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Health Care Fraud & Abuse Year in Review January 2013

I. FEDERAL LEGISLATION

07/09/12 President Obama signed legislation (S. Bill 3187) reauthorizing the user fees paid by medical device and drug companies and creating new user fee programs for generic drugs and biosimilar (or follow-on biologic) drugs.

12/04/12 President Obama signed legislation that will provide greater regulatory flexibility for labs under the Clinical Laboratory Improvement Amendments (CLIA).

12/31/12 Congress passed legislation to avoid the so-called fiscal cliff, but the legislation increased the statute of limitation for overpayment recoveries to five years.

II. FRAUD AND ABUSE SETTLEMENTS

01/01/12 Bristol Hospital and Bristol Gastroenterology Associates paid $157,000 to resolve alleged FCA violations based on improper lease arrangements under Stark. Although a relatively small settlement amount, the DOJ pursued the hospital and physician group for Stark Law violations related to office space leases.

01/06/12 Denver Health paid $6.3 million to resolve claims related to observation and outpatient services billed as inpatient services.

01/17/12 Stryker Biotech LLC pleaded guilty to one misdemeanor count of misbranding a medical device and paid $15 million in connection with the unapproved marketing and misbranding of bone growth products.

01/19/12 Cancer Genetics Inc. paid $1 million to settle allegations that it improperly submitted claims to Medicare for chromosome karyotyping studies. The government alleged that the company billed Medicare for studies using 20 karyotypes when only two or three karyotypes were medically necessary.

01/25/12 Cayuga Medical Center paid $3.5 million to resolve Stark Law and False Claims Act violations stemming from physician recruitment agreements. Cayuga self-disclosed additional non-compliant physician agreements during the course of the investigation on the basis that, "administrative oversight" led to old agreements falling out of compliance with loan forgiveness.

02/06/12 Smith & Nephew paid $16.8 million and entered into a deferred prosecution agreement to resolve allegations of improper payments by the company and certain affiliates in violation of the Foreign Corrupt Practices Act.

02/07/12 Fourteen hospitals in seven states paid a total of $12 million to settle allegations they submitted false claims to Medicare regarding the medical procedure kyphoplasty.

02/07/12 Accela Medical, a laboratory company, paid $6 million to resolve allegations that it fraudulently billed the Medicare for tests. The alleged fraud was detected by an analysis of billing records, which showed the labs were using a particular billing code more than any other Medicare provider in the nation.

03/05/12 Odyssey HealthCare Inc., a hospice, paid $25 million to resolve 3 whistleblower lawsuits, alleging that the company improperly billed Medicare for continuous care services. Whistleblowers received $4.6 million under the settlement.

03/13/12 BlueCross BlueShield of Tennessee paid $1.5 million to resolve HHS claims of insufficient protection of personal health information in an enforcement action under the HITECH Breach Notification Rule. The alleged violation stems from a 2009 theft of unencrypted data on 57 hard drives and the loss of information including the names, Social Security numbers, diagnosis codes, dates of birth, and health plan identity numbers of more than 1 million current and former BCBST members. The Tennessee Blues plan said no misuse of the personal data has been found to date.

03/23/12 WellCare Health Plans Inc. paid $137.5 million to end four whistleblower lawsuits for allegedly falsely inflating the amount it claimed to be spending on medical care, by knowingly retaining overpayments and "cherry-picking" health patients.

03/30/12 Calloway Laboratories Inc. paid $20 million to resolve allegations that it engaged in an elaborate kickback scheme that resulted in millions of dollars in payments by the state Medicaid program for unnecessary urine drug screens.

04/10/12 Tenet Healthcare Corp. paid $42.75 million to settle civil allegations that it overbilled Medicare for inpatient rehabilitation treatment.

04/12/12 AmMed Direct paid $18 million to settle allegations it violated state and federal law by improperly marketing diabetic supplies to Medicare and Medicaid beneficiaries. AmMed offered a free "Better Care Kit" that included a dessert cookbook, meal planning guide, and personal testing logbook through television advertisements. Prosecutors said company representatives would contact individuals who responded to the free cookbook advertisement who said they were covered by Medicare, Medicaid, or Blue Cross/Blue Shield and try to sell them the firm's diabetic testing supplies.

04/17/12 A small cardiology practice in Phoenix paid $100,000 and implemented a corrective action plan to settle allegations it violated HIPAA.

04/18/12 Sound Shore Medical Center and Mount Vernon Hospital paid $2.3 million to settle a Medicaid fraud investigation into overbilling for J-Code drug prices. The two hospitals allegedly had improperly charged Medicaid more than the price they paid for the physician-administered drugs and "pocketed a profit."

05/01/12 Sierra Vista Hospital paid $3.45 million to resolve allegations that the psychiatric facility in Sacramento failed to provide the number of services required to qualify for per diem payment under Medicare's partial hospitalization program.

05/03/12 Apex Medical Group paid $4.36 million to resolve allegations it fraudulently billed government health programs. Other alleged fraudulent activities involved re-billing for services for which the providers already had been reimbursed, receipt of kickbacks from drug companies, and routinely billing for medical services that were not necessary.

05/04/12 Lenox Hill Hospital paid $11.75 million to settle allegations it fraudulently inflated its charges to obtain Medicare outlier payments for FY 2002 and 2003.

05/07/12 Abbott Laboratories paid $1.5 billion to settle allegations of off-label marketing of the anti-seizure drug Depakote.

05/15/12 Pharmacy benefits manager Express Scripts Inc. paid $2.75 million to resolve allegations that it failed to have security procedures in place to prevent the theft or loss of controlled substances from its mail-order pharmacies. The FDA alleged that Express Scripts employees used invalid DEA numbers in the company's computerized prescription processing system to process certain controlled substances prescriptions at all its mail-order facilities.

05/22/12 A physician-owner of several Kansas heart clinics paid $1.5 million to settle allegations that his clinics submitted false claims to Medicare. The government contended that, from 2005 to 2009, he submitted claims for services that took place when he was not at the clinic.

05/24/12 South Shore Hospital paid $750,000 to resolve allegations of privacy law violations arising from a 2010 data breach involving personal data on as many as 800,000 people. The Hospital reported that it had not received destruction verification certificates from a firm it hired to destroy unencrypted backup computer tapes.

05/31/12 St. Jude Medical paid $3.65 million to resolve allegations that it unlawfully inflated the cost of replacement pacemakers and defibrillators by failing to apply pricing credits to devices that were replaced while covered under warranty.

05/31/12 Main Line Hospital paid just over $1 million to resolve allegations that it billed Medicare for E&M services that were not allowable under the program. The Hospital allegedly billed using modifier 25 inappropriately for services, that were not significant, separately identifiable, and above and beyond the usual preoperative and postoperative care.

05/31/12 Hospice Family Care paid $3.7 million to resolve allegations that the company by submitted claims for payment for patients who were either completely or partially hospice ineligible, or were provided a higher level of hospice care than was necessary or allowable.

06/07/12 Orthofix paid $42 million to resolve civil and criminal liability relating to sales of its bone growth stimulators. The settlement included $34.2 million to settle FCA allegations and a $7.7 million criminal fine. Orthofix Inc. agreed to plead guilty to a felony of obstruction of a federal audit, and to pay the criminal fine. The Company's criminal guilty pleas involved its failure to disclose information about its practices regarding certificates of medical necessity to a Medicare contractor during a June 2008 audit. Five individual Orthofix employees previously plead guilty to criminal charges.

06/14/12 Christus Spohn Health System paid $5.1 million to resolve whistleblower allegations that six hospitals submitted false claims to Medicare using inpatient codes for procedures that should have been billed under an outpatient code.

06/15/12 Voyager Hospice Care paid $6.1 million to resolve allegations that it submitted or caused the submission of false Medicare claims for beneficiaries who did not have a terminal prognosis of six months or less.

06/19/12 Atlantic Health System Inc. paid $9 million to resolve whistleblowers' claims that one of its hospitals fraudulently billed Medicare for inpatient care for people who should have been treated as outpatients. The hospital press release states: "Overlook had initially hired the two employees who filed the lawsuit specifically to help ensure that inpatients met admission criteria before claims were submitted to Medicare."

06/26/12 Alaska's Medicaid agency paid $1.7 million to settle allegations it violated HIPAA. HHS began investigating data privacy and security practices after the state agency reported a data breach. The breach occurred when a USB hard drive on which PHI was stored was stolen from a DHHS employee's car.

06/29/12 Maury Regional Medical Center paid $3.6 million to settle allegations the hospital improperly billed Medicare for ambulance services that were not medically necessary.

07/02/12 GlaxoSmithKline plead guilty and paid $3 billion to resolve its criminal and civil liability arising from allegations of unlawful promotion of certain prescription drugs, its failure to report certain safety data, and alleged false price reporting practices. GSK will pay a total of $1 billion, including a criminal fine of $956 million and forfeiture in the amount of $43 million. GSK also paid $2 billion to resolve its liabilities under the False Claims Act.

07/02/12 NextCare Inc. paid $10 million to settle allegations that it submitted false claims to numerous public health plans. NextCare was accused of billing unnecessary allergy, H1N1 virus, and respiratory panel testing, as well as upcoding for urgent care services.

07/03/12 DaVita, Inc. paid $55 million to settle a whistleblower lawsuit alleging overutilization and off-label use of the drug Epogen.

07/17/12 A Georgia hospice paid $555,000 to settle a whistleblower lawsuit alleging it billed patients for higher inpatient rates for services at its inpatient facility when they did not qualify for the higher level of care because they did not require or receive care for acute or chronic symptom management that could not be managed in settings outside an inpatient facility.

07/27/12 McKesson Corp. paid more than $151 million to several state governments to resolve claims that it reported inflated pricing information for a large number of prescription drugs. The settlement involved 29 states and the District of Columbia.

07/30/12 Accretive Health Inc. paid $2.5 million to settle a claim that the theft of a company laptop had resulted in the loss of individually identifiable health information.

08/02/12 The Mayo Clinic paid more than $1.2 million to settle a whistleblower's lawsuit alleging the health provider submitted claims to Medicare, Medicaid, and other federal programs for work it did not perform.

08/10/12 CareAll Management, a home health provider, paid $9.4 million for allegedly causing Medicare to overpay by falsely concealing its relationship with its management company.

08/10/12 Altec Medical Inc., a South Carolina pharmaceutical distribution company, paid $3 million in connection with a drug diversion scheme.

08/14/12 Jack Baker, a Houston radiologist, paid $650,000 to settle whistleblower litigation alleging that he paid illegal compensation to 17 doctors to induce them to refer patients to a diagnostic imaging center he owned.

08/23/12 SCAN Health Plan paid $320 million to resolve whistleblower allegations that it received overpayments from Medi-Cal, California's Medicaid program. for more than two decades. The whistleblower alleged that the health plan unlawfully caused an inflation in some patients' "risk adjustment scores," which then inflated Medicare payments to the company.

08/23/12 Memorial Health Care System (Tennessee) paid $1.28 million to settle charges by federal prosecutors that it illegally provided financial incentives for providers to refer patients to its hospitals.

08/23/12 Pacific Health Corp. and three subsidiary hospitals paid $16.5 million to resolve allegations that the companies participated in an illegal kickback scheme involving the recruitment of homeless individuals and false billings to Medicare and Medi-Cal.

08/28/12 A New York Downtown Hospital paid $13.4 million to resolve charges that it participated in a kickback scheme involving illegal patient referrals from a detoxification services management company to several New York City hospitals. The detox program was run without having the necessary state license.

09/05/12 Pinnacle Medical Solutions LLC paid nearly $1.8 million to settle a whistleblower lawsuit alleging it billed the government for insulin pump kits and blood glucose test strips that were medically unnecessary.

09/17/12 Massachusetts Eye and Ear Hospital paid $1.5 million to the federal government to resolve allegations it violated the HIPAA Security Rule by failing to properly protect patients' protected health information maintained on portable devices based upon a data breach that occurred because a doctor's laptop computer containing unencrypted patient data was stolen.

09/19/12 Georgia Cancer Specialists I PC paid $4.1 million to settle claims that it billed Medicare for E&M services not permitted by Medicare rules. Settlement related to used modifier-25.

09/19/12 HCA Inc. paid $16.5 million to settle allegations that its Chattanooga, TN hospital had leases with physicians that were not FMV. The whistleblower was a real estate appraiser.

09/28/12 Wyoming Medical Center paid $2.7 million in a settlement of a whistleblower case that accused the facility of submitting fraudulent claims to Medicare by submitting requests for reimbursement that were inconsistent with patient treatment records; by changing the admission status of patients from outpatient to a higher-paying inpatient status without a physician order; and by billing Medicare for unnecessary inpatient admissions.

10/01/12 Anthem Blue Cross paid $150,000 and implement new technical safeguards for its data management system to settle allegations that it illegally disclosed the Social Security numbers of some 33,000 of its Medicare Supplement and Medicare Part D subscribers between April 2011 and March 2012.

10/15/12 CVS Caremark Corp. paid $5.25 million to resolve a False Claims Act civil lawsuit alleging deceptive drug pricing submissions to Medicare.

10/24/12 Westchester County Health Care paid $7 million to settle allegations that it failed to provide core documentation required for outpatient services Medicaid billings by its hospital mental health center.

10/25/12 Boehringer Ingelheim Pharmaceuticals paid $95 million to settle a whistleblower lawsuit alleging that the drugmaker marketed drugs for uses not approved by the Food and Drug Administration.

11/02/12 Blackstone Medical Inc. paid $30 million to settle a *qui tam* lawsuit alleging that the company paid illegal kickbacks to induce doctors to use its spinal products. The settlement resolves allegations that Blackstone paid kickbacks to spinal surgeons, including sham consulting agreements, sham royalty arrangements, sham research grants, and travel and entertainment. The whistleblower will receive $8 million from the settlement. The government did not intervene in the action.

11/19/12 Harmony Care Hospice paid $1.3 million to settle allegations for allegedly routinely and knowingly billing Medicare for hospice care, even though the terminally ill requirements were not met.

11/19/12 Coventry Health Care Inc., a provider of group and individual health insurance, paid $3 million and enter into a non-prosecution agreement to settle allegations that Coventry employees inappropriately accessed a Medicare database to obtain eligibility information for the sale of Medicare set-aside products, granting it an unfair competitive advantage.

11/20/12 Morton Plant Mease Health Care paid $10,169,114 to resolve whistleblower allegations that Morton Plant improperly billed for certain interventional cardiac and vascular procedures as inpatient care when those services should have been billed as less costly outpatient care or as observational status.

12/06/12 Healthpoint Ltd. and DFB Pharmaceuticals paid $48 million to resolve allegations that they caused Medicare and Medicaid to pay for the unapproved wound care prescription drug Xenaderm. The government alleged that Healthpoint submitted false statements concerning the regulatory status of Xenaderm to the government in violation of the False Claims Act.

12/12/12 Pfizer Inc. paid $55 million plus interest to resolve allegations that its Wyeth unit promoted the drug Protonix for unapproved uses. Specifically, the settlement resolves allegations that Wyeth illegally introduced and caused the introduction into interstate commerce of Protonix, a misbranded drug, between February 2000 and June 2001.

12/19/12 WakeMed paid $8 million and executed a deferred prosecution agreement to settle allegations it falsely billed Medicare for inpatient stays. The hospital billed Medicare for inpatient stays, when they actually were outpatient visits. WakeMed allegedly billed Medicare for inpatient stays even though, in many instances, the referring physician did not order the beneficiary to be admitted and the patient never occupied an inpatient bed.

12/19/12 Amgen paid $762 million to resolve allegations of off-label marketing of the anemia drug Aransep. Amgen also pleaded guilty to one misdemeanor charge of misbranding. The settlement resolves allegations that Amgen illegally sold Aransep at doses that the FDA had rejected and for a treatment that the FDA had not approved as well as allegations of kickbacks to influence health care providers to select Amgen products.

12/19/12 Sanofi U.S. Inc. paid $109 million to resolve allegations that it gave health care providers free units of its knee injection drug Hyalgan to induce the providers to prescribe the drug. The settlement resolves claims that the company submitted false average sales price reports for Hyalgan that omitted the free units distributed.

12/27/12 Victory Pharma Inc., a San Diego-based specialty drug company, paid $11.4 million to resolve federal civil and criminal liability arising from the marketing of its products. The company allegedly paid kickbacks such as tickets to professional and collegiate sporting events, tickets to concerts and plays, spa outings, golf and ski outings, dinners at expensive restaurants, and numerous other out-of-office events.

III. COURT DECISIONS

01/20/12 Whitaker v. Health Net of California Inc., E.D. Cal. No. 2:11-cv-910. The court dismissed a data breach action holding that the Plaintiffs failed to show actual injury. Plaintiffs, whose personal and medical data was compromised when a technology company lost nine server drives containing the information, did not have standing to sue the company under California law.

02/02/12 United States v. Krikheli, 2d Cir., No. 11-2865. The Second Circuit upheld the Medicare fraud convictions of a couple involved in a bribery and kickback scheme for referring Medicare patients to a particular diagnostic imaging facility, affirming the "one purpose test" intent standard under the AKS.

02/07/12 Fox v. Good Samaritan Hospital LP, 9th Cir., No. 10-15989. A California doctor was not able to overcome the presumption that the Health Care Quality Improvement Act (HCQIA) granted a hospital immunity for suspending the physician's privileges, the Ninth Circuit said in affirming summary judgment of the hospital. The court held that HCQIA reached actions taken based on a physician's refusal to follow hospital administrative rules.

02/08/12 United States ex rel. Hendren v. Mayo, N.D. Miss., No. 2:09-cv-00210. The court dismissed a whistleblower lawsuit filed by a psychologist and an administrator for failing to substantiate with more than suspicion that a behavioral hospital in Mississippi violated the False Claims Act. A psychologist claimed the behavioral facility revoked her privileges for complaining about a physician who allegedly was "poaching" her patients.

02/10/12 GOS Operator LLC v. Sebelius, S.D. Ala. No. 1:12-cv-00035. The court denied a motion for a preliminary injunction to halt HHS from revoking a skilled nursing facility's provider agreement for not complying with Medicare participation rules.

02/13/12 United States ex rel. Johnson v. Golden Gate National Senior Care LLC, D. Minn., No. 0:08-cv-01194. The court refused to dismiss a whistleblower complaint filed by a woman alleging that her former employer fraudulently billed Medicare for occupational and physical therapy services for time she spent watching patients exercise in a skilled nursing facility's fitness room.

02/14/12 United States ex rel. Watine v. Cypress Health Systems Florida Inc., N.D. Fla., No. 1:09-cv-00137. The court denied a motion to dismiss a whistleblower lawsuit. The whistleblower alleged the hospital pressured him and other doctors to upcode their reports so the hospital would receive greater reimbursement from Medicare. The hospital argued that it should not be held liable for fraud that occurred before 100 percent of its stock was transferred from a predecessor entity.

02/14/12 United States v. McKesson Corp., N.D. Miss., No. 2:08-cv-00214. The court denied three defense motions for summary judgment in a lawsuit alleging that a nursing home chain and a medical supplier violated the Anti-Kickback Statute. The court rejected MediNet's argument that it was exempted from the AKS's penalties under the discount safe harbor because neither Beverly nor MediNet had any duty to disclose or report the alleged "discount" provided by MediNet, as no cost report is required for subcontracted services.

02/17/12 Doe v. Guthrie Clinic Ltd., W.D.N.Y., No. 6:08-cv-6227. The court held that a medical clinic is not vicariously liable for an employee's dissemination of a patient's private health information regarding his treatment for a sexually transmitted disease. The clinic could not be held liable for a nurse's conduct because she was acting outside the scope of her official duties when she revealed confidential information about a patient.

02/27/12 United States ex rel. McDonough v. Symphony Diagnostic Services, Inc., S.D. Ohio, No. 2:08cv-00114. The court denied a motion to dismiss a whistleblower lawsuit claiming a mobile X-ray service gave nursing homes illegal kickbacks. The case alleges that the X-ray company offered skilled nursing facilities substantial discounts for X-ray services covered by the nursing homes' per diem reimbursements. The discounts were allegedly in exchange for patient referrals of the nursing homes' other Medicare and Medicaid service needs.

03/02/12 United States ex rel. Vainer v. Davita Inc., N.D. Ga., No. 1:07-cv-2509. The court refused to dismiss two of three claims filed by two whistleblowers alleging that DaVita caused providers to fraudulently bill for injectable prescription drugs that actually were discarded as wastage.

03/06/12 United States ex rel. Drennen v. Fresenius Medical Care Holdings Inc., D. Mass., No. 1:09-cv-10179-GAO. The court refused to dismiss a whistleblower's suit alleging that Fresenius Medical Care Holdings Inc. billed for unnecessary tests.

03/14/12 United States ex rel. Allen v. Guidant Corp., D. Minn., No. 0:11-cv-00022. The court refused to dismiss a whistleblower's suit alleging that Guidant Corp. violated the False Claims Act by falsely representing to Medicare and the Veterans Administration that Prizm 1861 implantable cardioverter defibrillators were free from known defects.

03/26/12 United States ex rel. Conrad v. Healthpoint Ltd., D. Mass., No. 02-11738. The court refused to dismiss a whistleblower's suit alleging that the pharmaceutical manufacturer violated the False Claims Act by submitting reimbursement claims for a topical wound ointment, Xenederm, that was ineligible for payment because an identical drug's effectiveness determination had been rescinded.

04/09/12 United States ex rel. Banignan v. Organon USA Inc., D. Mass., No. 07-12153. The court dismissed one of the defendants in a *qui tam* suit alleging that Organon USA Inc. engaged in a scheme to offer illegal remuneration to long-term care pharmacies to prescribe its antidepressants, finding that it lacked personal jurisdiction over Organon's Dutch parent company.

04/13/12 United States ex rel. Yanity v. J & B Medical Supply Co., E.D. Mich., No. 2:08-cv-11825. The court refused to dismiss a whistleblower suit by three former medical supply company employees who alleged the defendant unlawfully billed Medicaid for supplies that were not delivered.

4/26/12 Bechtel v. St. Joseph Medical Center Inc., D. Md., No. 1:10-cv-3381. The court ruled that a physician assistant who helped a False Claims Act *qui tam* plaintiff gather information about a hospital named as a defendant in the FCA case can maintain a lawsuit alleging that she was fired by the hospital in retaliation for her actions.

5/10/12 United States v. Zhou, 9th Cir., No. 10-50231. The court of Appeals for the Ninth Circuit held that Defendants who access private health information without knowing that their actions are illegal can be prosecuted under the misdemeanor criminal provisions of HIPAA.

5/15/12 United States ex rel. Davis v. District of Columbia, D.C. Cir., No. 11-7039. The court of Appeals reinstated a *qui tam* action alleging that the District of Columbia and its schools violated the False Claims Act by submitting a Medicaid reimbursement claim without maintaining adequate supporting documentation. Overruling its own previous decision, the Court held that it will no longer require that a relator provide information to the government prior to any public disclosure of substantially similar allegations.

05/21/12 United States ex rel. Goldberg v. Rush University Medical Center, 7th Cir., No. 10-3785. The court of Appeals reinstated a False Claims Act *qui tam* action filed by two former residents who alleged the hospital billed Medicare for operations performed by residents who were not properly supervised by attending physicians. The court found that prior audits did not prevent the residents from being an original source.

05/30/12 PremierTox Inc. v. Kentucky Spirit Health Plan Inc., W.D. Ky., No. 1:12-cv-10. The court ruled that claims for reimbursement brought by affiliated Kentucky laboratory services firms against a Medicaid managed care company must be resolved by a state court.

06/01/12 United States ex rel. Banignan v. Organon USA Inc., D. Mass., No. 07-12153. The court dismissed whistleblower claims alleging that drug manufacturer and long-term care pharmacy provider solicited kickbacks in exchange for switching patients to "preferred drugs." The court found these allegations failed under both the FCA's first-to-file and public disclosure bars.

06/14/12 Morgan v. Sebelius, 4th Cir., No. 10-2270. The Fourth Circuit affirmed a district court's decision that barred a doctor from practicing in Medicare programs for five years after the doctor diverted hydrocodone samples for his personal use.

07/03/12 United Sates ex rel. Streck v. Allergan Inc., E.D. Pa., No. 2:08-cv-05135. The court declined to dismiss a whistleblower lawsuit alleging that drug companies fraudulently reported prices to the government to pay smaller Medicaid rebates, but dismissed some claims and companies from the case.

07/05/12 United States ex rel. Heineman-Guta v. Guidant Corp., D. Mass., No. 1:09-cv-11927. The court dismissed a relator's complaint for not being the first to file because of an earlier-filed complaint, albeit procedurally invalid.

07/09/12 United States ex rel. Ruhe v. Masimo Corp., C.D. Cal., No. 2:10-cv-8169. The court refused to dismiss claims against the manufacturer of hemoglobin measuring devices, alleging it violated the False Claims Act in seeking payment from federal health care programs for devices that were not accurate.

07/13/12 Sandoz Inc. v. State, Ala., No. 1081402. The Alabama Supreme Court overturned a $78.4 million jury verdict against Sandoz Inc., citing lack of evidence to support a charge of fraud over Medicaid drug reimbursements. The state alleged that Sandoz defrauded it by reporting certain pricing information (such as AWP) that induced the Alabama Medicaid Agency to pay too much for drugs when it reimbursed providers. In a 7-1 ruling, the court ruled the state failed to prove that Sandoz defrauded the Alabama Medicaid Agency because the state knew that Sandoz's drug prices were "not what the State claims they should have been," so any reliance on them was not reasonable.

07/19/12 In re Baycol Products Litigation, D.Minn., No. 08-cv-05758. The court dismissed a whistleblower suit against Bayer Corp. over allegedly false claims that state and federal health programs paid for Bayer's cholesterol drug Baycol.

07/23/12 Tate v. University Medical Center of Southern Nevada, 9th Cir., No. 11-15602. The appeals court upheld the dismissal of due process and contract-based claims brought by a trauma surgeon against a Nevada hospital that terminated his on-call duties.

07/30/12 Friedman v. Sebelius, D.C. Cir., No. 11-5028. A divided appeals court panel agreed with the government that misdemeanor misbranding convictions, based on the responsible corporate officer doctrine (RCO), were crimes "relating to fraud" that could support program exclusions. The court of Appeals held that the HHS was arbitrary and capricious in barring three senior drug company executives from federal programs for 12 years under the responsible corporate officer (RCO) doctrine.

07/30/12 United States v. Kernan Hospital, D.Md., No. 1:11-cv-02961. The court dismissed the federal government's False Claims Act lawsuit against a hospital because it failed to connect an alleged scheme of "systemic upcoding" of malnutrition to claims for Medicare, Medicaid, and TRICARE reimbursement. The court said, in a "telling moment of candor," the government in a hearing conceded that the inclusion of Kwashiorkor as a secondary diagnosis would not necessarily increase the hospital's funding. This admission "underscore[d] the failure of the [g]overnment's [c]omplaint to adequately identify the false claims at issue."

08/03/12 United States ex rel. Provuncher v. AngioScore Inc., No. 1:09-cv-12176. The court dismissed a whistleblower's lawsuit against a medical device manufacturer alleging the company violated the False Claims Act by deliberately suppressing "adverse event reporting" of injuries and incidents involving separation of a catheter and selling it with knowledge of its defect.

08/14/12 United States ex rel. Parks v. Alpharma Inc., 4th Cir., No. 11-1498. The court of Appeals affirmed the dismissal of a *qui tam* relator's retaliation claim, finding that she filed to establish that her employer knew that FCA litigation over its promotion of the sustained-release morphine product Kadian was a possibility. The Fourth Circuit found that relator's complaints were clearly couched in terms of concerns and suggestions, not threats and warnings of FCA litigation.

08/17/12 United States ex rel. Black v. Health & Hospital Corp of Marion County, 4th Cir., No. 11-1726. The court of Appeals upheld the dismissal of a whistleblower's lawsuit alleging a scheme orchestrated by an Indiana provider in which Medicaid reimbursements were fraudulently obtained for nursing home expenditures that were never made.

08/30/12 Assaf v. Trinity Medical Center, 7th Cir., No. 11-3918. The court of Appeals found that a physician seeking to enforce a settlement agreement entered in a breach of contract action was entitled to recover professional fees he would have earned had his former employer re-employed him in accordance with the settlement, notwithstanding the Stark Law.

09/06/12 United States v. Orthofix Inc., D. Mass., No 12-CR-10169. A federal judge rejected a plea agreement under which Orthofix Inc. would pay nearly $42 million in criminal and civil penalties arising from its allegedly illegal promotion of bone growth stimulators.

09/07/12 Cohlmia v. St. John Medical Center, 10th Cir., U.S. District Court for the Northern District of Oklahoma (D.C., No. 4:05-CV-00384). The court of Appeals upheld the dismissal of claims based upon peer review action.

09/10/12 United States ex rel. Coots v. Reid Hospital & Health Care Services Inc., S.D. Ind., No. 1:10-cv-00526. The court allowed a *qui tam* lawsuit to proceed based on allegations the hospital submitted false claims to Medicare and Medicaid, while also dismissing some claims that failed to state a legally-cognizable claim. The whistleblower was a consultant and certified medical coding specialist who was contracted to evaluate the Hospital's billing practices.

09/11/12 Palomar Medical Center v. Sebelius, 9th Cir., No. 10-56529. A federal appeals court ruled that providers are not entitled to appeal a Medicare Recovery Audit Contractor's decision to reopen a Medicare payment decision, even if no good cause is shown for the reopening decision.

09/26/12 Bontrager v. Indiana Family & Social Services Administration, 7th Cir., No. 11-3710. The court of Appeals held that Indiana's $1,000 cap on Medicaid coverage for medically necessary dental services most likely violates the rights granted to Medicaid recipients by federal law and affirmed a preliminary injunction preventing the state from enforcing its limitation.

09/26/12 United States ex rel. Gale v. Omnicare Inc., N.D. Ohio, No. 1:10-cv-00127. The court refused to dismiss a whistleblower's claims alleging that a supplier of prescription drugs to long-term care facilities, violated the False Claims Act by offering and providing "prompt payment" discounts and per diem pricing as an inducement for patient referrals for which it could bill insurance programs.

09/28/12 United States ex rel. Jamison v. McKesson Corp., N.D. Miss., No. 2:08-cv-214. The court entered judgment for durable medical equipment suppliers and contract billers that were accused of violating the federal False Claims Act by falsely certifying that they complied with federal regulations relating to Medicare and Medicaid reimbursement.

09/28/12 United States ex rel. Osheroff v. Humana Inc., S.D. Fla., No. 1:10-cv-24486. The court dismissed a relator's False Claims Act complaint against Humana Inc., finding it was barred by prior public disclosures.

10/01/12 United States ex rel. Upton v. Family Health Network Inc., N.D. Ill., No. 1:09-cv-06022. The court dismissed a *qui tam* action, finding that the relators (former marketing representatives for the defendant managed care organization) failed to prove that allegedly false certifications of regulatory compliance made in the course of a cherry-picking scheme were conditions for payment. The court also rejected the relators' argument that their allegations were sufficient because they alleged that the certifications were "conditions for participation."

10/02/12 United States ex. rel. Robinson-Hill v. Nurses' Registry and Home Health Corp., E.D. Ky., No. 5:08-cv-00145. The court refused to dismiss the government's False Claims Act complaint against a home health care services company that allegedly upcoded patients' medical symptoms and provided medically unnecessary therapy visits to obtain more and larger reimbursements from Medicare.

10/05/12 United States ex rel. Williams v. Renal Care Group Inc., 6th Cir., No. 11-5779. The court of Appeals overturned a summary judgment ruling against a dialysis provider and found that the provider's attempts to comply with "ambiguous" regulations did not violate the False Claims Act and that conditions of participation are not the predicate for a FCA action.

10/10/12 United States ex rel. Yanity v. J & B Medical Supply Co., E.D. Mich., No. 2:08-cv-11825. The court refused to dismiss a whistleblower lawsuit by three former medical supply company employees who alleged the defendant unlawfully billed Medicaid for supplies that were not delivered.

10/12/12 Sandoz Inc. v. Commonwealth ex rel. Conway, Ky. Ct. App., No. 2010-CA-000626. The Kentucky Court of Appeals reversed a more than $30 million jury award against Sandoz Inc. and AstraZeneca LP. The court found the prior findings of the jury "clearly unreasonable" since the state knew how average wholesale pricing worked.

10/23/12 United States ex rel. Tucker v. Christus Health, S.D. Tex., No. 4:09-cv-01819. The court allowed a False Claims Act *qui tam* lawsuit to proceed against four defendants that allegedly billed Medicare for medically unnecessary inpatient stays, specialty care, and use of medical equipment.

10/29/12 United States ex rel. Armfield v. Gills, M.D. Fla., No. 8:07-cv-02374. The court denied summary judgment to a whistleblower in a lawsuit alleging violations of the AKS, finding that rental and service agreements between the defendants and a physician who provided preoperative exams at an eye treatment complex they owned were sufficiently specific to fall within the AKS's safe harbor provisions for space leases.

11/01/12 United States ex rel. Ge v. Takeda Pharmaceutical Co., D. Mass, No. 1:10-cv-11043. The court dismissed claims brought against Japanese drug firm Takeda by a former medical reviewer for the company alleging that Takeda violated the False Claims Act by not disclosing adverse event reports related to several of its drugs.

11/01/12 American Hospital Ass'n v. Sebelius, D.D.C., No. 1:12-cv-1770. The American Hospital Association and four hospital systems filed a lawsuit against the Department of Health and Human Services, alleging that HHS audit contractors improperly demanded that hospitals return certain Medicare payments for services they provided to Medicare patients.

11/09/12 In re Porter, Vt., No. 2012-045. The Vermont Supreme Court ruled that a supervising physician may not be subject to a discipline under state law solely because of the unprofessional actions of a physician assistant. The Vermont high court said a state law holding supervising physicians "legally liable" for the actions of PAs to whom they delegate patient care responsibilities does not impose "professional responsibility" on the supervising physician for the unprofessional conduct of those PAs.

11/15/12 United States ex rel. Polansky v. Pfizer Inc., E.D.N.Y., No. 1:04-cv-00704. The court dismissed a whistleblower's case alleging Pfizer's marketing of Lipitor violated the False Claims Act. The court found that the company's promotion of its cholesterol medication did not constitute off-label promotion leading to false claims.

11/20/12 United States v. Kernan Hospital, D. Md., No. 1:11-cv-02961. The court set aside a civil investigative demand by the Dept. of Justice against a hospital after dismissing a False Claims Act *qui tam* complaint against it, ruling that CIDs are not allowed after a complaint has been dismissed.

11/23/12 Foglia v. Renal Ventures Management, D.N.J., No. 1:09-cv-01552. The court dismissed a whistleblower action after finding that the registered nurse who alleged a dialysis provider falsely certified compliance with health care regulations failed to connect alleged violations of state licensing rules with conditions of payment under Medicare.

12/14/12 United States ex rel. Dunn v. North Memorial Health Care., D. Minn., No. 0:10-cv-04673. The court dismissed a False Claims Act lawsuit by a former heart clinic employee who alleged that a hospital failed to provide direct supervision of outpatient cardiac and pulmonary rehabilitation services, finding the pertinent regulations did not require physicians to periodically assess patients' progress.

12/20/12 United States ex rel. Spay v. CVS Caremark Corp., E.D. Pa., No. 2:09-cv-04672-RB. The court declined to dismiss a whistleblower's case against CVS Caremark for allegedly defrauding the Medicare Part D program. The court said the complaint against the pharmacy benefits manager (PBM) company properly pleaded falsity under both a false certification theory and a worthless services theory.

IV. HHS INSPECTOR GENERAL PRONOUNCEMENTS

A. ADVISORY OPINIONS

03/15/12 Advisory Opinion 12-01 (concerning a proposal to establish a group purchasing organization ("GPO") that would be wholly owned by an entity that also wholly owns many of the potential participants in the GPO, and to pass through to participants in the GPO a portion of the payments received by the GPO from vendors)

03/27/12 Advisory Opinion 12-02 (concerning a proposal to operate a website that would display coupons and advertising from health care providers, suppliers, and other entities)

04/11/12 Modification of Advisory Opinion 08-17 (concerning regarding a tax-exempt, charitable organization's proposed arrangement to provide counseling from a law firm regarding financially needy patients' eligibility for federal and state funded

benefits programs and, for patients who appear to be eligible, assistance from the law firm in applying for benefits)

04/26/12 Advisory Opinion 12-03 (concerning a proposal by a municipal fire department to share certain costs related to dispatch and other services with hospital-based ambulance providers that participate in the local 911 emergency dispatch system)

04/30/12 Advisory Opinion 12-04 (concerning certain aspects of an exclusive contract for emergency transport services between a municipality and an ambulance company that reimburses the municipality for dispatch services and for certain costs incurred when municipal firefighters drive transports)

05/01/12 Advisory Opinion 12-05 (concerning a rewards program under which consumers would earn gasoline discounts based on the amount spent on purchases in retail stores and pharmacies, including cost-sharing amounts paid in connection with items covered by Federal health care programs)

06/01/12 Advisory Opinion 12-06 (concerning two proposals by an anesthesia services provider to enter into contracts with physician-owned professional corporations or limited liability companies to provide anesthesia services)

06/20/12 Advisory Opinion 12-07 (concerning an exclusive arrangement between a county and an emergency medical services company whereby the company provides emergency ambulance services to county residents)

06/29/12 Advisory Opinion 12-08 (concerning a proposal for an independent diagnostic testing facility to hire a doctor to read and interpret test results when that doctor is closely related to the owners of the independent diagnostic testing facility and is employed by a company that also employs other potential referral sources)

07/30/12 Advisory Opinion 12-09 (concerning reduced-rate arrangements for the provision of therapy services at state-operated veterans' homes)

08/30/12 Advisory Opinion 12-10 (concerning a proposal by a radiology group to offer free insurance pre-authorization services to physicians and patients)

09/11/12 Advisory Opinion 12-11 (concerning an ambulance supplier's proposal to routinely waive cost-sharing amounts for emergency medical services rendered on a part-time basis)

09/13/12 Advisory Opinion 12-12 (concerning a proposed bundle billing arrangement for basic life support advanced life support joint responses)

10/05/12 Advisory Opinion 12-13 (concerning a proposal by a hearing aid supplier to begin billing Medicare for certain audiometric testing, while continuing to offer free hearing tests to prospective hearing aid customers)

10/16/12 Advisory Opinion 12-14 (concerning a rewards program under which consumers would earn gasoline discounts based on the amount they spend on purchases in retail supermarkets, including cost-sharing amounts paid in connection with items covered by Federal health care programs purchased in the in-store pharmacies)

10/30/12 Advisory Opinion 12-15 (concerning an existing arrangement under which a hospital pays a per diem fee to physicians for providing on-call coverage for the hospital's emergency department)

11/05/12 Advisory Opinion 12-16 (concerning a proposal to waive cost-sharing amounts on a non-routine, unadvertised basis for insured patients, including Federal health care program beneficiaries, based on individualized determinations of financial need)

11/09/12 Advisory Opinion 12-17 (concerning a proposal for a hospice to establish a volunteer program to provide non-skilled services to terminally ill patients who do not qualify for hospice care)

12/06/12 Advisory Opinion 12-18 (concerning a proposed arrangement whereby three municipalities will reciprocally waive the otherwise applicable cost-sharing obligations of each other's bona fide residents when providing backup emergency medical services transportation to such individuals in certain circumstances)

12/07/12 Advisory Opinion 12-19 (concerning four proposed arrangements involving a pharmacy company's provision of items and services to community homes in which its customers reside)

12/19/12 Advisory Opinion 12-20 (concerning a hospital's proposal to provide free access to an electronic interface to community physicians and physician practices that would allow those physicians and practices to transmit orders for certain services to, and receive the results of those services from, the hospital)

01/03/13 Advisory Opinion 12-21 (concerning a Federally qualified health center's proposal to offer grocery store gift cards to certain patients in capitated managed care plans as an incentive to receive health screenings or other clinical services)

01/07/13 Advisory Opinion 12-22 (concerning an arrangement in which a hospital pays a cardiology group compensation that includes a performance bonus based on implementing certain patient service, quality, and cost savings measures associated with procedures performed at the hospital's cardiac catheterization laboratories)

B. OIG CIVIL MONETARY PENALTIES ACTIONS

01/06/12 Nathaniel Brown, M.D., Mississippi, paid $108,000 for allegedly violating the CMP Law. The OIG alleged that Brown caused improper claims to be submitted to Medicare from Mississippi Care Partners, Inc., for physical therapy and related health care items or services that Brown did not personally render or did not directly supervise.

01/20/12 After it self-disclosed, Advanced Physical Therapy, PLLC and Richard Brannin, PT (collectively respondents), West Virginia, paid $62,460 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that the respondents accepted patients for treatment who presented with a physician's written order for physical therapy from Richard Brannin's spouse. The respondents indirectly paid remuneration to Richard Brannin's spouse. As a result, the respondents presented claims to Medicare for physical therapy services that were furnished pursuant to prohibited referrals.

02/13/12 After it self-disclosed, Reid Hospital & Health Care Services, Inc., Indiana, paid $96,645.70 for allegedly violating the CMP Law. The OIG alleged that Reid made and used false records to secure payment of false and fraudulent claims for items and services furnished under Medicare.

02/22/12 Ronald V. Myers, Sr., M.D., Mississippi, paid $25,500 for allegedly violating the CMP Law. The OIG alleged that Myers caused improper claims to be submitted to Medicare from Select Care, Inc. and Primary Physical Medicine, Inc., for physical therapy and related health care items or services that Myers did not personally render or did not directly supervise.

04/03/12 After it self-disclosed, Transitional Services for New York, Inc., New York, paid $141,275 for allegedly violating the CMP Law. The OIG alleged that TSNYI submitted to Medicare upcoded claims for reimbursement for outpatient psychotherapy and psychiatric services.

05/10/12 After it self-disclosed, Animas Corporation, Pennsylvania, paid $1,683,000 for allegedly violating the CMP Law. The OIG alleged that Animas submitted reimbursement to Medicare and Medicaid for infusion pumps and supplies that were based upon documentation that included signed written orders received from physicians which had been altered without the physician's approval.

06/22/12 After it self-disclosed to the OIG, Good Samaritan Hospital Medical Center, New York, paid $604,780.73 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that Good Samaritan paid remuneration to a physician in the form of salary and benefits under a contract for leadership, teaching, and administrative services. The salary and benefits paid were above fair market value.

06/22/12 After it self-disclosed, Good Samaritan Hospital Medical Center and South Bay OB/GYN, New York, paid $1,753,447.40 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that Good Samaritan paid remuneration to South Bay physicians that were more than fair market value because they did not account for the value of the benefits of malpractice insurance premium payments made for the physicians.

06/27/12 After it self-disclosed, The Memorial Hospital at North Conway, New Hampshire paid $20,479.50 for allegedly violating the CMP Law. The OIG alleged that TMH submitted upcoded E&M services provided by one of TMH's physicians.

07/05/12 After it self-disclosed, LipoScience, Inc., North Carolina, paid $151,785 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that LipoScience paid remuneration to employees and referring doctor's offices in the form of thousands of gift cards.

07/06/12 After it self-disclosed, the Treatment and Learning Centers, Inc., Maryland, paid $28,214.16 for allegedly violating the CMP Law. The OIG alleged that TLC knowingly presented claims for items or services that TLC knew or should have known were not provided as claimed and were false or fraudulent. The OIG alleged that TLC improperly submitted claims to Medicare for services rendered by two audiologists, using the Medicare enrollment information and National Provider Identifier of a third audiologist employed by TLC.

07/24/12 After it self-disclosed, Dartmouth-Hitchcock, Vermont, paid $65,934.00 for allegedly violating the CMP Law. The OIG alleged that Dartmouth-Hitchcock submitted claims to Medicare and Medicaid for outpatient ambulatory clinic visits provided by a physician that were not supported by medical record documentation.

08/01/12 After it self-disclosed, Laurence Rosenfield, M.D., P.A., and Spinal Diagnostics & Interventional Pain Medicine, Texas, paid $110,000 for allegedly violating the CMP Law. The OIG alleged that Dr. Rosenfield and SDIPM, through a contracted company, improperly billed Federal health care programs for services provided by a physician that did not have a Medicare provider number. The services were billed using Dr. Rosenfield's provider number.

08/07/12 After it self-disclosed, Supervalu, Inc. paid $184,464.03 for allegedly violating the CMP Law. The OIG alleged that Supervalu submitted claims to Federal health care programs for a branded drug when it dispensed the authorized generic drug.

08/15/12 After it self-disclosed, Colorado Surgical Services, PC, Colorado, paid $13,616.57 for allegedly violating the CMP Law. The OIG alleged that CSS employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

09/11/12 After it self-disclosed, New England Sinai Hospital, Inc., Massachusetts, paid $1,149,396.50 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that NESH paid remuneration to two physicians in the form of: 1) free, or less than fair market value, space and staff; 2) payment for services not performed and services performed pursuant to expired agreements; and 3) paid remuneration to a physicians group in the form of payment for services not performed and services performed without a written agreement.

09/11/12 After it self-disclosed, Sleep Services of America, Inc. paid $1,006,104 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that the problematic arrangements included leases with doctors, medical directorships, personal services contracts and loans to referral sources.

09/25/12 After it self-disclosed, Carlsbad Medical Center, LLC, New Mexico, paid $995,380 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that CMC paid remuneration to three orthopedists in the form of improper payments for on-call coverage, malpractice insurance, travel reimbursement, and overpayments under an income guarantee agreement.

09/26/12 After it self-disclosed, North Canton Medical Foundation, Ohio, paid $1,018,877 for allegedly violating the CMP Law. The OIG alleged that NCMF submitted claims to the Federal health care programs for podiatry services which were not supported by medical documentation.

09/26/12 After it self-disclosed, Salida Hospital District d/b/a Heart of the Rockies Regional Medical Center, Colorado, paid $120,580.25 for allegedly violating the CMP Law. The OIG alleged that HRRMC employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

10/07/12 After it self-disclosed, ABQ Health Partners, LLC, New Mexico, paid $1,096,112 for allegedly violating the CMP Law. The OIG alleged that ABQ submitted claims to Federal health care programs for services performed by pharmacy clinicians during new and established patient visits based on E&M codes that ABQ knew or should have known were not reimbursable.

10/25/12 After it self-disclosed, Colorado Retina Associates, P.C. and Douglas Holmes, M.D., Colorado, paid $71,867.58 for allegedly violating the CMP Law. The OIG alleged that CRA and Dr. Holmes submitted to Federal healthcare programs claims for evaluation and management services that were not provided as claimed and were false or fraudulent.

11/02/12 ForTec Medical, Inc., paid $126,249.30 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that ForTec provided customers (including physicians) an all-expense paid trip to the Masters Golf Tournament. The OIG concluded that the trips were intended to induce referrals.

11/13/12 Safeway, Inc., Wyoming, paid $56,994 for allegedly violating the CMP Law. The OIG alleged that Safeway, Inc. submitted claims to Medicare Part D for the branded drug Protonix when it dispensed the authorized Protonix generic drug known as pantoprazole.

C. OIG - MISCELLANEOUS

02/08/12 The OIG issued an Alert to physicians to exercise caution when reassigning their Medicare payments, stating that physicians may be liable for false claims submitted by entities receiving reassigned Medicare payments.

03/13/12 OIG issued a Fraud Alert concerning callers pretending to be from the government, a diabetes association, or Medicare, and offer free diabetes supplies, including glucose meters and diabetic test strips. Some callers may also offer patients additional free medical supplies, such as orthotics and heating pads.

03/20/12 OIG issued a report finding that 81% of provider audits performed by Medicaid Integrity Contractors (MICs) between January and June 2010 failed to uncover any overpayments.

03/29/12 The HHS proposed altering the National Practitioner Data Bank (NPDB) system of records to allow Privacy Act exemptions for law enforcement agencies accessing NPDB information.

06/01/12 OIG announced revised standards for assessing the performance of state Medicaid Fraud Control Units (MFCUs). The revised standards are effective as of June 1, 2012.

V. CENTERS FOR MEDICARE AND MEDICAID SERVICES

01/20/12 The CMS issued an informational bulletin (CPI-B 12-02) clarifying when states must terminate providers from participation in state Medicaid programs. CMS said in the regulations that the requirement to terminate applies only in cases where providers have had their billing privileges terminated "for cause."

05/20/12 The CMS published a final rule granting state Medicaid programs up to a year from the discovery of an overpayment to collect it and return the federal portion (77 Fed. Reg. 31,499). Previously, states had 60 days to collect Medicaid overpayments and return the federal portion.

11/27/12 The CMS submitted the final rule to implement the Physician Payment Sunshine Act to the Office of Management and Budget for clearance. The final rule, Transparency Reports and Reporting of Physician Ownership of Investment Interests, is the direct result of the Patient Protection and Affordable Care Act, the seventh title of which contains the Physicians Payment Sunshine Act. The Sunshine Act is intended to make transparent all transfers of "value" to medical professionals to help curb both actual and perceived conflicts of interest.

VI. OTHER FRAUD AND ABUSE DEVELOPMENTS

09/24/12 Letter from Attorney General Holder and HHS Secretary Sebelius to 5 hospital associations stating concern that electronic medical records could be used to "game" the system by misuse of template documentation and cutting and pasting documentation.

10/16/12 The internal Revenue Service has identified a universe of 3,377 tax exempt hospitals whose community benefit activities will be reviewed to determine if they are meeting the requirements for tax exemption.

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