crimes of the defendant....

18 U.S.C. § 3553(a).

At sentencing, the prosecution may argue that the financial harm caused by fraudulent health insurers, albeit typically quite large, dwarfs when compared to the health consequences of not receiving needed medical treatment and the emotional and psychological toll suffered by those who purchased the fraudulent insurance. There are undoubtedly victims who delayed, or perhaps ultimately did not receive, critical medical treatment as a result of the fraud, including treatments for life-threatening diseases such as cancer. Moreover, these victims may have suffered the additional trauma of receiving repeated collection notices and phone calls from medical providers demanding payment for services rendered. Evidence concerning the unique harms caused by this particular type of fraud will, hopefully, induce the court to impose a substantial sentence. These considerations contributed to the imposition of a term of imprisonment of twenty-five years against Graf in the Employers Mutual case.

III. Conclusion

The investigation and prosecution of fraudulent health insurers may be challenging, time-consuming, and costly. The case of Employers Mutual required several years of intensive investigation, discovery, pretrial litigation, trial litigation, and sentencing litigation. In addition to the resources of the Department of

Justice, a number of other agencies devoted substantial resources to the investigation and prosecution of the case, particularly the Employee Benefits Security Administration of the United States Department of Labor and the Internal Revenue Service. Moreover, the litigation has not ended since Graf has filed a notice of appeal of his conviction and sentence. However, the danger that fraudulent health care insurers pose to the public warrants the devotion of resources to these important criminal cases.❖

ABOUT THE AUTHOR

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Understanding the Office of Inspector General Advisory Opinion Process and Survey of Recent Notable Opinions

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I. Introduction

In the decade since its inception, the advisory opinion process of the Department of Health and Human Services's Office of Inspector General (OIG) has become an integral part of the OIG's efforts to promote integrity in federal health care programs. Established by Congress in the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936 (1996) (codified as amended at 42 U.S.C. § 1320a-7d (2007)), the advisory opinion process offers health care industry stakeholders a mechanism for determining whether existing or proposed arrangements run afoul of specific fraud and abuse authorities, including the federal antikickback statute. Congress assigned the opinion process to the Secretary of the Department of Health and Human Services (the HHS), who, in turn, delegated it to the OIG. Mindful of the Department of Justice's (Department's) lead role in criminal enforcement, Congress directed that advisory opinions be issued in consultation with the Attorney General. The advisory opinion process became effective in February 1997. Since then, the OIG has reviewed

more than 600 requests for opinions from industry stakeholders and has issued 159 advisory opinions.

The benefits of advisory opinions for the industry are self-evident.

- Eliminate legal guesswork.
- Mitigate potential legal problems.
- Yield insight into the OIG's interpretation of fraud and abuse statutes and regulations.

The advisory opinion process also benefits the government.

- Provides a means for encouraging fraud prevention.
- Supplements existing regulatory and sub-regulatory guidance.
- Establishes compliance benchmarks.
- Puts industry stakeholders on notice about legal requirements.
- Informs industry stakeholders about the OIG's view of the law.

Moreover, advisory opinions can reassure risk-adverse parties and counter the perceived chilling effect of the antikickback statute on certain innocuous and beneficial activities.

The advisory opinion process has helped the OIG formulate and recommend better approaches

to antifraud enforcement and regulation; identify areas where more guidance is needed; and, in a complex and fluid business environment, better distinguish between *bona fide* business transactions and disguised fraud schemes. The OIG's understanding of health care arrangements has been informed by the review of hundreds of detailed advisory opinion submissions and informal consultations with industry stakeholders. As a result, the Industry Guidance Branch (IGB)—the group of attorneys within the OIG responsible for the advisory opinion process—has become a repository of expertise on the antikickback statute and related fraud and abuse matters. Advisory opinions reflect the OIG's thinking on the application of the antikickback statute, the "safe harbor" regulations, and other fraud and abuse authorities to specific fact patterns. They offer useful guidance for government prosecutors and agents evaluating the merits of kickback cases or responding to arguments of defense counsel. IGB attorneys are available to consult with prosecutors and other law enforcement personnel.

This article briefly reviews the statutory and regulatory requirements of the OIG's opinion process, case law addressing OIG advisory opinions, and recent notable opinions.

II. Statutory and regulatory requirements

The advisory opinion process is found at section 1128D(b) of the Social Security Act (the Act), 42 U.S.C. § 1320a-7d(b) (2007); *see also* the implementing regulations at 42 C.F.R. Part 1008 (2006), and Frequently Asked Questions (FAQs) About the Advisory Opinion Process, at <http://oig.hhs.gov>. By statute, the OIG can opine in five areas: (1) what constitutes prohibited remuneration under the federal antikickback statute, section 1128B(b) of the Act, or the civil monetary penalties law at section 1128A(i)(6) of the Act; (2) whether an arrangement, or proposed arrangement, fits in a statutory exception to the antikickback statute; (3) whether an arrangement, or proposed arrangement, fits in a regulatory "safe harbor" under the antikickback statute; (4) what constitutes a payment to reduce or limit services under section 1128A(b) of the Act; and (5) whether any activity or proposed activity constitutes grounds for sanctions under sections 1128, 1128A, or 1128B of the Act. *See* Section 1128D(b)(2) of the Act; 42 U.S.C. § 1320a-7d(b)(2) (2007); 42 C.F.R. § 1008.5 (2006).

Opinion requests come from a wide variety of health care industry stakeholders, including hospitals, physicians, suppliers, ambulance services, pharmaceutical manufacturers, and others. Most requests seek guidance about the application of the federal antikickback statute and related civil monetary penalty (CMP) and exclusion authorities. *See* 42 U.S.C. § 1320a-7b(b) (2007); 42 U.S.C. § 1320a-7a (2007); 42 U.S.C. § 1320a-7(b) (2007). Other areas of significant interest include the CMP for beneficiary inducements at 42 U.S.C. § 1320a-7a(a)(5) (2007), the CMP for paying physicians to reduce or limit care at 42 U.S.C. § 1320a-7a(b) (2007), the exclusion authority for charging Medicare substantially more than other customers at 42 U.S.C. § 1320a-7(b)(6) (2007), and the civil monetary penalty authorities for employing an excluded individual at 42 U.S.C. § 1320a-7a(a)(6) (2007).

Notably, the OIG does not opine on the application of the physician self-referral law at section 1877 of the Act, 42 U.S.C. § 1395nn (commonly known as the "Stark law"). In section 1877(g)(6) of the Act, Congress directed the Secretary of the HHS to issue opinions addressing the physician self-referral law. 42 U.S.C. § 1395nn(g)(6) (2007). The Secretary delegated the responsibility for those opinions to the Centers for Medicare and Medicaid Services (CMS), which conducts its own advisory opinion program, in consultation with the OIG and the Department, as appropriate. The OIG and CMS coordinate internally when a requesting party seeks an opinion from both agencies on the same arrangement. (The OIG has authority to impose administrative sanctions for knowing violations of the physician self-referral law. 42 U.S.C. §§ 1395nn(g)(3) and (4) (2007).)

The OIG's goal is to "render meaningful and informed opinions based on a complete and comprehensive understanding of the relevant facts and circumstances of a given arrangement, protecting in the process only those arrangements that pose little or no risk of fraud or abuse to the Federal health care programs." 63 Fed. Reg. 38311, 38312 (July 18, 1998). A favorable opinion protects the requesting parties from OIG sanctions for the approved arrangement. To obtain an opinion, a requesting party must submit a detailed written description of its proposed or existing business arrangement, including the identities of any business partners. 42 C.F.R. § 1008.36 (2006). The OIG may request

additional information, as necessary, to ensure a full and complete understanding of the facts. The OIG often engages in informal discussions with requesting parties to better understand an arrangement. However, the requesting party must certify all facts, in writing, under penalty of perjury. If untruthfulness or material omissions are later discovered, a favorable opinion is without force and effect. 42 C.F.R. §§ 1008.38, 1008.45(b)(1) (2006). By statute, the OIG charges a fee for the costs of preparing the opinion. 42 C.F.R. § 1008.31 (2006). The statute and regulations provide that the OIG must issue an opinion within sixty business days. 42 C.F.R. § 1008.43 (2006).

The OIG will not opine on hypotheticals, model arrangements, or arrangements of third parties, nor will the OIG issue an opinion to an anonymous requestor or to a trade association. 42 C.F.R. § 1008.15 (2006). If an arrangement is proposed, the requesting party must certify its good faith intent to implement the arrangement, if the opinion is favorable. 42 C.F.R. § 1008.38(b) (2006).

Advisory opinions are fact-specific determinations based on the totality of the facts and circumstances presented. Consequently, even small differences in facts between arrangements that may appear similar in nature and scope can affect the outcome of an opinion. By statute, an OIG advisory opinion is binding only as to the Secretary and the party or parties requesting the opinion. Section 1128D(b)(4)(A) of the Act; 42 U.S.C. § 1320a-7d(b)(4)(A) (2007). An opinion may not be relied upon by any individual or entity other than the requesting party. Moreover, the regulations provide that "[a]n advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law." 42 C.F.R. § 1008.55(b) (2006). The statute bars the government from introducing a party's failure to seek an opinion into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B. Section 1128D(b)(4)(B) of the Act; 42 U.S.C. § 1320a-7d(b)(4)(B) (2007); 42 C.F.R. § 1008.55(a) (2006).

Importantly, the OIG will not accept a request or issue an opinion when "the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the HHS or another

government agency." 42 C.F.R. § 1008.15(c)(2) (2006). Accordingly, newly submitted opinion requests are vetted early in the process within the OIG, as well as with the Department, the Federal Bureau of Investigation (FBI), and the Medicaid Fraud Control Units. Later, draft opinions are circulated for comment to the Department. OIG coordinates with the Department through the Criminal Division, which, in turn, circulates request summaries and draft opinions to counterparts in the Civil Division, the designated civil and criminal health care fraud coordinators in the United States Attorneys' offices, and the FBI Health Care Fraud Unit. The goal of this process is to ensure that advisory opinions do not interfere with, or adversely impact, ongoing investigations or litigation. The OIG also seeks comment from the HHS's Office of General Counsel/CMS Division, to ensure accuracy with respect to programmatic issues.

Under the regulations, parties may withdraw their opinion requests at any time before the opinion is issued. 42 C.F.R. § 1008.40 (2006). In practice, the majority of requests are withdrawn, typically because parties conclude from discussions with OIG counsel that they are likely to receive an unfavorable opinion or for reasons unrelated to the opinion request, such as a collapse of financing or withdrawal of venture partners. As a result, the number of issued opinions is lower than the number of requests evaluated, and the issued opinions tend to skew disproportionately toward favorable results. Attorneys reading advisory opinions for guidance purposes should be mindful that a health care arrangement they may have under consideration might have more in common with dubious arrangements withdrawn from OIG consideration than with low-risk arrangements ultimately approved in favorable advisory opinions.

Congress barred the OIG from opining in two specific areas. First, the OIG may not opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. Section 1128D(b)(3)(A) of the Act; 42 U.S.C. § 1320a-7d(b)(3)(A) (2007). Thus, in arrangements where fair market value is relevant, the OIG must rely on the requesting party's certification that payments are fair market value. This reliance effectively shifts an important compliance burden to the requesting party, since a favorable opinion predicated on a requesting party's fair market value certification is without force and effect if the certification is untrue.

Moreover, while the OIG cannot determine whether an amount paid is fair market value, the OIG is permitted to scrutinize the party's valuation methodology for suspicious elements, such as variability based on the volume or value of referrals. Second, the OIG may not opine on whether an individual is a *bona fide* employee within the requirements of section 312(d) of the Internal Revenue Code of 1986. Section 1128D(b)(3)(B) of the Act; 42 U.S.C. § 1320a-7d(b)(3)(B) (2007). As with fair market value, where this issue is relevant, the OIG must rely on certifications. In practice, the OIG has declined to accept certifications where the circumstances suggest they are not credible.

The regulations provide that the OIG may rescind, terminate, or modify opinions where the public interest requires. 42 C.F.R. § 1008.45 (2006). In particular, the OIG may rescind an opinion retroactively to the original date of issuance where relevant and material facts were not fully, completely, and accurately disclosed to the OIG. The OIG may terminate an opinion prospectively, if, for example, changes in reimbursement rules or clinical practice cause an arrangement to become unacceptably risky under the fraud and abuse laws. 63 Fed. Reg. 38311, 38320 (July 16, 1998). Requesting parties are given notice and an opportunity to respond. *Id.* In the case of a termination, parties are given a reasonable opportunity to unwind their arrangements. To date, the OIG has modified one opinion based on facts subsequently ascertained, but has never rescinded an opinion. *See* OIG Advisory Opinion No. 98-5 (Apr. 24, 1998); Final Notice of Modification of OIG Advisory Opinion No. 98-5 (Aug. 17, 2001) (modifying the opinion to reflect a favorable result). *Available at* <http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.html>

Perhaps the most challenging aspect of the advisory opinion process is issuing binding opinions about the application of the federal antikickback statute, an intent-based, criminal statute. It is virtually impossible to determine whether parties have acted, or will act, "knowingly and willfully," based on written submissions from the parties and without independent investigation. This is particularly true because parties to questionable arrangements may have incentives to shade the truth or hide the ball. Moreover, determining actual intent is properly the province of the judicial system. Thus, although the OIG sometimes considers inferences

of intent, the typical approach has been largely to set aside the issue of intent and instead to engage in a risk assessment, approving only those arrangements where, even if the parties were to have bad intent, the risk that an arrangement would involve payments for referrals or might result in harm to the federal programs or beneficiaries is very low. For example, the OIG looks for objective, verifiable facts and safeguards that demonstrate that an arrangement will not lead to overutilization, increased program costs, inappropriate patient steering, or unfair competition. When risks are relatively low, the OIG also considers whether an arrangement offers identifiable, nonspeculative community benefits, such as increased patient access to needed health care or savings to the public treasury. However, even substantial community benefits will not save an arrangement with elevated fraud and abuse risks and insufficient safeguards. With this risk-based approach, the bar for obtaining a favorable opinion is very high.

The OIG's advisory opinions are made available to the public on the OIG website at <http://oig.hhs.gov>. As a matter of practice, the OIG redacts identifying information, but that same identifying information is made available to OIG's government partners. *See* 42 C.F.R. § 1008.47 (2006); 63 Fed. Reg. 38311, 38321 (July 16, 1998).

III. OIG advisory opinions and case law

Congress enacted the advisory opinion process despite the objections of law enforcement, including the OIG and the Department. A primary concern was the potential misuse or abuse of advisory opinions by industry stakeholders to thwart or complicate ongoing investigations and criminal prosecutions. For example, concerns were raised that defendants might claim they lacked unlawful intent because they relied on opinions issued to other parties, even if the facts were distinguishable or the reliance was erroneous or constituted an after-the-fact justification. Concerns were further raised that prosecutions might be hampered by new factual issues and additional evidentiary burdens related to the existence of advisory opinions.

Some investigators and prosecutors have had defendants raise the existence of advisory opinions to defend against government allegations of impropriety, but the frequency of such circumstances is difficult to gauge. A survey of

reported judicial decisions reveals only a handful that mention an OIG advisory opinion.

In *Klaczak ex. rel. U.S. v. Consolidated Medical Transport*, 458 F. Supp. 2d 622 (N.D. Ill. 2006), relators urged that OIG Advisory Opinion 99-2, an unfavorable opinion regarding a suspect ambulance pricing scheme, supported their theory that hospital defendants had engaged in an illegal kickback scheme involving ambulance services. The court, citing caveats in the opinion addressing reliance by third parties, use of the opinion as evidence, and scope of the opinion, concluded that "[i]n light of these limitations, it is difficult to envisage how this letter can support any inferences concerning specific contracts in the case *sub judice*." *Id.* at 685-86.

In *Robert Wood Johnson University Hosp., Inc. v. Thompson*, No. Civ. A. 04-142 (JWB), 2004 WL 3210732, (D. N.J. Apr. 15, 2004), a hospital challenged a Medicare demonstration project on the grounds, *inter alia*, that the demonstration improperly waived the CMP for payments to physicians to reduce or limit hospital services. The defendant, Secretary of HHS, conceded that the demonstration project violated the CMP on its face. The court concluded that the demonstration project participants' failure to obtain a favorable OIG advisory opinion assuring OIG's forbearance from imposition of sanctions "leaves the Demonstration Project in fatal conflict with the CMP." *Id.* at *12. The court noted that an OIG opinion previously issued about a similar arrangement "provides no substantive support for implementation of the present Demonstration Project. It was limited strictly to the facts of the application then before the OIG with 'no applicability to other arrangements, even those that appear similar in nature or scope.'" *Id.* at n.15

The most extensive judicial treatment of an OIG advisory opinion occurs in *Zimmer v. Nu Tech Medical, Inc.*, 54 F. Supp. 2d 850 (N.D. Ind. 1999). There, the plaintiff, a manufacturer of medical products, sought a declaratory judgment that an agreement with the defendant, an independent contractor, was void because the agreement violated the antikickback statute. The plaintiff relied upon an unfavorable opinion it had obtained from the OIG. *Id.* at 854-55. The defendant countered that the opinion should not be considered because the plaintiff had supplied the OIG with inaccurate, misleading, and incomplete information. *Id.* at 856. The court disagreed, finding the OIG's determination that the parties' agreement posed more than a minimal

risk of abuse to be reasonable and noting that the disputed agreement itself had been submitted to the OIG for review. *Id.* at 857. The court concluded that "[b]ased on the statute's broad scope and the Agreement's clear language, the court agrees with the OIG's conclusion in Advisory Opinion 98-1 that the parties' Agreement might involve prohibited remuneration under the statute." *Id.* at 862. The defendant further argued that the advisory opinion did not find an actual violation, but only determined that the agreement might involve prohibited remuneration, if the parties had the requisite unlawful intent. In rejecting this argument and granting declaratory judgment, the court observed that the plaintiff was not required to prove that a prosecution would result and concluded that, in light of the plaintiff's OIG advisory opinion, "any future performance under the Agreement would appear likely to amount to a knowing and willful action." *Id.* at 863.

IV. Survey of recent notable opinions

Since 1997, the OIG has issued advisory opinions to a wide variety of industry stakeholders and across the spectrum of business and charitable arrangements. A summary chart of opinions by subject area is attached as *Appendix A* at pages 34-35. The following discussion briefly summarizes notable opinions of recent vintage. Each of the following OIG Advisory Opinions may be found on the web at <http://oig.hhs.gov>.

In **OIG Advisory Opinion No. 06-2 (Mar. 21, 2006)**, the requestor, a durable medical equipment (DME) and orthotics manufacturer and supplier, proposed two management programs it would offer physicians to enable them to profit from the provision of DME and orthotics to their patients. The OIG concluded that the proposed programs, whether viewed separately or collectively, posed significant risk of fraud and abuse. Under the first program, physicians would purchase or rent DME and orthotics from the requestor and, in turn, bill private pay patients for them. The requestor would provide management services to the physicians to operate the program. Federal beneficiaries would be excluded. Under the second program, the requestor would pay participating physicians for certain inventory management and related services in connection with the requestor's products sold to federal and nonfederal patients. The fees would be calculated, in part, as a percentage of revenues generated from sales to nonfederal patients.

The OIG's unfavorable opinion concluded that the first program essentially amounted to a "contractual joint venture" for private pay business with all of the hallmarks of an abusive program, including little or no business risk to the physicians. The OIG observed that the attempted "carve out" of federal business was not dispositive, since a wholly private pay arrangement may violate the antikickback statute by disguising remuneration for federal business as payments purportedly related to nonfederal business. The OIG also noted that any attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services (*e.g.*, management agreement, lease, and others), and then to qualify each separate contract for protection under a safe harbor, may be ineffectual and place parties at risk for prosecution.

The OIG concluded that the percentage fee structure in the second program was inherently problematic because such fees relate to the volume or value of business generated. The fact that the fee would be based wholly on nonfederal business and be paid wholly out of nonfederal funds was also not dispositive, as the source of the funding for a potential kickback payment is not determinative of the intent of the payment and since it might be relatively easy to inflate the percentage applied to the nonfederal business to reward the generation of federally payable business. Notably, the OIG did not accept the requestor's certification of fair market value with respect to the second program's additional ancillary contracts.

Finally, the OIG observed that arrangements for manufacturers and suppliers to furnish "management" or similar services to physicians require close scrutiny. No apparent business rationale appears to exist for a manufacturer or supplier to forge such ties with physician practices, apart from the potential for generating additional business for the manufacturer or supplier.

In **OIG Advisory Opinion No. 06-03 (Apr. 18, 2006)**, the requestor, a pharmaceutical company, sought to operate two patient assistance programs (PAPs). The PAPs would give requestor's drugs free to financially-needy patients, including Medicare beneficiaries enrolled in the Medicare Part D outpatient prescription drug benefit. The drugs would be provided, without cost, to a Part D plan, any beneficiary, or the Medicare program. The

assistance would be particularly important to beneficiaries needing help affording drugs during the "coverage gap" in the Part D benefit.

Although the requestor would be giving free drugs to Medicare beneficiaries, the OIG concluded that it would not impose sanctions because the arrangement contained a number of safeguards that reduced the risk that the free drugs would induce beneficiaries to obtain Medicare-payable drugs. This opinion is notable as the first approved pharmaceutical manufacturer PAP. Since 06-03, the OIG has issued favorable opinions to other manufacturers operating similar PAPs. *See* OIG Advisory Opinion Nos. 06-14 (Sept. 21, 2006); 06-19 (Oct. 26, 2006); 06-21 (Nov. 2, 2006); and 07-04 (Mar. 30, 2007).

The OIG has also approved a number of PAPs operated by independent charitable organizations that aggregate charitable donations by pharmaceutical companies and other donors and dispense subsidies to financially-needy patients, including Medicare beneficiaries. *See* OIG Advisory Opinion Nos. 98-17 (Nov. 6, 1998); 02-01 (Apr. 4, 2002); 04-15 (Oct. 29, 2004); 06-04 (Apr. 20, 2006); 06-09 (Aug. 18, 2006); and 06-10 (Sept. 14, 2006).

In **OIG Advisory Opinion No. 06-06 (May 1, 2006)**, a city issued a request for proposals for an exclusive contract with an ambulance supplier to provide emergency ambulance transportation services when the city's paramedic units provide on-the-scene first responder services. The ambulance supplier would agree to pay the city a per-response fee and would charge uninsured residents at reduced rates. The expected payments to the city would be less than the city's costs of operating its 911 system and providing first responder services.

The OIG approved the arrangement based on a number of factors, including the fact that the proposed arrangement would be established by a valid governmental entity legally empowered to regulate the provision of emergency medical services in the city pursuant to an open, competitive bidding process. In addition, the payments to the city would only partially compensate it for its first responder costs, and thus there would be no overpayments to the source of referrals, a typical antikickback concern. The Medicare payment system expressly contemplates that first responders will look to second responders for payment. The OIG observed that there is typically little risk of

overutilization of emergency 911 services. In addition, the putative prohibited remuneration to the city would inure to the public, not private, benefit by reducing the costs of first responder services to the public.

The proposed arrangements in **OIG Advisory Opinions Nos. 06-11 (Sept. 18, 2006)** and **06-12 (Sept. 18, 2006)** also involved cities entering into exclusive ambulance contracts, but for non-emergency inter-facility transports. In each arrangement, the city proposed to pass an ordinance authorizing it to enter into an exclusive contract with a service provider for non-emergency inter-facility transports through an open, competitive procurement process. The contract would require the transport service to pay the city \$50,000 annually. The "pay to play" fee structure was a different twist, but for reasons similar to those in **OIG Advisory Opinion 06-06**, the **OIG** issued favorable opinions. The "pay to play" fee was fixed and did not vary with the volume or value of business (or the identity of the successful bidder); moreover, the fee was uniform for all bidders and no bidder would offer any additional remuneration. The fee constituted only partial reimbursement of the cities' costs for dispatch and other shared services. While the relative lack of exigency in nonemergency transports can create an opportunity to steer patients to a provider favored by the transport service, the **OIG** considered the risk low because the proposed arrangements were limited to non-emergency inter-facility transports, pursuant to which patients would be predestined for a particular facility before the transport was initiated.

In **OIG Advisory Opinion No. 06-16 (Oct. 3, 2006)**, an unfavorable opinion, the requesting party, a manufacturer of DME, proposed to give selected DME suppliers free advertising (including staffing of call centers to field inquiries generated by the advertising) and reimbursement consulting services. The **OIG** concluded that the arrangement could potentially violate the antikickback statute because the requestor would give something of value to DME suppliers who purchase requestor's products, which may induce DME suppliers to generate federal business for requestor. While prior **OIG** guidance has recognized that certain limited, freestanding product support services that have no independent value to the purchaser may not implicate the antikickback statute, the consulting services

proposed by the requestor would be neither limited in nature nor freestanding.

In **OIG Advisory Opinion No. 06-20 (Nov. 1, 2006)**, a DME supplier sought review of an existing arrangement that provided Medicare beneficiaries with free home oxygen and a proposed arrangement to provide Medicare beneficiaries with free overnight oximetry testing. The services would be made known to beneficiaries through recommendations by physicians. The **OIG** issued a negative opinion. The free oxygen was clearly something of value to beneficiaries. The value of the free testing was more than nominal and, while the oximetry tests had no value for purposes of qualifying for Medicare coverage, the free testing was delivered in a manner that would lead a reasonable beneficiary to conclude that he or she was receiving a valuable service that might expedite access to covered oxygen and contribute to a successful clinical outcome. The **OIG** concluded that both arrangements were likely to influence the beneficiaries to choose the DME supplier and that both arrangements appeared calculated to generate federally payable business for the supplier. The **OIG** also noted that the proposed arrangement appeared to be a thinly veiled scheme to evade the barrier interposed between beneficiaries and oxygen suppliers by the Medicare rule that bars DME suppliers (except hospitals) from performing the oximetry test necessary to qualify a beneficiary for covered oxygen.

In **OIG Advisory Opinion No. 07-02 (Mar. 7, 2007)**, a hospital proposed to subsidize the costs of ambulance transportation for Medicare beneficiaries transported to the hospital from outside the hospital's local area. The **OIG** issued a negative opinion, concluding that the subsidy for nonlocal transportation would constitute remuneration to the beneficiaries to induce them to use the hospital, as the hospital would be assuming payment for an expense ordinarily borne by the beneficiary. The beneficiaries were cardiac patients likely to develop ongoing relationships with the hospital. The fact that the subsidies were not advertised to patients was not persuasive, since the program would be publicized to their physicians.

V. Conclusion

Since 1997, OIG advisory opinions have been a key component of the OIG's efforts to promote compliance with the fraud and abuse laws through meaningful guidance to industry stakeholders. The process is carefully structured to avoid any adverse impact on ongoing investigations or prosecutions. Published opinions offer insight into the OIG's thinking on the application of the antikickback statute, the "safe harbor" regulations, and other fraud and abuse authorities to specific existing and proposed business arrangements. In addition, the advisory opinion process enhances the government's ability to distinguish arrangements that are problematic from those that are not. IGB attorneys who focus on advisory opinion work are available to share their acquired expertise with prosecutors and agents engaged in case evaluations, investigations, and prosecutions. ❖

ABOUT THE AUTHOR

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Appendix A -- Opinions by Subject Area

TOPIC	ADVISORY OPINION NUMBER
Ambulance Restocking	97-06; 98-07; 98-13; 98-14; 00-09; 02-02; 02-03; 06-06
Ambulance Copay Waivers	99-01; 01-10; 01-11; 01-12; 01-18; 02-08; 02-15; 03-09; 03-11; 04-02; 04-06; 04-12; 04-13; 04-14; 05-09; 05-10; 06-07
Ambulances (other)	98-3; 99-02; 99-05; 00-11; 01-05; 03-11; 03-14; 04-10; 05-07; 06-06; 06-11; 06-12; 07-02
Ambulatory Surgery Centers	97-04; 98-12; 01-17; 01-21; 02-09; 03-02; 03-05
Beneficiary Inducements	97-01; 97-02; 97-04; 98-06; 99-6; 99-07; 99-12; 00-3; 00-05; 01-14; 01-07; 02-07; 02-14; 02-16; 03-04; 04-01; 04-04; 06-01; 06-20; 07-1; 07-02
Clinical Trials	98-06; 00-5; 02-16; 04-01
Copay Waivers (non-ambulance)	97-04; 98-05; 98-06; 99-06; 99-07; 00-05; 01-03; 01-07; 01-13; 01-14; 01-15; 02-07; 02-16; 04-01
Discounts	98-02; 98-05; 98-15; 99-2; 99-03; 99-13; 00-10; 01-03; 01-08; 02-06; 02-10; 03-10; 04-16
DME	98-1; 98-08; 99-03; 01-08; 02-04; 06-02; 06-16; 06-20
Donations	97-01; 97-02; 98-03; 98-17; 99-10; 00-06; 00-11; 01-02; 01-09; 01-19; 02-01; 02-11; 04-05; 04-18; 05-11 (see also PAPs)
Employment	98-09; 01-16; 00-02; 03-01; 04-09; 07-03
ESRD	97-01; 97-02; 98-17; 03-07; 04-16; 07-01
Exclusions	98-08; 01-16; 03-01
Free goods and/or services	98-01; 98-16; 99-11; 99-14; 00-03; 00-06; 00-07; 01-05; 01-19; 02-14; 03-04; 03-06; 04-04; 05-07; 05-08; 05-11; 06-01; 06-05; 06-16; 06-18
Group Practices/Physicians	98-19; 00-04; 01-07; 02-05; 02-09; 03-15; 04-08; 04-09; 04-11; 06-02 (see also Hospitals, DME, Joint Ventures, Lab Services, etc.)
Group Purchasing Organizations	98-11; 01-06
Hospice	00-03; 01-20; 04-18
Hospitals	99-04; 01-01; 01-04; 01-09; 03-15; 04-07; 04-11; 04-19; 05-01; 05-02; 05-03; 05-04; 05-05; 05-06; 06-05; 06-18; 06-22 (see also Physicians, Joint Ventures, etc.)
Joint Ventures (non-ASC)	97-05; 98-19; 03-12; 03-13; 04-17; 05-12; 06-02
Lab Services	99-13; 04-05; 04-16; 04-17; 05-08
Leases/Rentals	98-18; 99-14; 01-05; 03-08; 04-08
Managed Care	98-05; 98-19; 99-09; 01-13; 01-15; 02-12; 06-15; 06-17
Management Agreements	98-01; 98-04; 00-01; 03-02; 03-08
Marketing	98-01; 98-10; 99-03; 99-08; 99-10; 99-12; 02-12; 04-03; 06-16
Pharmaceutical	98-02; 98-15; 98-16; 99-10; 00-10; 01-20; 04-03
Patient Assistance Programs (PAPs)	98-17; 02-01; 02-13; 03-03; 04-15; 06-03; 06-04; 06-08; 06-09; 06-10; 06-13; 06-14; 06-19; 06-21; 07-04

Recruitment	01-04
Referral Service	00-08
Telemedicine	98-18; 99-14; 04-07
Transfer Assets	97-3

The Increased Utilization of Stolen Physician and Beneficiary Information in Recent Health Care Fraud Cases and the Medicare Fraud Strike Force

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I. Introduction

Any assessment of the United States' health care fraud problem over the past decade would likely show widespread theft from the Medicare program. Fraudulent schemes targeting Medicare affect virtually all sectors of the health care industry in every judicial district. The Department of Health and Human Services (HHS) and the Department of Justice (Department), *Health Care Fraud and Abuse Control Program Annual Report for FY 2005*, available at www.usdoj.gov/dag/pubdoc/hcfareport2005.pdf. Yet, in certain parts of the country, for a variety of reasons, the magnitude of the fraud is simply greater than in others.

In the southeastern United States, for example, the fast lane for Medicare fraud runs through Miami-Dade County. Every day, contractors for the Centers for Medicare and Medicaid Services (CMS) pay out hundreds of thousands of dollars in Medicare Part B cash. The money is intended to pay for critical health care services on behalf of some of the most vulnerable citizens in Miami. However, the program is plagued by fraudulent durable medical equipment (DME) companies, infusion clinics, and other supposed Medicare providers and suppliers whose offices dot the landscape throughout Miami-Dade County.

It is difficult to go to any office building, strip mall, or other commercial space in the city, without coming across at least one of these entities. Their corporate names, often two letters surrounding an ampersand, followed by the phrase

Medical Supplies or Services Corporation, appear to be selected from the next available letters in the alphabet soup of combinations registered online with the Florida Secretary of State. They sprout like kudzu, and their densest growth seems to be centered in and around Hialeah. They bill the Medicare program for hundreds of thousands, in many cases, millions of dollars. Then, when the federal government, or their bank, asks questions about their unusual business activities, they disappear, only to be replaced by the next fraudulent entity, which often moves right into the same office space.

This article is intended to reveal the extent to which the fraudulent schemes have begun to rely so heavily upon the theft of the personal information of physicians and beneficiaries. In addition, it will describe the work of the new Medicare Fraud Strike Force (MFSF or strike force) that has been working to target providers who steal personal information.

II. DME fraud

In 2004, Medicare spending totaled nearly three hundred billion dollars nationally. Of this total, about \$6.5 billion (2.2%) was for DME. HHS Office of the Inspector General (OIG) and Medicare Program Safeguard Contractor (PSC) fraud referrals for investigation reveal that DME fraud is far more prevalent than its relatively small proportion of overall Medicare claims, accounting for 12.2% of all fraud referrals to HHS. DME fraud is the third most prevalent type of health care fraud scheme under investigation by HHS-OIG, nearly equaling the number of fraud allegations involving hospitals, and ranking behind only referrals for fraud by physicians and medical practices.

Currently, the DME fraud problem is most acute in South Florida. Miami-area DME suppliers have accounted for nearly 10% of all active HHS fraud referrals involving DME

suppliers nationwide since 2000. Only Los Angeles has received a higher number of HHS fraud allegations involving DME during this time. Miami-area DME fraud, however, produced the highest number of HHS referrals for investigation in 2006, surpassing Los Angeles by 50%. DME fraud perpetrated by fictitious and utterly fraudulent entities is a major problem in South Florida.

Facts from a recent investigation are illustrative. In January of 2005, an individual moved from Cuba to Miami-Dade County and enrolled as a Medicare provider. From April 23 until June 3, this new provider billed over \$4.1 million and was paid \$1.65 million. He has since disappeared.

Even though Miami-Dade County has approximately 35,000 active provider numbers, over 1,700 new Medicare numbers are issued in Florida every month. CMS reports that Miami-Dade County has approximately one DME supplier per 225 Medicare beneficiaries, as compared to the rate for the entire State of Florida which has 1 DME supplier per 1,760 beneficiaries. Fifty-nine percent of Florida's DME companies are located in Miami-Dade County, even though only 10% of the Medicare beneficiaries live there.

Today in Miami, the most prevalent DME scheme appears to involve what its perpetrators commonly call burning the DME. Burning the DME involves the following actions.

- Acquiring control of a company that has been enrolled to submit claims to Medicare.
- Or, alternatively, hiring an individual to enroll the company as a Medicare supplier.
- The DME supplier bills Medicare for large amounts of fraudulent claims, and immediately shuts the company down.

The owners of the company siphon the Medicare funds from the corporation's bank account, by the use of check cashers, between the time Medicare claims are paid and the time they abandon the company. These individuals are paid a small fee to cash the DME's corporate checks at check cashing stores, where few questions are asked. Alternatively the Medicare funds are quickly removed from the company's account via electronic funds transfer to other companies that have been set up to launder the Medicare money. The owners know that they will likely be paid for only a small fraction of the claims that they

submit, due to computer edits in the Medicare program's billing and payment system, which are designed to ferret out fraud. A few claims are submitted to test the system and to determine which Health Care Common Procedure Coding System (HCPCS) codes will be paid. The corporation relies upon the volume of the claims submitted to ensure that enough will make it past the system's edits.

The DME supplier in Miami-Dade County often has no assets, employees, inventory, or patients to serve. In fact, its sole asset is its status as a Medicare supplier—its ability to submit claims to Medicare. There are minimal barriers to obtaining entry and maintaining status as a Medicare supplier. The obstacles are usually surmounted by the prior owners of the company, and they are paid for their services when they sell the company to the perpetrators of the fraudulent billing. The DME supplier must have a physical location and meet certain lenient survey and certification requirements; thus, the storefront operations that dot the landscape in Miami. The office will usually be an 8' x 10' room containing a desk, business licenses framed on the wall, and perhaps a few samples of medical products, none of which are the types of products that the company ultimately bills to Medicare. A sign on the front door of the office will set forth what purports to be the company's minimal office hours, along with a phone number for emergencies, those being unannounced inspections on behalf of the Medicare program. The primary business of the DME company is not durable medical equipment at all, but identity theft.

III. Infusion therapy fraud

In 2003, a ring of physicians and clinics in South Florida initiated a fraudulent scheme that has billed the Medicare program over \$500 million dollars for infusion therapy services provided to Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) patients, that were medically unnecessary, and in many cases, that were not provided. Infusion therapy is the administration of nutrients, antibiotics, and other drugs and fluids, either intravenously or through a feeding tube. Individuals with HIV qualify for Medicare services if they are disabled.

The schemes typically involve individuals who were paid by a clinic to recruit beneficiaries from homeless shelters, homes for the mentally ill,

and drug rehabilitation facilities. The recruiters transport the patients to and from various clinics in the Miami area in order for them to receive infusion therapy. The clinics pay each patient a kickback per visit. The clinic's records often disclose that patients receive infusion therapy three times a week. In some cases, Medicare billing records reflect that patients visited up to seven different clinics a week.

The most common drug therapies included RhoGam mixed with saline, WinRho with Vitamin C, Vitamin B6 or Vitamin B12, ProCrit, Rituximab, Neupogen, and Corticotropin. Some clinics require that the patients sign in upon arrival at the facility. This practice is used so that they can bill the government for infusion services, even though the patient may ultimately have been turned away because the clinic ran out of its drug supply. Other facilities provide placebo therapy, rather than infusion therapy, for the treatment of HIV. These schemes may result in patient harm as many HIV and AIDS patients are abandoning their primary care physicians in favor of clinics paying kickbacks. As a result, these individuals may not be receiving necessary antiretroviral treatment for HIV.

The precise scope and magnitude of the financial losses to the Medicare and Medicaid programs from these schemes is unknown. Cases prosecuted to date and analysis of questionable claims, however, suggest that losses to government health care programs are in the hundreds of millions of dollars a year in Miami-Dade County alone.

The barriers to entry for fraudulent infusion clinics appear to be slightly higher than for DME suppliers. Significantly, the clinic must have a medical director (physician). In theory, and at legitimate operations in Florida, the medical director is an important person in the operation of the clinic. *See* Fla. Stat. §§ 400.9935(1)(a)-(g), (2), (3). He or she is ultimately responsible for seeing that the clinical staff maintain their licenses, keeping certain records on behalf of the clinic, and conducting systematic reviews of the clinic's billing practices to ensure that they are not fraudulent. Thus, the state licensing agency relies upon a clinic's medical director to know the clinic's medical staff, to report adverse events, and to generally know what is going on at the clinic.

At fraudulent Miami-area infusion clinics, medical directors are paid to look the other way while the fraud is perpetrated. This is usually

accomplished through the medical director's supposed supervision of a physician assistant (PA) working at the clinic. The PA allows the physician to deny that he was providing any care—he was just serving as the clinic's medical director and supervising the PA. He can claim that he had no idea that expensive AIDS medications were being billed to Medicare while a mixture of saline solution and vitamins were provided. On the other hand, the PA can report that she was following the orders of the physician, and did not realize that the phlebotomists and technicians working at the clinic were not providing the appropriate medications.

By the time that law enforcement puts together a health care fraud case, which traditionally takes a matter of months or even years, the technicians have usually moved onto another fraudulent operation set up by the clinic's real owner. Thus, as in the case of burning the DME schemes, the government's ability to move quickly is key when prosecuting infusion clinics.

IV. Closing the gap

A. The Medicare Fraud Strike Force

The strike force's primary goal is to decrease the amount of time between the government's detection of a fraudulent scheme and the arrest and prosecution of the offenders. By placing prosecutors and agents in the same workspace, organized into teams comprised of federal, state, and local agents, the strike force attempts to bring the same level of coordination among law enforcement that the fake clinic owners, crooked physicians, check cashers, identity thieves, and paid-off patients, bring to their enterprise. This increased coordination, combined with real-time Medicare billing analysis, and close relations with financial institutions, is specifically intended to quicken the government's reaction time when combating the fraudulent schemes. Equally important, the strike force attempts to identify program weaknesses drawn from actual cases and investigations on the front lines of Medicare fraud enforcement, and to communicate those program weaknesses, along with recommendations for improvement, to CMS as rapidly as possible.

B. Strike force results

On May 9, 2007, Attorney General Alberto Gonzales joined Secretary Michael Leavitt of the HHS and announced the creation of the strike force. *See* <http://www.usdoj.gov/opa/pr/2007/>

May/07_ag_339.html. Between March 1 and May 9, 2007, the strike force indicted thirty-four cases involving health care companies that collectively billed the Medicare program for \$142,061,059. The strike force cases revealed that almost none of the services were medically necessary and most were never provided. In these first thirty-four cases, four teams of agents and prosecutors made thirty-eight arrests based on investigations originated through Medicare claims data extracted from the Health Care Information System (HCIS), coupled with real-time billing data from the PSCs, and cases generated through cooperating sources. See <http://homecaremag.com/news/medicare-fraud-strikeforce/>.

V. Identity theft and fraud

A. Medicare suppliers

In many strike force cases, phony DME suppliers and infusion clinic owners use identity theft and nominee owners as the key to unlock the Medicare trust fund. When agents from the Federal Bureau of Investigation (FBI) and the HHS-OIG receive a tip from a financial institution in Miami that large Medicare payments have been deposited into the account of a purported medical clinic, but that there are no corresponding payments of business expenses for purchases of medical supplies, payroll, or other operating costs, experience tells them that the signatory on the corporate account is usually not the real owner of the company. Experience also tells them that multiple layers of identity theft will make these cases hard to prove.

In most cases, no one listed on the fraudulent clinic documents will admit that they saw anything amiss, much less any sort of Medicare fraud. When tracked down by investigators, most clinics' owners are not helpful. They may state that they were paid \$500 for allowing their name to be listed as the owner of the clinic, but that they are not the actual owner. In fact, they may never have seen the physical location of the clinic. Of course, they do not know what types of services the clinic provides or how many employees it has. They cannot provide more than the most general description of the true owner, whom they knew years ago, by first name only, when they drove taxicabs in their home country in the Caribbean. It quickly becomes clear that the nominal owner was simply paid to assume the risk of prosecution.

B. Theft of Uniform Physician Identification Numbers (UPINs)

On April 4, 2007, Eduardo Moreno, the owner of DME companies, Brenda Medical Supply, Inc. and Faster Medical Equipment, Inc., was arrested by strike force agents. On April 13, 2007, a Grand Jury returned a six count indictment charging that from October 2006 through February 2007, Moreno's companies billed Medicare for \$1,977,336. A search of Faster Medical revealed a 10' x 10' foot closet with buckets of tar on the floor and a broken oxygen concentrator—no patient files, computer, or telephone. Further, both companies submitted claims for patients that had died years earlier.

All physicians used by these companies on Medicare claims were interviewed by strike force agents and stated that they had no knowledge of: (1) any of the patients; (2) any of the purported prescribed services or items; or (3) the DME companies or defendants. For purposes of claims submission, the physicians' UPINs had been stolen and used by the defendants. Since the physicians did not receive any notification from payers of the utilization of their UPINs, they were unaware that Moreno had used their UPINs as the basis of his claims. This is just one example of a scheme which has become far too common.

On June 6, 2007, Moreno's codefendant, Harley Fernandez, the president, vice-president, and secretary, listed in all the corporate filings for Faster and Brenda, entered his guilty plea to three counts of the indictment. At this time, Moreno remains a fugitive. He was released on a \$250,000 Corporate Surety Bond and a cosigned \$100,000 personal surety bond. A bench warrant was issued after Moreno failed to report to court on April 16, 2007. The strike force placed a lien on his half million dollar home and 2004 Rolls Royce Phantom. An overview of this case is available at <http://miami.fbi.gov/dojpressrel/pressrel07/mm20070509.htm>

C. Theft of beneficiary information

In a recent case in Ft. Lauderdale, Fernando Ferrer, Jr. and Isis Machado, were convicted of conspiracy, identity theft, computer fraud, and wrongful disclosure of individually identifiable health information (HIPAA violations). See <http://www.usdoj.gov/usao/fls/PressReleases/070124-02.html>. Machado and Ferrer obtained the personal information of patients (name, date of birth, Social Security Number, Medicare number,

and address) from the Cleveland Clinic, and used that information to submit fraudulent claims for Medicare reimbursement on behalf of more than 1,100 victims in an amount in excess of \$2.5 million. Ferrer encouraged Machado to sell stolen personal identification information to her coconspirators. Machado accessed the Cleveland Clinic's computer system to print personal information of patients. Machado provided the information to Ferrer, in return for payment. Ferrer then caused the personal information to be used to file fraudulent Medicare reimbursement claims. Recently, Ferrer was sentenced to eighty-seven months in prison, three years of supervised release, and ordered to pay restitution in the amount of \$2,505,883. Machado was sentenced to three years probation, including six months of home confinement, and also ordered to pay restitution in the amount of \$2,505,883.48. *United States v. Ferrer and Machado*, 06-60761 CR (S.D. FL. Sept. 11, 2006).

VI. Conclusion

Among other reasons, the *Ferrer* case is significant because it highlights a trend in health care fraud in Miami. Previously, infusion clinic owners were content to pay kickbacks to beneficiaries who came to their clinics for questionable therapy. More recently, however, the owners have decided that stealing beneficiaries' information is a quicker and easier way to perpetrate the fraud. As criminals change the way they commit crime, so must law enforcement change the way it investigates and prosecutes criminals.❖

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❑ **Robert K. DeConti** is a Senior Counsel in the Administrative and Civil Remedies Branch, Office of Counsel to the Inspector General, United States Department of Health and Human Services. Over the past seven years at the Office of Inspector General (OIG), he has worked extensively with Department of Justice Trial Attorneys and Assistant United States Attorneys to resolve health care fraud matters involving the OIG's permissive exclusion authorities and he has negotiated Corporate Integrity Agreements (CIAs) with a wide range of providers from across the health care industry. He also litigates exclusion appeals on behalf of the OIG, handles matters arising under the OIG's Civil Monetary Penalties Law, and monitors providers operating under CIAs. Mr. DeConti has been on detail to the Criminal Division, Fraud Section, handling health care fraud matters during 2007. Prior to working at the OIG, he worked in the general counsel's office at a managed care organization in Maryland.✽

Health Care Fraud and Corruption: A European Perspective

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I. Introduction

This may be surprising, but health care fraud and corruption is not generally considered to be an issue of concern for the average European. This is in stark contrast to the United States where the majority of citizens are aware of this crime, and up until 9/11, the FBI considered health care fraud to be its number one problem. Partially as a response to this lack of understanding, the European Health Care Fraud and Corruption Network (EHFCN) was established specifically to raise awareness and share best practices.

This article will examine the establishment of the EHFCN, the recommended approach to dealing with the problem of health care fraud and corruption, what EHFCN means by health care fraud and corruption, and lastly, some success stories and what is hoped to be achieved in the coming year. The National Health Service (NHS) Counter Fraud Service in England and Wales will be used as a case study throughout the explanation of the recommended approach.

II. The establishment of a European network: why and how?

In 2003, the NHS Counter Fraud Service (CFS) in England, took the initiative to set up a European network of organizations countering fraud and corruption in health care. The rationale for this was to enable partners in Europe to learn from each other's experiences and to disseminate good practices. During fact finding visits in 2003 and 2004, Counter Fraud and Security Management Service (CFSMS) personnel found that there was little acknowledgment and awareness of the problem in other European countries. Additionally, it was found that many of the countries which were aware of the issues lacked a comprehensive approach to dealing with them. This was alarming, especially considering

the cross-border flow of persons, capital, goods, and services, within the European Union.

To this end, the NHS CFS applied to the European Commission (Directorate-General for Justice and Home Affairs) for funding to host the first European conference on the issue. As part of the funding arrangement, NHS CFS joined with other organizations in Europe that also wanted to see action taken in this area:

- AOK Lower Saxony, Germany (statutory health insurer).
- The Dutch Association of Health Insurers (ZN), Netherlands.
- The Ministry of Health, Poland.
- The Bureau for the Prevention of Corruption, Slovakia (government body).
- The College of Pharmacists in Madrid (COFM), Spain (regulator).

A two day conference took place in London in October 2004, with over 150 people attending from more than thirty countries. The result of the conference was a declaration outlining the intention to work together applying a comprehensive, integrated, and professional approach to countering fraud and corruption in health care. A copy of the document is available at <http://www.ehfcn.org/index.asp?id=1163142>.

As a result of the success of the conference the group applied for, and received, further funding from the European Union. This funding covered a second conference in Bratislava, Slovakia in 2005, made up of six working groups, which looked at the following topics within the field of health care fraud and corruption.

- Training.
- Legal arrangements.
- Risk measurement.
- Technology.
- Staff exchanges.
- Raising awareness.
- Examining the practicalities of formally establishing a self-funding European network.

III. The EHFCN

In December 2005, the EHFCN was legally established as a not-for-profit organization in Brussels, Belgium. The EHFCN is a network of corporate members financed through subscription fees. There are currently twenty-six corporate members based in seventeen European countries. Members are made up of government departments (Austria, Lithuania, Malta, Poland, Turkey, and the UK), national social insurance administrations (Norway and Sweden), professional regulators, private and statutory health insurers, and other interested parties. The EHFCN is confident that, with the new fee system in place as of May 1, 2007, our membership will continue to grow.

The EHFCN exists primarily to set professional, common working standards, raise awareness of the problem, and stimulate and facilitate pan-European communication. Real, tangible benefits for European health care systems can be gained through working together to implement effective mechanisms to reduce losses to health care fraud and corruption. Through the promotion of opportunities, joint work, and sharing good practices it is possible to produce savings and social benefits through more cost-effective patient care.

The work of the EHFCN is overseen by an Executive Committee consisting of nine members elected on an annual basis. To become a member of the Executive Committee you must be an employee of a corporate member organization.

IV. Health care fraud and corruption defined

There are several definitions of fraud and corruption in European jurisdictions. Generally, all definitions include giving false, incorrect, or incomplete information to gain a benefit (funds, clients, or property), and in most definitions, intent is required.

Health care fraud is committed by all parties in the health care sector, as the following examples demonstrate.

- Patients falsifying their claims before sending them in to their insurance company.
- Medical professionals claiming money for fictitious treatments or even deceased patients; upcoding or unbundling.
- Staff of health care insurers transferring money into personal accounts.

- Companies supplying drugs, services, or equipment, at illegally geared high prices (cartel).

V. What is health care corruption?

Health care corruption can be committed by public officials or by people working in the private sector. Corruption usually consists of an undue advantage for oneself or a third party. It is committed intentionally and involves the person acting (or refraining from acting) in breach of one's duties.

Health care corruption is also committed by several parties in the health care sector, as in the following instances.

- Patients offering to give doctors gifts to be treated sooner than other patients.
- Doctors requiring patients to pay them extra to receive treatment more quickly.
- Staff being bribed for awarding a supply contract to a specific company.
- Drug companies taking doctors on luxurious trips so they will prescribe their drugs.

VI. The holistic approach advocated by the EHFCN

It may be an obvious statement, but health care systems in Europe vary from country-to-country. The types of fraud and corruption committed within these systems is the same, and indeed is mirrored in North America and other parts of the globe. What is markedly different is the approach used to counter the problem. The EHFCN, learning from the experience of the NHS CFS, strongly advocates a holistic approach to countering fraud and corruption in health care (see the strategic document written by Jim Gee entitled *Countering Fraud in the NHS* at <http://nww.cfs.nhs.uk/pub/cfs/aboutcfs.section.html>). The key elements of this approach are identified below.

A. Identifying the problem—risk measurement

It is important to know the nature and scale of the problem to tackle it effectively. A comprehensive measurement program should be the starting point of any process to effectively counter fraud and corruption. Once a base line is established, resources can be directed accordingly, systems can be changed, and the process repeated

at regular intervals to provide assurance that targets are met and losses are reduced.

Within the network, a risk measurement methodology designed and tested by the NHS CFS was further piloted in four other European countries. The method proved to be applicable in these countries and health care systems. The experiences gained by the five organizations that have used the method have been collected in a *Risk Measurement Toolbox*. This toolbox consists of twelve documents available to EHFCN members on the secure extranet and includes the methodology and statistical guidelines. Due to intellectual property restrictions, it is not possible to discuss the actual method within the scope of this article.

The NHS in England has used this methodology to measure progress for the last seven years and has seen more than a 50% reduction in prescription, dental, and optical patient fraud.

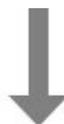
B. Developing a strategy and action plans to counter fraud and corruption

As with any organization, it is important to have corporate goals and objectives and to build a strategy to achieve them. Using the NHS as an example, the overarching aim of the NHS CFS, since its creation in 1998, is to reduce fraud and corruption in the NHS to an absolute minimum within ten years and to put arrangements in place to permanently hold this level. The objectives of the NHS CFS, stated simply, are the creation of an antifraud culture, maximum deterrence, successful prevention, prompt detection, professional investigation, effective sanctions, and effective methods to seek redress. Every part of the strategy is integrally linked to the others, as shown on the following chart.

DETERRENT	PREVENTION	DETECTION	INVESTIGATION	SANCTIONS	REDRESS
Publicizing action across the generic range to emphasize that fraud is serious and takes resources away from patients and important services.	Systematic prevention methods support individual interventions to counter fraud that has not been deterred.	Individual vigilance, supported by standardized detection systems, ensures that fraud which has not been prevented is promptly detected.	Fraud of all types and values is tackled and all appropriate investigative methods are used.	All appropriate sanctions are sought in cases of proven fraud, demonstrating that action will always be taken and fraud will not be tolerated.	Money lost to fraud is returned to the NHS for improved patient care and service provision.



Antifraud Culture



Mobilizing the honest majority of staff to be active in protecting NHS resources

C. Developing a structure to apply the strategy

The structure developed to support the strategy is dependent on the goals and objectives of the organization. Again, by way of example, the NHS CFS structure consists of a central unit comprising directorates of risk measurement, policy, human resources, information systems including a forensic computing unit, finance, research, and corporate affairs which further includes a communications team. Separate from this, there are eleven operational (investigative) teams, including two specialist teams specifically looking at pharmaceutical and dental fraud.

D. A range of action to counter health care fraud and corruption

The action taken to meet the objectives can be varied. Outlined below is the range of action the EHFCN recommends.

- The creation of a real **ANTIFRAUD** and **ANTICORRUPTION CULTURE** among both health care users and service providers, and ultimately among all European citizens. At the forefront of this objective is the development of an understanding of the importance of tackling fraud and corruption in health care and one's role and responsibility to mobilize the honest majority against the dishonest minority through the creation of a real antifraud and anticorruption culture. This objective will be furthered through the raising of awareness on this issue.
- To use all possible presentational and publicity opportunities to act as a **DETERRENT** to those who are of a mind to engage in health care fraud or corruption. This ensures that those who are inclined to commit health care fraud and corruption are aware that being caught has serious consequences and that criminal, civil, and disciplinary sanctions will be enforced.
- The use of effective **PREVENTION** systems so that when fraudulent or corrupt activities are attempted, they will fail. The opportunity to commit fraud and corruption is greatly reduced when there are strong systems and controls in place.
- The use of **DETECTION** systems that will promptly identify occurrences of health care fraud and corruption. If fraud and corruption are committed, it is important to detect the

crime as quickly as possible. Detection systems include an effective whistleblower policy, data mining, a telephone reporting line, and proactive exercises to check systems (audits).

- The professional and objective **INVESTIGATION** of all cases of alleged health care fraud and corruption. Once a suspicion of fraud or corruption is aroused, it should be investigated thoroughly, objectively, and fairly, to ascertain whether any fraud or corruption has taken place.
- Where fraud is proven, the imposition of appropriate **SANCTIONS**, namely criminal, civil, and disciplinary, should be applied. Committing fraud or corruption should have serious consequences and multiple sanctions should be used where possible. This adds to the deterrent effect and to the development of a real antifraud and anticorruption culture.
- Financial **REDRESS** should be sought in respect to health care resources lost to fraud and corruption. EHFCN advocates that recovered resources should be returned to the area of patient care or services for which they were intended.

EHFCN and the NHS CFS recognize that this approach can be applied to fraud and corruption in other areas and hope that the U.S. Department of Justice is able to consider the range of action described above. How resources are directed will depend on the nature and scale of the problem.

VII. Additional EHFCN activities

The EHFCN has other projects currently underway. The project and research work is undertaken in various subcommittees composed of EHFCN employees, member organizations, and other nonmember experts.

A. Propriety checks

The integrity and propriety of employees is especially important in this line of work. In the UK, one preemployment check company found that up to 62% of people have discrepancies on their curriculum vitae. As part of preventative action, it is important that applicants understand that their applications will be verified before they are interviewed or hired.

In recognition of this, the EHFCN has adopted a top-down approach to propriety checks. We have developed an internal propriety policy to thoroughly check all persons with responsibility for EHFCN matters, namely members of the Executive Committee and employees. Checks include residency, criminal and financial records, previous employment, academic history, and identity. Externally, it is recommended that EHFCN members consider, as a minimum standard, undertaking checks on employees who work to counter fraud and corruption. Additionally, there is a dedicated area on the secure Web site where information on the benefits of this approach can be found, as well as information on how and why to undertake these checks.

B. Operational work

As of September 2006, the operational subcommittee is reviewing how cases are detected and investigated across Europe. This large subcommittee is given financial support from the European Commission and is currently working on a Manual of Guidance to be published at the beginning of 2008 on the EHFCN secure extranet. The manual will contain information on methods of detection and investigation, best practices on areas such as whistle blowing, and will contain a list of operational contact points across Europe.

C. Communications and raising awareness

Communication is a key issue for both the EHFCN itself, to stimulate communication between members, and also for the members to communicate to the public. How is the difficult subject of fraud and corruption communicated to others? How is awareness raised among health care professionals (doctors, nurses, dentists, pharmacists, and others), patients, managers, support staff, and other parties such as contractors? The EHFCN, following in the steps of the NHS CFS, organizes an annual awareness campaign. Members can use the materials designed by the EHFCN at presentations and events organized in their countries.

The first awareness month took place between October 9 and November 9, 2006. The end date coincided with the United Nations anticorruption day. Many countries took part and events ranged from press conferences to more specific presentations aimed at health care professionals.

D. Training

Counter fraud and corruption work should be undertaken by people who are professionally trained. There are different training needs in the different European countries. To this end, the training subcommittee is currently compiling a dossier of different training courses, specific to health care fraud and corruption, that are available across the globe. This dossier will be available in the fall of 2007. It is hoped that a syllabus will be created, which can be used as a common, professional qualification for counter fraud and counter corruption specialists in Europe and beyond.

E. Legal database and research

Legal arrangements are very important in countering all types of fraud and corruption. What are the legal limitations to investigations? How are fraud and corruption defined? What are the procedures for sanctioning criminals and, of course, how is the money traced? The answers to these questions will differ greatly from country to country. Policy makers and legal advisors can learn from the arrangements of others, and the EHFCN has a subcommittee which looks at these issues.

Results from this work include a legal arrangements database and a legislation library which holds a wealth of information on these issues. At this time, the arrangements of fifteen European countries are available in the database. The next two steps for the network are to complete the database and also to conduct legal research into "triple sanctions policy" and "barriers to investigation".

F. Conferences and events

The EHFCN organizes an annual conference in October in a member organization's city. This year the conference will be on October 23-24 at the Sheraton Hotel in Warsaw, Poland. This event allows the members of the network an opportunity to meet each other and learn about developments.

This year the EHFCN held its first seminar on setting up a counter fraud and counter corruption function. This was aimed at those who are new to this work and was well attended. These seminars are aimed at exchanging experiences in a small group (maximum of forty people) and are open to members and nonmembers. We hope to organize more seminars later in the year.

G. General advice and information

A lot of information is available for members on the EHFCN secure extranet. Members can place case studies, documents, and fraud and corruption indicators, on the site. There is also a discussion forum and information on the work of all the subcommittees and a contacts database.

A success story: One member of the EHFCN is the Ministry of Health in a former communist country. Prior to joining the EHFCN, it had no health care counter fraud and counter corruption measures in place. As of this year, a counter-corruption hotline has been established and a government working group is dedicated to this area. In the opinion of many people within this country, corruption in the health service is a wide-ranging and harmful problem. It affects not only patients in the public health service, but also the family and loved ones. In response to the problem, the national government has undertaken several activities aimed at combating this culture, the hotline being a prime example. The hotline allows patients to report incidences of corruption in the health service. The hotline has nationwide coverage, is free, and operates from Monday to Friday from 9 a.m. to 9 p.m. It is worth noting, that in the majority of cases, the person calling the hotline wishes to remain anonymous.

Offers of money in return for a reduced waiting time for treatment or for the provision of treatment otherwise withheld, are the most commonly reported problems. The hotline operators inform callers of the regulations in force and, in particular, draw attention to the fact that according to law, those persons accepting financial or personal benefits are as criminally liable as those who provide such benefits. Should the person providing the financial benefit report this to the investigating body, before they find out themselves, this person may escape punishment.

The catalyst for the establishment of this hotline was a high profile arrest of a prominent hospital consultant. The case concerned the suspicion of multiple instances of bribery and a public appeal to report incidences of corruption involving this physician, as well as all cases of corruption in the health service. The response to this public appeal has been very positive as numerous instances have been reported, not only of corruption, but of other irregularities in the health service.

VIII. The future of the European fight against health care fraud and corruption

The EHFCN is a very new organization. In 2004, there were no contacts, annual conferences, or organization dedicated to dealing with this issue in Europe. Three years later, much has been achieved. The key lesson learned is that, although health care systems vary greatly, the fraud and corruption experienced within them is the same throughout Europe. This has provided a firm basis for us to work together.

To date, the work of the EHFCN has been undertaken on a voluntary basis by the Executive Committee and employees of member organizations. As of May 2007, EHFCN will employ its first staff member and intends to have a head of the EHFCN office in place by July 2007.

Besides formalizing the office arrangement, EHFCN will be expanding to new areas of work. It is anticipated that these will consist of the following.

- Research projects to identify the best strategies to counter fraud and corruption.
- Developing recommendations to improve European legislation concerning fraud and corruption, such as creating possibilities to exchange more operational information.
- Expanding the network from European to worldwide.

IX. Conclusion

As we say, *together we are strong, divided we are weak.*

For more information: please visit www.ehfcn.org or e-mail inquiries to enquiries@ehfcn.org. ❖

ABOUT THE AUTHOR

❑ **Laura Davies** is the Head of Research at the NHS Counter Fraud (NHS CFS), for England and Wales. The focus of her work is to initiate and oversee research projects that measure the progress of CFSMS in all areas of counter fraud and corruption actions, including the creation of an antifraud culture, deterrence, prevention, detection, investigations, sanctions, and redress.

Prior to joining CFSMS, Ms. Davies studied Law and worked in the Department of Health in the Finance and Performance Management directorate and in an NHS Primary Care Authority as a Community Health Adviser. In 2002, she joined the NHS Counter Fraud Service as a Research Officer where she undertook training in investigations (law and procedure), investigative interviewing, proactive evidence gathering, and principles of good practice.

She became Head of the Research Unit in 2003. During her time in this post, she has overseen the production of the first Bachelor of Science in Counter Fraud Studies and is now coordinating and contributing to the final academic stage of the learning route; the Master of Science in Counter Fraud and Counter Corruption Studies to be launched in October 2007. These two pieces of work are an integral part of the evolution of the wider counter fraud and counter corruption profession.

She has been involved with the EHFCN from the outset. As Head of Research, one of her key objectives was to ascertain the level of health care counter fraud and corruption activity across the European Union. It is from this project that the Network has grown and she has remained at the heart of its development. She is now Vice President and currently manages the day-to-day activities of the EHFCN.✂

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