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Health Care Enforcement in 2012: A Year in Review

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Last year was another busy year in health care fraud enforcement. In 2012, the Office of Inspector General for the Department of Health and Human Services (HHS-OIG) reported total expected recoveries of $6.9 billion from all of its enforcement initiatives. Additionally, HHS-OIG excluded 3,131 individuals and entities from participation in federal health care programs; brought criminal actions against 778 individuals and entities alleged to have engaged in crimes against HHS programs; and filed 367 civil actions — including federal False Claims Act (FCA) suits, federal actions under the Civil Monetary Penalties Law, and other administrative proceedings. Also, 2012 saw the single largest takedown (in terms of the amount of Medicare false billings at stake) in the history of the Medicare Fraud Strike Force. Two hundred HHS-OIG special agents, forensic examiners, and analysts executed a takedown across seven cities of over 100 individuals involved in Medicare fraud schemes linked to $452 million in total Medicare false claims. [1]

The enforcement numbers speak for themselves and reinforce a message that has become increasingly clear over the past few years: the federal government's commitment to health care fraud enforcement remains steadfast, and its investment in such efforts is still paying dividends. This report will review some of the enforcement trends that continued from 2011 into 2012 and highlight the areas in which we expect to see intensified enforcement efforts in the coming year.

Trends & Areas of Focus Continuing from 2011

Home Health Care

Perpetuating a long-standing trend that began well before 2011, the government continued to investigate and take enforcement action against home health care agencies (HHAs) in 2012. This past year, countless HHA providers, business owners, and employees were investigated for, charged with, and, in a number of cases, convicted of health care crimes. At least seven of those cases involved such individuals receiving lengthy prison sentences. A few examples demonstrate that the government's commitment to enforcement against HHAs shows no signs of waning:

- On June 19, 2012, a federal judge in Miami sentenced the owner and an employee of an HHA to 108 months (9 years) and 46 months (3 years and 10 months) in prison, respectively, for their roles in a $22 million Medicare fraud scheme. Both defendants were also sentenced to three years of supervised release and ordered to pay $14 million and $2 million, respectively, in restitution. The defendants (and co-conspirators) submitted approximately $22 million in false Medicare claims and, from those claims, received approximately $14 million in payments. Their scheme involved a conspiracy with patient recruiters to bill the Medicare program for unnecessary home health care and therapy services. The defendants paid kickbacks and bribes to patient recruiters in return for patients. Then, the defendants

used nurses and office staff to falsify Medicare beneficiary files to make it appear that such beneficiaries qualified for home health care and therapy services and generated prescriptions, plans of care, and certifications for these illegally obtained patients that were used to fraudulently bill Medicare for medically unnecessary therapy and home health services.

- On December 20, 2012, a federal judge sentenced the former co-owner of a Chicago-area HHA to ten years in prison after he was convicted of submitting tens of thousands of false claims to Medicare (misrepresenting the services provided) worth approximately $2.9 million. The ten-year sentence was the maximum allowable sentence for each of the seven charges against the defendant (but the judge ordered them to be served concurrently). This fraud scheme involved billing for: (1) services that were not medically necessary; (2) services purportedly provided by physicians when, in fact, they were provided by physician assistants; (3) services performed by a podiatrist whose license had been suspended (despite a representation that a licensed podiatrist was providing services); and, (4) false certifications of patients as eligible for home care services.

This continued focus on HHAs may be attributable, in large part, to HHS-OIG's conclusion that one in four HHAs exceeded a high-billing threshold used to detect questionable billing practices. In its most recent Semiannual Report to Congress, HHS-OIG reported that in 2010, the federal government inappropriately paid approximately $5 million in claims submitted by HHAs that fell into one of three categories: (1) claims that overlapped with inpatient hospital stays; (2) claims that overlapped with skilled nursing facility stays; and, (3) claims for services allegedly rendered after a patient's death. Most of these errors came from HHAs in California, Florida, Michigan, and Texas. To prevent recurrence of this conduct, HHS-OIG recommended, in part, increased monitoring of billing for home health services and initiation of actions against the identified inappropriate payments and the HHAs with questionable billings.[2] This recommendation may well be a harbinger of ongoing enforcement actions against HHAs in 2013.

DME Companies & Patient Recruiters

Durable medical equipment (DME) companies and patient recruiters also continued to draw law enforcement's attention in 2012. Throughout the year, a number of them were convicted of Medicare fraud and received lengthy prison sentences. As in the past, the lengths of the sentences clearly signal that the government takes its fraud enforcement initiatives seriously. Below are a few examples of cases that resulted in stiff penalties, including prison sentences:

- On November 16, 2012, one patient recruiter was sentenced to 87 months (7 years and 3 months) in prison and was ordered to pay $887,085 in restitution after a two-month trial resulted in conviction on one count of conspiracy to commit a kickback violation and one count of violating the Anti-Kickback Statute (AKS). A second patient recruiter was sentenced to 42 months (3 years and 6 months) in prison and ordered to pay $300,876 in restitution. In this case, the defendants solicited, and were paid, kickbacks to refer ineligible Medicare beneficiaries to a purported partial hospitalization program (PHP). A PHP is a form of intensive treatment for severe mental illness. Many of the patients admitted to the PHP were not eligible for such services because they (1) were chronic substance abusers; (2) suffered from conditions that would not benefit from group therapy; or (3) had no mental health diagnosis whatsoever but were seeking fraudulent mental health treatment in order to be declared exempt from certain requirements for their applications for United States citizenship. This scheme involved over $50 million in false claims submitted to federal health care programs.

- On August 21, 2012, the owner of multiple DME companies was sentenced to 180 months (15 years) in prison for his role in numerous Medicare fraud schemes involving fraudulent claims and illegal kickback payments for unnecessary DME. In addition to a 15-year prison sentence, the defendant was ordered to serve three years of supervised release and pay $13,397,759 in restitution (jointly and severally with his co-defendants). The defendant owned and operated several Louisiana-based DME companies that fraudulently billed Medicare for medical

equipment that either was not medically necessary or not actually provided. The defendant also hired patient recruiters to obtain Medicare beneficiary information and prescriptions for medical equipment (including leg braces, arm braces, power wheelchairs, and wheelchair accessories). These prescriptions were then used to submit fraudulent claims to the Medicare program. Over the course of this scheme, the defendant's companies submitted more than $22.5 million in fraudulent claims to the Medicare program. During this same time period, the defendant worked as a patient recruiter for yet another DME company, which submitted more than $4.5 million in fraudulent claims to the Medicare program.

The False Claims Act, Often in Combination with Criminal Cases

The civil FCA also gave rise to robust enforcement efforts in 2012. The Department of Justice (DOJ) reported recovering $4.9 billion in settlements and judgments under the FCA in 2012. Trends in pending FCA litigation are also instructive; approximately 55 qui tam cases were unsealed, in whole or in part, last year. Of the unsealed cases, the government declined to intervene in 49 cases and intervened in four. Upon review, the majority of the remaining cases (approximately 19) targeted physicians or physician group practices, and the most common claims were either violations of Medicare conditions of payment or false certifications of compliance with the AKS.

Large Settlements in 2012 in the Pharmaceutical Industry: Of the $4.9 billion in reported recoveries from last year's FCA settlements, two of the largest involved GlaxoSmithKline (GSK) ($2 billion) and Abbott Laboratories (Abbott) ($800 million).

In July 2012, GSK pled guilty to three misdemeanor violations of the federal Food, Drug, and Cosmetic Act (FDCA), agreed to implement compliance measures as part of its plea agreement, paid $1 billion to resolve the criminal claims, and paid an additional $2 billion to resolve federal civil liabilities under the FCA. The government alleged that GSK engaged in off-label promotion of two products and failed to provide required clinical data about a third product. Under the plea agreement, GSK's Board of Directors must annually review the effectiveness of its compliance program and summarize that review in a resolution. In addition, the President of GSK's North America Pharmaceutical Division must annually review GSK's compliance program and certify that the program includes the compliance policies and procedures required by the plea agreement and complies with the Reportable Incident reporting requirement.

Similarly, in May 2012, Abbott pled guilty to a misdemeanor violation of the FDCA and agreed to pay $1.5 billion to resolve its criminal and civil liability for unlawful promotion of the prescription drug Depakote for uses not approved by the FDA. Abbott also paid a criminal fine of $500 million, forfeited $198.5 million in assets, and will be on probation for five years. In its plea, Abbott admitted that it had used a specialized sales force to market Depakote in nursing homes for the control of agitation and aggression in elderly dementia patients. It also admitted that it had marketed Depakote to treat schizophrenia in combination with other antipsychotic drugs, even though clinical trials failed to demonstrate the effectiveness of this combination.

In addition, to resolve civil suits under federal and state FCAs, Abbott agreed to pay $800 million to the federal government and participating state governments to settle allegations, arising from several qui tam complaints, that off-label marketing of Depakote and violations of the federal AKS had caused false claims to be submitted to government health care programs. The allegedly unlawful promotion included making false and misleading statements about the safety, efficacy, dosing and cost-effectiveness of Depakote for some of the unapproved uses, "and claiming use of Depakote to control behavioral disturbances in dementia patients would help nursing homes avoid the administrative burdens and costs of complying with … regulatory restrictions applicable to antipsychotics." Abbott also allegedly offered and paid kickbacks to health care professionals and long-term-care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly influence the content of company-sponsored Continuing Medical Education (CME) programs.

In connection with the civil settlement, Abbott entered into a Corporate Integrity Agreement, which, among other things, imposes additional compliance obligations.

Anti-Kickback Cases: Many of the FCA cases settled in 2012 were predicated on alleged violations of the AKS. In addition, approximately 23% of the FCA qui tam cases unsealed last year involved allegations of false certification of compliance with the AKS.

The following are examples of 2012 FCA settlements that included alleged AKS violations:

- In August 2012, Pacific Health Corporation (PHC) resolved, for $16.5 million, federal and state claims alleging that it had violated the AKS and the FCA. The government contended that three PHC-affiliated hospitals had engaged in a scheme to pay recruiters to transport homeless Medicare or Medi-Cal beneficiaries by ambulance from "Skid Row" in Los Angeles to the hospitals for medically unnecessary treatments.
- In December 2012, Victory Pharma Inc. agreed both to a criminal forfeiture of $1.4 million to resolve federal AKS allegations and to a FCA settlement of $9.9 million. The government had alleged that Victory paid kickbacks to doctors to induce them to write prescriptions for Victory's products.
- In December 2012, Sanofi U.S. agreed to pay $109 million to resolve allegations that it had violated the FCA by giving physicians free units of a drug, in violation of the AKS, to induce them to purchase and prescribe the product.

Potential Implications/Issues for 2013

Increased Relators' Shares Incentivizing Whistleblowers: In reviewing its 2012 enforcement successes, the DOJ highlighted the significant recoveries that resulted from actions brought by relators. For example, four GSK whistleblowers will receive 15 – 25% of an approximate $1 billion settlement while whistleblowers in two other qui tam suits will receive a percentage of approximately $250 million. Similarly, in the Abbott settlement the whistleblowers will receive $84 million from the federal portion of the settlement.

Increased Focus on Compliance: As noted above, both the GSK and Abbott plea agreements include substantial compliance requirements for the company and for board members and executives. The agreements have many common provisions and reveal the government's thinking about corporate compliance measures that will effectively prevent off-label marketing. Many such provisions are summarized and compared below:

Compliance Obligation	GSK — Addendum to Plea Agreement	Abbott — Plea Agreement
Reportable Events	The company will report quarterly "reportable incidents," which are any probable FDCA violations related to pharmaceutical marketing.	The company will report quarterly to the probation office any "reportable events," which are probable FDCA violations.
Board Certifications	The Board of Directors will review and evaluate the effectiveness of the company's compliance program and submit a resolution that the company has implemented an effective compliance program to meet the requirements of federal health care programs, FDA requirements, and the Addendum to the Plea Agreement.	The Board of Directors will review the effectiveness of the company's compliance program and submit to the probation officer a resolution that the company had in effect policies and procedures designed to prevent violations of the FDCA.

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Executive Certifications	GSK's U.S. President will review and certify that the company's compliance measures continue to include the compliance measures in the plea agreement and that reportable incidents have been properly reported.	The CEO shall review the effectiveness of the company's compliance program and certify to the probation officer that the company's compliance program includes the compliance policies and procedures in the plea agreement and that "reportable events" have been properly reported. This is a probation requirement.
Compensation	Compensation and sales incentives cannot be based on the volume of sales. The sales force will be evaluated based on business acumen, customer engagement, and scientific knowledge of GSK products.	Compensation for sales representatives cannot inappropriately motivate off-label marketing or promotion of products.
Medical Education Must Be Free from Marketing's Involvement	Independent medical education (IME) program and medical education grant-making will have no commercial involvement.	CME and grant-making decisions cannot be approved by sales and marketing organization.
Control Over Medical Education Programs	Third parties must maintain control over the content, faculty, educational methods, materials, and venue for IME programs.	Third-party CME providers must maintain control over selection of content, faculty, educational methods, materials, and venue for CME programs.
Clinical Trials and Research Must Be Approved by the Medical or Research Organization	GSK-sponsored research must be approved by medical or research organizations, and its policies and procedures will require that sales and marketing personnel cannot participate in the design, conduct, or publication of GSK-sponsored research.	Clinical trials funded or controlled by Abbott must be approved by medical or scientific organizations, and its policies and procedures must require that it will not approve scientific research purely for the purposes of developing an article or reprint for sales representative's use.
Verifying Unsolicited Requests for Off-Label Use	Sales personnel must refer all requests for information about off-label uses to its medical affairs personnel and must obtain signatures from medical personnel who verbally requested written information about an off-label use to confirm that the request was unsolicited.	N/A

Health care providers and pharmaceutical and medical device manufacturers may wish to review these compliance obligations and consider whether to implement similar provisions, as they represent the government's views (at least in part) on ways to prevent improper marketing and promotion of FDA-approved products.

In addition, the board resolutions and the individual executive certifications in the GSK and Abbott plea agreements summarized above could subject the certifying individuals to personal liability should the certifications prove to be false or not supported by the requisite due diligence. According to Ellyn Sternfield, a Member of Mintz Levin's Health Care Enforcement Defense Group, "[i]t is no secret that in cases of corporate misconduct, federal prosecutors are looking to establish individual liability at the executive or board level. But, if they cannot prosecute individual officers or board members at the front end of a case, government attorneys are incorporating settlement terms that will make it easier for the government to establish individual liability in future cases."

New Areas of Focus in 2012

FCPA Enforcement in Health Care

Health care enforcement by the DOJ in 2012 expanded internationally through the use of the Foreign Corrupt Practices Act of 1977 (FCPA). [3] The statute's anti-bribery provisions prohibit the corrupt "giving, offering, or promising [of] anything of value, directly or indirectly, to a foreign official for the purpose of obtaining or retaining business." The FCPA also contains an "accounting books and records" provision enforced by the Securities and Exchange Commission (SEC) that requires public companies to "maintain truthful, accurate, reasonably detailed records reflecting domestic and foreign transactions, disposition of assets, and management approval" of such transactions. The FCPA generally applies to U.S. companies, citizens, nationals, residents, and any persons or entities acting in furtherance of a corrupt payment while in U.S. territory.

Key definitions within the statute, such as the terms "anything of value" and "foreign official," have extreme ramifications in the health care industry. For instance, "anything of value" can include situations where an offeror intending to influence a foreign official provides a charitable donation to an entity with which the foreign official is involved in exchange for his or her business. Additionally, the "foreign official" definition includes such individuals as physicians and nurses employed by state-run hospitals. Furthermore, the FCPA's anti-bribery provisions impose liability for third-party conduct. Thus, a company cannot be willfully blind to the acts of non-employee third-party distributors or agents who commit acts of bribery to advance the company's business. [4]

Since 2009, Assistant Attorney General Lanny Breuer has made it clear that the health care industry is a major target of FCPA enforcement, declaring that the DOJ "will be intensely focused on rooting out foreign bribery in [the health care product] industry." In 2012, the DOJ entered into four Deferred Prosecution Agreements (DPAs) with three medical device companies and one pharmaceutical company alleged to have violated the FCPA's anti-bribery provisions: [5]

Company & Settlement Date	Alleged Conduct	Monetary Penalties & Compliance Obligations [6]
Smith & Nephew (Feb. 6, 2012)	Affiliates and employees allegedly authorized the payment of approximately $9.4 million to a third-party distributor's shell companies, some or all of which was passed on to physicians to corruptly induce them to purchase the company's medical devices.	DOJ: $16.8 million SEC: $5.4 million disgorgement of profits
Biomet (Mar. 26, 2012)	Subsidiaries, employees, and agents allegedly made improper payments to publicly employed health care providers in Argentina, Brazil, and China to secure lucrative business with hospitals.	DOJ: $17.28 million SEC: $5.4 million in disgorgement of profits
Orthofix (Jul. 10, 2012)	Mexican subsidiary allegedly bribed officials of government-owned health care and social services provider with cash, laptop computers, televisions, and appliances directly or indirectly through front companies.	DOJ: $7.4 million in penalties
Pfizer H.C.P. (Aug. 7, 2012)	Indirect wholly owned subsidiary of Pfizer Inc., allegedly made a broad range of improper payments through sham consulting contracts and an exclusive distributorship to hospital administrators, regulatory and purchasing committee members, and other health care professionals in Bulgaria, Croatia, Kazakhstan, and Russia to influence government decisions regarding the approval and registration of Pfizer Inc. products, the award of pharmaceutical tenders, and the level of sales of Pfizer Inc. products.	DOJ: $15 million penalty

Smith & Nephew's and Biomet's DPAs [7] also required the companies to implement rigorous internal controls, to cooperate with the DOJ in future investigations of similar conduct within the industry, and to retain an external compliance monitor for 18 months. In addition, health care companies that settled FCPA cases in 2012 with DPAs are required to perform compliance self-assessments on a periodic basis over the next two to three years, as specified in the DPA.

Although DOJ FCPA enforcement has decreased overall in the past few years, health care companies have become a larger proportion of DOJ's enforcement targets. Four of the nine corporate DOJ FCPA enforcement actions brought in 2012 were against health care companies, and the aggregated criminal penalties for these actions totaled approximately $56 million or approximately 40% of all DOJ FCPA penalties for calendar year 2012. By comparison, DOJ only settled with one health care company in 2011, out of 11 total corporate FCPA enforcement actions. Of note, no individuals were prosecuted under the FCPA in any industry this year, although the statute permits it. Six of the 12 (50%) FCPA enforcement actions brought by the SEC and/or DOJ involved pharmaceutical or other health care-related entities. These six enforcement actions generated 65% of the all civil and criminal fines and penalties of the $260 million imposed under the FCPA in calendar year 2012.

The focus on the health care industry is ongoing. According to one blog, out of the 88 active FCPA investigations that had been publicly disclosed in SEC filings by December 31, 2012, 15 involved companies in the health care industry. [8] These investigative targets include pharmaceutical companies, medical device and imaging companies, renal dialysis providers, and laboratory corporations — and prosecutions of individuals related to these companies are still a possibility. Paul Pelletier, former principal deputy chief of the DOJ Criminal Division's Fraud Section and a current Member in Mintz Levin's Litigation Practice and its Health Care Enforcement Defense Group, noted in early 2012 that DOJ was using investigative targets as "[j]unior G-men" to report their competitors' alleged FCPA violations to demonstrate cooperation with the government. [9] Thus, new additions to the list of investigative targets could result from increasingly sophisticated investigative practices, companies informing on one another, and companies self-reporting to preempt informant reports.

Off-Label Marketing

Generally, 22 U.S.C. §331 prohibits the "alteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce." Under this provision, the government typically asserts that when a drug is marketed for uses unapproved by the FDA, the drug is misbranded because its existing label does not adequately address the off-label use. In 2012, the government often used this provision and resolved criminal and civil cases regarding off-label marketing to recover substantial settlements. A few examples include:

Defendant	Settlement Amount	Alleged Conduct
Amgen	$762 million to resolve criminal and alleged civil liabilities.	Amgen pled guilty in December 2012 to illegally selling a misbranded drug.
Pfizer	$491 million	"Third-quarter 2012 reported earnings in comparison with the year-ago quarter were unfavorably impacted by a $491 million charge resulting from an agreement-in-principle with the U.S. Department of Justice to resolve an investigation into Wyeth's historical promotional practices in connection with Rapamune …."

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Pfizer	$55 million	Tabletext Pfizer in December 2012 agreed to settle charges of off-label marketing of Protonix.
Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI).	$95 million	In October 2012, BIPI agreed to pay $95 million to resolve alleged civil False Claims Act violations arising from the unlawful marketing of, Aggrenox, Combivent, and Micardis.

Notably, in late 2012, in *U.S. v. Caronia*, the United States Court of Appeals for the Second Circuit overturned a conviction of off-label promotion. The defendant was an employee of Orphan Medical, Inc. (Orphan) which developed Xyrem. The FDA approved Xyrem for two uses related to narcolepsy. In 2005, a doctor recorded two calls with Mr. Caronia during which he promoted Xyrem for unapproved uses. Mr. Caronia was convicted by a jury following a trial during which the government argued that these conversations constituted off-label promotion and violated FDCA's misbranding provisions. Mr. Caronia appealed to the Second Circuit. On December 3, 2012, in a split decision, the Second Circuit overturned Mr. Caronia's conviction of conspiracy to introduce a misbranded drug into interstate commerce. The court held that the government had prosecuted Mr. Caronia for his speech alone, which is not permissible under the First Amendment.

Significantly, in its case against Mr. Caronia, the government did not allege that any of his statements were false or that he was involved in fraudulent conduct. Instead, its case was based solely on the off-label promotional statements he made. In the future, the government may bring cases that focus on false statements or fraudulent conduct associated with off-label statements. Additionally, it is likely that relators and the government will choose to bring off-label cases under other laws, such as state consumer protection statutes, rather than tangle with the First Amendment issues that will now surely be raised in any off-label FCA case. In any event, with the plethora of pending off-label marketing cases, both criminal cases and parallel civil False Claims Act cases, lawyers will all be paying close attention to what happens next. [10]

Medicaid Fraud

Last year, in addition to focusing its efforts on national and international initiatives, the federal government also focused its resources on state-level enforcement. In 2012, there were some interesting cases in the Medicaid fraud arena, specifically involving dentists and orthodontists:

- On December 13, 2012, Dr. Michael David Goodwin, a Texas orthodontist, pleaded guilty to one count of health care fraud relating to a scheme he devised to defraud the Texas Medicaid program of approximately $2.6 million. Dr. Goodwin admitted that from January 2008 to March 2011 he: (1) billed Texas Medicaid for services that were not medically necessary; (2) billed for services provided by dental assistants without supervision by a dentist or orthodontist; (3) billed for services rendered to Medicaid patients scheduled for treatment on days when Dr. Goodwin was not in the state and which, instead, were rendered by dental assistants; (4) hired dentists who were not enrolled in Texas Medicaid to provide the appearance of supervision while dental assistants treated patients and billed for those services; and (5) instructed dental assistants to falsify patient records to reflect an "adjustment" when none had been performed. On February 11, 2013, Dr. Goodwin was ordered to forfeit $1.56 million of the funds he received under the scheme; he will be further sentenced later this year.

- On June 20, 2012, Robin Lockwood, a dentist from Oklahoma City, Oklahoma, was charged with health care fraud. Dr. Lockwood was accused of (1) submitting claims for dental services she never rendered and (2) providing non-reimbursable services but writing her treatment notes (on which her practice relied when submitting Medicaid claims) as though the services that she had performed were reimburseable.

- On May 16, 2012, Dr. Carlos Armin Morales-Ryan, a dentist, and his wife, Dr. Nelia Patricia Garcia-Morales, an orthodontist, both of whom practiced in Laredo, Texas, pleaded guilty to a criminal information admitting they made false statements on bills to Texas Medicaid. Specifically, each provider admitted to submitting a claim for services provided to one patient, on one occasion, on a day when neither provider was in Texas. To resolve the charges stemming from these two claims, the providers signed a plea agreement under which they received five years' probation and were ordered to pay $686,545 in restitution. The magnitude of this sentence, when compared to the underlying conduct, is yet another indication of the seriousness with which the government pursues its enforcement efforts, no matter how minor the alleged misconduct may appear.

Despite the apparent spike in enforcement against dentists for fraudulent Medicaid claims, the federal government's involvement in the above cases is not so much indicative of a stronger commitment to fighting fraud in dentistry, as it is a reflection of a larger potential future trend of increased attention to state enforcement initiatives — and recoveries. A number of factors appear to be responsible for this new trend.

First, in recent years, state and federal agencies have been working together with increasing regularity on health care fraud cases of national import. For example, when the DOJ reported the settlement reached in the Abbott case (discussed above), it noted that several state and federal agencies were involved, including the Virginia Attorney General's Medicaid Fraud Control Unit; the Internal Revenue Service - Criminal Investigation; the FDA - Office of Criminal Investigation; the Defense Criminal Investigative Service; the Department of Health and Human Services - Office of Inspector General; the West Virginia State Police; the Office of Personnel Management - Office of Inspector General; the Department of Veterans' Affairs Office of Inspector General; the Department of Labor - Office of Inspector General; and TRICARE Program Integrity. Through their collaborative efforts on "big" cases, state and federal agencies have developed relationships that seem to have carried over into state cases.

Second, in the past few years especially, Congress has pressured investigative and enforcement agencies to produce quantifiable returns on the investment of taxpayer dollars in health care fraud enforcement initiatives. As such, bodies like the Health Care Fraud Prevention Enforcement and Action Team (HEAT), which is a collaborative initiative between HHS and DOJ, are incentivized to produce "big numbers" (i.e., recovery of large sums and other stringent penalties). This pressure to secure demonstrable enforcement successes seems to have directed some attention toward state enforcement, in addition to federal enforcement issues.

Finally, the increasing federal attention to state-level cases (including Medicaid cases) may be related, in part, to rising FCA enforcement at the state level. At present, 29 states and the District of Columbia have their own FCAs. In addition to an uptick in qui tam FCA cases at the state level, state attorneys general are hiring private legal counsel (to serve as special attorneys general) to pursue these cases and secure large settlements on behalf of the state. Because the federal government is entitled to recover "a share of Medicaid overpayments, damages, fines, penalties, and any other component of a legal judgment or settlement when a State recovers pursuant to legal action under its State FCA," the federal government is paying more attention to these cases and looking to secure its share. [11]

"Worthless Services" Cases

In addition to exploring new industries for increased enforcement focus, the federal government appears to be considering the increased use of at least one relatively "new" theory of misconduct: the "worthless services" theory. While the "worthless services" theory is not actually a new legal doctrine (as it has previously been asserted as the basis for FCA claims), it may represent the newest lens through which the federal government views alleged health

care fraud. The crux of this theory is that "the performance of services is so deficient that for all practical purposes it is the equivalent of no performance at all." [12] At least two cases in 2012 involved this theory: one was an FCA suit filed by a whistleblower and the other was a case filed by the federal government. While it is difficult to predict what the utilization of this theory might mean for future enforcement, it is certainly an issue of which all health care providers should be aware.

On August 8, 2012, a federal trial judge unsealed a whistleblower suit alleging that Mimbres Memorial Hospital (Mimbres) in New Mexico had submitted claims to Medicare and Medicaid for microbiology services in violation of requirements imposed by the Centers for Medicare & Medicaid Services (CMS) for the certification of laboratories (under the Clinical Laboratory Improvement Acts of 1988 (CLIA)). The whistleblower worked at the hospital and alleged that, because a provider's eligibility for reimbursement for laboratory services depends on CLIA compliance, the hospital's failure to meet CLIA requirements rendered those claims a violation of the FCA. The relator also accused Mimbres, in part, of (1) failing to conduct routine quality-control procedures on instruments to ensure that they produced accurate and verifiable results; (2) failing to conduct required monitoring and internal reviews; and (3) using outdated equipment instructions. As a result, the relator contended, the accuracy of the test results used for diagnosis and treatment could not be validated. Moreover, the relator charged that Mimbres knowingly ignored the risks that such practices posed to patients' health and safety.

Although the United States and the state of New Mexico declined to intervene in the Mimbres case, it appears that the government has not dismissed the utility of the "worthless services" theory. On August 13, 2012, George D. Houser, the owner of a nursing home located in Georgia, was sentenced to serve 20 years in federal prison on charges of conspiring with his wife to defraud the Medicare and Georgia Medicaid programs by billing them for "worthless services" in the operation of three nursing homes.

Between July 2004 and September 2007, Mr. Houser billed Medicare and Medicaid approximately $41 million (and was paid $32.9 million) based on his certifications that residents in these homes had a safe, clean physical environment, nutritional meals, medical care, and services that would promote or enhance their quality of life. In reality, the government alleged that there was "a long-term pattern and practice of conditions at [Mr. Houser's] nursing homes that were so poor, including food shortages bordering on starvation, leaking roofs, virtually no nursing or housekeeping supplies, poor sanitary conditions, major staff shortages, and safety concerns…" [13] that any services that Mr. Houser rendered were of no value to the residents.

The court found that Mr. Houser "was well aware that ongoing jeopardy conditions existed at the nursing homes during this time. Rather than make a good faith effort to remedy the glaring issues impacting the residents' health and welfare, the evidence shows that [Mr. Houser] chose instead to divert significant nursing home funds [to] his real estate development ventures and for other personal expenses and that [the] defendant intentionally attempted to cover up and conceal from the surveyors the nursing homes' issues and his diversion of funds." [14]

This case was the first in which a defendant was convicted, following a trial in federal court, for submitting claims for worthless services. It may very well not be the last.

Conclusion

In and of themselves, trends in health care enforcement during 2012 have been significant in reinforcing the government's fraud investigation and recovery strategies. But these trends will likely intensify in the post-health reform era. Already, in 2013, we have seen the release of the final regulations [15] under the Sunshine Act, [16] which have far-reaching impacts to health care fraud enforcement against group purchasing organizations and manufacturers of drugs, devices, biologics, or medical supplies covered by certain federal health care programs. Also, health care privacy and security enforcement will likely increase in the aftermath of the recent release of the HIPAA Omnibus

regulations.[17] Given this trend, it is quite possible that 2013 may also bring the release of a final 60-Day Overpayment Rule[18] related to FCA and Civil Monetary Penalties Law liability for failures to report and return a federal health care program overpayment within 60 days of identifying its existence.

Overall, the enactment of new laws and regulations at the federal and state levels related to health care reform will provide the government with more opportunities to detect and seek out fraud and abuse in the industry. The impact of new laws and regulations implementing the federal health care program integrity provisions of the Affordable Care Act,[19] combined with the enforcement agencies' continued efforts in historically fruitful areas of fraud recoveries and increasing experimentation with new theories of potential liability, strongly suggest that 2013 may well be another landmark year in health care enforcement.

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ENDNOTES

[1] U.S. Dep't of Health & Human Services, Office of Inspector General, Semiannual Report to Congress, Apr. 1, 2012 – Sept. 30, 2012.

[2] U.S. Department of Health & Human Services, Office of Inspector General, Semiannual Report to Congress, Apr. 1, 2012 – Sept. 30, 2012, at 6.

[3] 15 U.S.C. §§ 78dd-1, et seq.

[4] The DOJ and SEC have recently published "A Resource Guide to the U.S. Foreign Corrupt Practices Act," (FCPA Guidance), which provides health care companies with additional insight into the "foreign official" and "instrumentality" definitions that put their practices into such peril. Additionally, the FCPA Guidance provides 10 "Hallmarks of Effective Compliance Programs" and more insight on the agencies' enforcement stance on unlawful gifts, entertainment, and travel practices that form a large part of FCPA violations.

[5] U.S. Department of Justice, Criminal Fraud Section, "FCPA and Related Enforcement Actions" (2012), (last accessed Jan. 15, 2013).

[6] For each violation of the FCPA's anti-bribery provisions, companies can be subject to up to $2 million in criminal penalties and civil fines of up to $16,000 per violation. Individuals can be required to pay up to $250,000 in criminal fines and $16,000 in civil fines for each violation and receive a prison term of up to five years. For each violation of the statute's accounting books and records provisions, companies can be subject to up to $25 million in criminal penalties and civil fines of up to $725,000 per violation. Individuals can be required to pay up to $5 million in criminal fines and $150,000 in civil fines for each violation and receive a prison term of up to 20 years. In addition to all of these penalties and fines, the SEC can pursue additional civil remedies, such as injunctions and disgorgement of profits, against a defendant.

[7] *United States v. Smith & Nephew, Inc.*, No. 12-CR-030-RBW, Deferred Prosecution Agreement, (Feb. 6, 2012); *United States v. Biomet, Inc.*, No. 12-CR-080-RBW, Deferred Prosecution Agreement, (Mar. 26, 2012).

[8] Richard L. Cassin, "The Corporate Investigations List," *The FCPA Blog* (Jan. 3, 2013); "'Contagion effect' spreads FCPA risks" (Jan. 7, 2013).

[9] Paul E. Pelletier and Stephanie D. Willis, "Ratting Out the Competition: New DOJ Strategies," *Law 360*, (Mar. 28, 2012).

[10] "Off-Label Marketing – First Amendment Challenge Ruling" (Dec. 6, 2012).

[11] Comment from Ellyn Sternfield, Member of Mintz Levin's Health Care Enforcement Defense Group (Jan. 22, 2013); Letter from Herby B. Kuhn, Deputy Administrator, Acting Director, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services (Oct. 28, 2008). At present, there is a struggle taking place between the federal government and various state governments regarding the issue of federal share. In its 2008 letter, CMS took the position that federal share must be paid on all portions of a Medicaid FCA judgment or settlement. Many states are pushing back on this position. This is a complex issue, which is not the subject of this advisory. Readers wanting more information on this topic should contact Mintz Levin.

[12] *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

[13] Press Release, Federal Bureau of Investigation, Atlanta Division, "Former Nursing Home Operator Sentenced to Prison for 20 Years for Health Care Fraud and Tax Fraud" (Aug. 13, 2012).

[14] *Id.*

[15] Centers for Medicare & Medicaid Services, "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests" (Feb. 8, 2013). Mintz Levin's Health Law Practice attorneys have provided analysis of the new rule here: Thomas S. Crane, Brian P. Dunphy, Karen S. Lovitch, and Kate F. Stewart, "CMS Publishes Final Sunshine Act Rule; Data Collection to Begin on August 1, 2013," *Health Law Alert* (Feb. 4, 2013).

[16] Section 1128G of the Social Security Act.

[17] Dianne J. Bourque et al., "HIPAA Omnibus Rule Reference Chart," *Health Law Alert* (Jan. 22, 2013); Dianne Bourque and Stephanie D. Willis, "Finally! HHS Office of Civil Rights Releases HIPAA Omnibus Rule with Sweeping Changes to Compliance Requirements and Enforcement," *Privacy & Security – HIPAA Compliance Alert* (Jan. 18, 2013).

[18] Medicare Program; Reporting and Returning Overpayments, 77 Fed. Reg. 9179 (proposed Feb. 16, 2012); Karen S. Lovitch and Stephanie D. Willis, "CMS Publishes Proposed Rule on Return of Medicare and Medicaid Overpayments," *Health Law Advisory* (Feb. 16, 2012).

[19] Pub. Law No. 111-148, as amended by Pub. Law No. 111-152 (2010).