I. LEGISLATION AND EXECUTIVE ORDER

A. FEDERAL

01/01/2010 The Mental Health Parity and Addiction Equity Act, known as the Parity Law and included in the Emergency Economic Stabilization Act of 2008, permanently extends and significantly expands upon existing mental health parity provisions in the Employee Retirement Income Security Act (ERISA), the Public Health Services Act, and the Internal Revenue Code. The Parity Law will take effect January 1, 2010, and applies to group health plans (GHPs) that include coverage for medical conditions and coverage for mental health conditions and/or substance abuse disorders. To comply, GHPs have two options: (1) create parity between medical benefits and mental health and substance abuse benefits, or (2) eliminate limited mental health and substance abuse benefits altogether, in which case the Parity Law would not apply.

02/04/09 Children’s Health Insurance Program Reauthorization Act of 2009. President Obama signed legislation reauthorizing the State Children's Health Insurance Program for 4.5 years, extending coverage to an additional 4 million underinsured children and maintaining coverage for nearly 7 million more. Among other things, the program now covers families with incomes up to 300% of the federal poverty level and allows states to drop a five-year waiting period for legal immigrant children and pregnant women who seek public coverage.

02/17/09 Health Information Technology for Economic and Clinical Health Act (HITECH). As part of the American Recovery and Reinvestment Act, the government will invest $20 billion in health information technology (“HIT”) infrastructure and Medicare and Medicaid incentives to encourage doctors and hospitals to use HIT to electronically exchange patients’ health information. Physicians will be eligible to receive up to $44,000 in total incentives per physician for “meaningful use” of a certified Electronic Health Record (EHR) starting in 2011. The Act also strengthens Federal privacy and security law to protect identifiable health information from misuse. The Act also includes a whistleblower protection provision that protects employees who reveal violations of the law related to stimulus funds.

05/20/09 Fraud Enforcement and Recovery Act of 2009. The law amends the False Claims Act to expand liability and investigational authority. The Act clarifies that liability under the False Claims Act attaches whenever a person knowingly makes a false claim to obtain money or property, without regard to whether the wrongdoer deals directly with the federal government. The amendments also provide that the False Claims Act extends to all false claims submitted to state Medicaid programs.

11/20/09 Executive Order 13520. This Order requires that the Office of Management and Budget (OMB) identify federal programs in which the highest dollar value or majority of government-wide improper payments occur. OMB must establish annual or semiannual targets for reducing improper payments associated with each program and, within 180 days, must publish on the internet information about improper payments, including the names of accountable officers, the amounts of the payments, and targets for recovering these payments.
B. COLORADO

03/31/09 Executive Order D 005 09. Colorado Governor Bill Ritter issued an executive order directing the establishment of new hospital patient safety rules that include a provision for the denial of Medicaid payment for avoidable medical errors. The order calls for the Department of Health Care Policy and Financing to implement a policy to deny or reduce payments for inpatient hospital Medicaid claims for procedures involving avoidable medical errors known as “serious reportable events.”

04/16/09 HMOs Offer Limited Benefit Plans (H.B. 1143). Colorado passed legislation allowing health maintenance organizations to offer basic health care services to enrollees through limited benefit plans, which are offered at low cost and limit the amount of payments on particular services and total coverage per person.

04/21/09 Colorado Health Care Affordability Act (H.B. 1293). The law authorizes the Colorado Department of Health Care Policy & Financing to collect a hospital provider fee, not to exceed 5.5% of net patient revenues. This amount, estimated around $600 million, will be matched by federal Medicaid dollars and used to expand health care coverage to more than 100,000 Coloradans.

04/22/09 Presumptive Eligibility Bill (H.B. 1103). This legislation allows for Medicaid coverage to commence immediately upon the completion of paperwork. If there is an ultimate determination of non-eligibility, the recipient is not liable for any retroactive payments.

05/02/09 Health Coverage During Clinical Trials (H.B. 1059). This law requires insurance companies to cover the cost of routine treatment for clients who choose to enroll in clinical trials for cutting-edge therapies.

06/01/09 Medical Benefits for Legal Immigrants (H.B. 1353). The law eliminates the waiting period for legally present pregnant women and children to enroll in Medicaid and CHIP+ programs.

II. FRAUD AND ABUSE SETTLEMENTS

01/14/09 Corporate holding company MIDI LLC and fourteen Open Advanced MRI centers agreed to pay a total of $1.2 million to settle a lawsuit alleging the centers paid illegal kickbacks to physicians in exchange for referrals. The suit alleged that the centers entered into sham lease agreements with physicians under which the physicians paid a reduced rate for MRI and CT scans, charged the patient’s insurance carriers a higher rate, and pocketed the difference.

01/15/09 SouthernCare Inc., a hospice care company based in Alabama, agreed to pay $24.7 million to settle allegations that it submitted false claims for patients treated at its hospice facilities who were not eligible for hospice care.

01/15/09 Eli Lilly and Co. admitted guilt to a misdemeanor criminal charge and agreed to pay more than $1.4 billion to resolve criminal and civil allegations that it promoted the drug Zyprexa for off-label uses, including aggression, dementia, Alzheimer’s, depression, and generalized sleep disorder. The criminal fine was $515 million. The settlement also resolved four 
qui tam
lawsuits filed against Eli Lilly. The company agreed to enter into a five-year corporate integrity agreement with OIG. Eli Lilly will post information on its Web site regarding payments to doctors, such as honoraria, travel, and lodging.
01/26/09 Temple Health Services agreed to pay $284,000 to resolve allegations that it violated the False Claims Act by billing Medicare for physical therapy treatments that were not medically necessary or not provided as billed.

01/27/09 The two physician owners of Manchester Internal Medicine P.C., agreed to pay $313,000 to resolve allegations that each owner violated the False Claims Act. The doctors allegedly submitted claims for services that were not medically necessary or not eligible for reimbursement.

02/09/09 NeuroMetrix Inc. agreed to pay a criminal penalty of $1.2 million and civil damages and penalties totaling $2.5 million under a deferral of prosecution for illegal payment of kickbacks to physicians. The government agreed not to prosecute if the company complies with its obligations, including compliance with a five-year corporate integrity agreement. According to prosecutors, NeuroMetrix marketed a medical device through two referral programs where the company paid physicians in the form of free disposable biosensors to induce them to recommend the purchase of an NC-stat system, used to assist in the diagnosis of neuropathies in peripheral nerves.

02/18/09 CVS agreed to pay $2.25 million after a coordinated investigation by the Department of Health and Human Services and the Federal Trade Commission (FTC) revealed potential violations of the Health Insurance Portability and Accountability Act for failure to implement adequate policies to safeguard patient information during the disposal process. CVS Caremark, the parent company of the retail pharmacy chain, also signed a consent order with the FTC to settle potential violations of the FTC Act.

03/12/09 San Mateo County Medical Center agreed to pay $6.8 million to settle allegations that it submitted false claims to boost its payments from Medicare and Medicaid. In particular, the claims alleged that the medical center falsely reported its available acute care bed count in order to obtain higher disproportionate share hospital payments, and that it improperly obtained Medicaid payments for services provided to patients at Institutes of Mental Disease who were between the ages of 22 and 64.

03/13/09 Healthaways Inc. agreed to pay $40 million to resolve alleged violations under the False Claims Act, the Anti-Kickback Statute, and the Stark Law. The allegations claimed that Diabetes Treatment Centers of America, formerly owned by Healthaways, paid medical directors illegally to induce referrals to its treatment centers.

04/03/09 Dr. Joseph P. Galichia and Galichia Medical Group PA, agreed to pay $1.3 million to settle allegations that he and his practice group violated the False Claims Act by submitting false claims for services that were not provided, and claims that did not have proper documentation.

04/13/09 Interstate Rehabilitation Services LLC paid $233,345 to settle allegations that it caused the submission of false claims to Medicare. The lawsuit alleged that the company improperly billed Medicare for services that were supposed to be provided by licensed physical therapists, but were instead performed by other employees without the presence of a licensed physical therapist.

04/21/09 Lahey Clinic Hospital paid $843,897 to settle allegations that it improperly submitted multiple billings to Medicare when only one unit of service should have been submitted. The billings were for drug infusion therapy, chemotherapy services, and blood transfusion therapy.

04/22/09 Youth and Family Centered Services Inc., based in Austin, Texas, and its Pittsburgh
subsidiary, Southwood Psychiatric Hospital Inc. agreed to pay $150,000 and implement systemic improvements at three of its facilities to resolve allegations that they violated the False Claims Act.

04/29/09 National Medicare Recovery Services Inc. agreed to pay $500,000 after self-disclosing that it presented false claims for wound care supplies.

05/06/09 WellCare Health Plans Inc. agreed to pay $80 million to settle a Florida Medicaid fraud investigation surrounding allegations that WellCare defrauded the state by improperly inflating the amount spent on care.

05/21/09 Three hospitals of HealthEast Care System agreed to pay $2.28 million to resolve allegations that they submitted false claims to Medicare in violation of the False Claims Act. All three hospitals are located in the Twin Cities area and were alleged to have overcharged Medicare each time they performed kyphoplasty, a procedure used to treat certain spinal fractures.

05/21/09 Regency Nursing and Rehabilitation Centers Inc. agreed to pay $4 million to settle allegations that it submitted false claims to Medicare and Medicaid. The government alleged that the nursing home chain submitted claims for reimbursement to Medicare and Medicaid for rehabilitation and skilled nursing services that were not reimbursable because the patients did not qualify for the services, the services were not medically necessary, or they were not supported by adequate documentation.

05/28/09 Aventis Pharmaceutical Inc. agreed to pay $95.5 million to settle allegations that it violated the False Claims Act by misreporting drug prices to reduce its Medicaid Drug Rebate obligations. The government alleged that Aventis knowingly misreported best prices for three steroid-based anti-inflammatory nasal sprays (Azmacort, Nasacort, and Nasacort AQ).

06/04/09 Alta Bates Group Inc., a 600-physician independent practice group, has agreed to settle Federal Trade Commission allegations that its methods of negotiation with health care insurers amounted to improper price-fixing. The group agreed to a consent order barring it from collectively negotiating fee-for-service reimbursements and engaging in related anti-competitive conduct.

06/08/09 Several Oklahoma orthopedic surgery and care providers, as well as Houshang Seradge, a physician with ownership interests in several orthopedic practices, agreed to pay $3.5 million to settle allegations that the providers and Seradge submitted false claims to Medicare. The complaint alleged that the defendants billed for procedures that were not performed, were not performed by a doctor, or were not performed with the required physician oversight.

06/09/09 The University of Medicine and Dentistry of New Jersey (UMDNJ) agreed to pay $2 million to settle allegations under the False Claims Act that it double-billed Medicaid. The hospital allegedly submitted Medicaid claims for outpatient services that also were billed by doctors working in outpatient centers. The double billing allegations were also the subject of a criminal complaint filed against UMDNJ by the government; UMDNJ agreed to implement a deferred prosecution agreement to avoid criminal prosecution for health care fraud in 2006.

06/19/09 Dr. Roberto Ruiz and Southwest Internal Medicine Group agreed to pay $525,000 to settle allegations that the practice falsely billed Medicare for treatment provided to several hospice patients in violation of the False Claims Act.

06/30/09 Johns Hopkins Bayview Medical Center, part of the Johns Hopkins Health System,
agreed to pay $2.75 million to resolve allegations that it submitted false claims to Medicare, Medicaid, and TRICARE in violation of the False Claims Act. The fraudulent claims were based on false statements the hospital made to the Health Services Cost Review Commission about the case mix severity.

07/01/09 Yale-New Haven Hospital agreed to pay $885,953 to settle charges that it billed the Medicare program for medically unnecessary inpatient hospital admissions for patients receiving Gamma Knife stereotactic radiosurgery procedures. The procedure is noninvasive that directs radiation to a specific target and is typically performed on an outpatient basis without general anesthesia.

07/07/09 Amgen Inc. and its subsidiary, Immunex Corp., agreed to pay $7.2 million to settle claims that the companies fraudulently published inflated wholesale prices, wholesale acquisition costs, wholesale acquisition prices, and direct prices for prescription drugs (Aranesp, Epogen, Neulasta, Neupogen, Enbrel and Leukine). The companies allegedly used the artificial spread between the inflated prices they reported and the actual prices they charged to pharmacies and providers to market, promote, and sell their drugs.

07/10/09 Inova Fairfax Hospital agreed to pay $528,158 after self-disclosing that it allegedly paid Arrhythmia Associates in the form of services provided by physician assistants within the organization’s office.

07/14/09 Endoscopic Technologies Inc. agreed to pay $1.4 million to resolve False Claims Act allegations that the company marketed its surgical ablation devices to treat atrial fibrillation, a use for which it had not received approval from the FDA.

07/17/09 Gabriel DeCandido, M.D. agreed to pay the government $1.7 million to resolve allegations that he violated the False Claims Act by billing Medicare for greater levels of service than actually rendered to patients and by billing for services not actually provided. In addition, the physician agreed to a corporate integrity agreement that requires him to engage in “significant compliance efforts” over the next five years.

07/21/09 The State of New York and New York City agreed to pay $540 million to the Department of Justice to settle allegations that they knowingly submitted, or caused to be submitted, false claims for reimbursement for school-based health care services provided to Medicaid-eligible children from 1990-2001. The allegations resulted from an investigation into reimbursement for speech therapy and transportation programs.

07/27/09 Tulare health agencies agreed to pay $2.4 million to settle allegations under the False Claims Act that they offered financial incentives for physician referrals and consequently submitted fraudulent Medicare claims. Specifically, the complaint alleged that Tulare leased office space to physicians below fair-market value, sold developed lots below fair-market value, and granted physicians forgiveness for money owed to the hospital.

08/13/09 Alpha Therapeutic Corp. agreed to pay the State of Texas $1.2 million to resolve allegations that the company improperly reported its drug prices, leading to Medicaid overpayments.

08/13/09 Pharmacy IV Associates of Dexter Inc., d/b/a Special Design Healthcare agreed to pay $4 million to settle charges that it violated the False Claims Act by submitting false claims for a drug called Synagis, which is used to prevent a respiratory disease in children.
08/25/09 Covenant Medical Center agreed to pay $4.5 million to resolve allegations that it violated the False Claims Act through illegal financial relationships with five physicians that violated the Stark Law. The physicians were paid compensation that allegedly exceeded the fair market value of the services provided.

09/02/09 Pfizer Inc. paid a $1.2 billion criminal fine and Pfizer subsidiary Pharmacia & Upjohn Co. will forfeit $105 million for illegally marketing the anti-inflammatory drug Bextra for uses that the FDA specifically had declined to approve because of safety concerns. In addition, Pfizer will pay $1 billion to settle allegations that the company violated the False Claims Act by illegally promoting Bextra and three other drugs. Pfizer also signed a corporate integrity agreement requiring it to post on its website information about payments to doctors, including honoraria, travel, and lodging.

09/17/09 Three New Jersey cardiologists agreed to pay a total of $960,000 to settle claims that they allegedly violated the federal anti-kickback law by accepting remuneration for referrals and caused the submission of false claims to Medicare as a result of those referrals. The remuneration was built into the salaries they accepted from the University of Medicine and Dentistry of New Jersey.

09/29/09 Six hospitals in Indiana and Alabama agreed to pay a total of $8 million to resolve allegations that they submitted false claims to Medicare. The hospitals allegedly overcharged Medicare each time they performed kyphoplasty, a procedure used to treat certain spinal fractures. The procedure allegedly can be performed safely on an outpatient basis, but the hospitals allegedly performed the procedure on an inpatient basis to increase their Medicare billings.

10/08/09 Harborside Healthcare, a long-term care nursing chain, agreed to pay $1.4 million and forego $480,000 in DME claims to settle allegations that it received kickbacks and assistance through a sham provider. Harborside allegedly created HHC Nutrition Services, a sham durable medical equipment provider, through which McKesson Corp, and its affiliate MediNet Corp., provided the kickbacks and assistance to Harborside. In return, Harborside purchased its DME from McKesson.

10/12/09 Eli Lilly and Co. agreed to pay $24 million to the State of Utah to settle a lawsuit over the company’s alleged “off-label” marketing of the antipsychotic drug Zyprexa. Zyprexa was approved only for the treatment of schizophrenia and certain types of bipolar disorders, but Eli Lilly was allegedly marketing the drug as treatment for dementia, Alzheimer’s, agitation, aggression, hostility, depression, and generalized sleep disorder.

10/19/09 Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca Pharmaceuticals, and Ortho-McNeil Pharmaceutical agreed to pay $124 million collectively to resolve allegations that they violated the False Claims Act by failing to pay appropriate drug rebates to state Medicaid programs. Allegedly, the companies underpaid the Medicaid Prescription Drug Rebate Program by misclassifying so-called innovator drugs manufactured by other companies as noninnovator drugs, also known as generic drugs. The rebate to Medicaid is higher for innovator drugs.

10/20/09 Mylan Inc. will pay $121 million to settle claims alleging that it violated the False Claims Act by selling drugs to Medicaid and then reimbursing the program at a lower rate. The law requires the drug companies to sell drugs to Medicaid at the lowest price they are sold to other customers.

10/20/09 Omni Home Care, a home health agency, agreed to pay $1.97 million to resolve allegations that it violated the False Claims Act by failing to obtain certain required physician signatures before submitting bills to Medicare.
11/04/09 Omnicare, Inc., the nation's largest nursing home pharmacy, agreed to pay $98 million to resolve allegations that the pharmacy engaged in kickback schemes with drug manufacturers and nursing homes. Ivax Pharmaceuticals, a subsidiary of Teva Pharmaceuticals Industries Ltd., will also pay the United States $14 million for allegedly receiving kickbacks from Omnicare.

11/04/09 McAllen Hospitals, d/b/a South Texas Health System, has agreed to pay $27.5 million to the government to resolve charges in a whistleblower lawsuit that it paid illegal compensation to doctors to induce them to refer patients to hospitals within the group in violation of the federal False Claims Act, the anti-kickback statute, and the Stark self-referral law. The payments to the doctors were allegedly disguised through a series of sham contracts, including medical directorships and lease agreements.

11/05/09 Atricure, Inc., an Ohio-based device company, announced a tentative settlement with the DOJ for $3.8 million to resolve issues raised in a DOJ investigation and related qui tam litigation for marketing surgical ablation devices for off-label or unapproved uses. Atricure will also sign a corporate integrity agreement.

11/12/09 Eight prescription drug manufacturers (Dey Inc., Abbott Laboratories, Amgen, Baxter International, Ben Venue Laboratories, Boehringer Ingelheim, Immunex, and Roxane Laboratories) agreed to pay a total of $4.3 million to Iowa to resolve allegations that they had reported false drugs prices so as to increase reimbursements under Iowa's Medicaid program.

11/12/09 Kaiser NW agreed to pay more than $1.8 million to settle allegations that it violated the False Claims Act by submitting uncertified bills for hospice care to Medicare. The government alleged that Kaiser billed Medicare without obtaining written certification of terminal illness.

11/16/09 Trinitas Regional Medical Center in Elizabeth, N.J., agreed to pay $3.02 million plus interest to resolve allegations that it inflated charges for inpatient and outpatient care to qualify for higher reimbursements, a violation of the False Claims Act. The hospital allegedly made costs appear unusually high in order to qualify for outlier payments to which it was not entitled.

11/16/09 Boston Scientific Corporation has agreed to pay $296 million to settle allegations that its heart-device subsidiary, Guidant, failed to include information in reports to the FDA. The alleged activity occurred one year before Boston Scientific acquired Guidant.

12/01/09 Kerlan Jobe Orthopaedic Clinic agreed to pay $3 million to settle allegations that it received kickbacks from HealthSouth Corp. for patient referrals. The kickbacks allegedly included stock-option grants, donations to the foundation, loan forgiveness, and a disproportionately high ownership interest in an ambulatory surgery center.

12/02/09 Mercy Medical Center of Sioux City, Iowa, agreed to pay $400,000 to resolve allegations that it had inflated charges for heart patients to qualify for outlier payments.

12/03/09 Kaiser Foundation Health Plan and three related entities in California agreed to pay $3.7 million to resolve allegations that they submitted false claims to Medicare and Medicaid. Kaiser allegedly billed for services provided by teaching physicians, when in fact the services were provided by resident physicians without supervision.
12/08/09 Meijer Inc. will pay $3 million to settle allegations that it employed four pharmacists who were barred from participation in federal programs.

12/09/09 Roxane Laboratories Inc. and its affiliates have agreed to pay $8.5 million to the State of Florida to settle a whistleblower lawsuit accusing the drug company of inflating prices for medications reimbursed by Medicaid.

12/14/09 Trinity Health-Michigan and St. Joseph Mercy Oakland Hospital, a Trinity affiliate, paid $205,000 to settle allegations of improper Medicare billing. Trinity allegedly billed Medicare for neonatologist or oncologist services, when in fact the services were performed by nurse practitioners, clinical nurse specialists, and physician assistants.

12/15/09 Lourdes Medical Center of Burlington County, New Jersey agreed to pay $7.9 million plus interest to settle allegations that it improperly inflated its charges for inpatient and outpatient care for Medicare patients to qualify for outlier payments in violation of the False Claims Act.

12/22/09 Rheumatology & Allergy Institute of Connecticut agreed to pay $222,855 to settle allegations that it improperly billed Medicare for patient visits and treatment, including billing for more expensive office consultation visits instead of new patient visits.

12/22/09 St. John Health System agreed to pay $13.2 million to resolve allegations that it submitted claims to Medicare and Medicaid that were tainted by the hospital’s financial relationships with referring physicians. The settlement resulted from the hospital’s self-disclosure of Stark law violations.

12/23/09 Visiting Physicians Association, a home health services company, agreed to pay $9.5 million to settle allegations that it submitted false claims to Medicare, TRICARE, and the Michigan Medicaid program for unnecessary home visits, tests and procedures, and for more complex evaluation and management services than it actually provided.

12/23/09 Boston Scientific Corp. agreed to pay the federal government $22 million to resolve allegations that subsidiary Guidant Corp. knowingly and intentionally used four post-market studies as a means of increasing sales of its pacemakers and defibrillators. Guidant allegedly targeted physicians who favored competing devices and paid them fees of $1,000 to $1,500 to participate in the post-market studies.

12/28/09 Genesys Health System, an affiliate of Ascension Health, agreed to pay the government $669,413 to settle allegations that it submitted false claims to Medicare by billing for higher levels of evaluation and management services than actually provided to cardiology patients.

12/29/09 Spectranetics Corp., a Colorado-based device company, agreed to pay $4.9 million plus a $100,000 forfeiture to resolve multiple claims of wrongdoing, including the submission of false claims for importation of unapproved devices, off-label promotions, and violation of FDA regulations regarding clinical studies.

III. COURT DECISIONS

01/22/09 United States ex rel. Smart v. Christus Health, No. C-05-287 (S.D. Tex.). The trial court dismissed a qui tam action alleging that Christus Spohn Health System Corp. exchanged below-market rents for physician referrals, finding the allegations lacked
the specificity required for fraud claims. Although the defense argued that the suit was barred because its allegations had been disclosed publicly in state action, the court held that the jurisdictional bar did not apply because the relator’s suit was not “based upon” the allegations in the state suit.

01/27/09 United States ex rel. Coiner v. EBI L.P., No. 06-CV-0353 (S.D.W.Va.). A qui tam lawsuit was brought against EBI L.P. surrounding a West Virginia osteopathic surgeon’s alleged use of devices in a manner unapproved by the FDA. The complaint alleged that the doctor conducted clinical research without informed consent and without any reasonable basis to conclude that it would be successful. The complaint also alleged that EBI established a system of kickbacks, paying a bonus to a doctor for the prescription of EBI Ionic Spacers.

01/21/09 United States ex rel. Kosenske v. Carlisle HMA Inc., No. 07-4616 (3d Cir.). The Third Circuit determined that an arrangement between an anesthesiology group and a hospital did not satisfy the personal service exception to the Stark and Anti-Kickback Acts, and thus reversed the dismissal of a qui tam action. The court said the arrangement between Blue Mountain Anesthesia Associates PC (BMAA) and Carlisle HMA Inc. implicated the Stark and Anti-Kickback Acts because BMAA received benefits such as office space and medical equipment in return for the exclusive right to prove all anesthesia and pain management services to Carlisle. This did not fall into the personal services exception because there was no written contract setting forth the relevant arrangement, and no arm’s length negotiations that could vouch for the fair match of the service and compensation.

02/12/09 United States ex rel. Vuyyuru v. Jadhav, No. 07-1455 (4th Cir.). The Fourth Circuit upheld the dismissal of a qui tam action alleging a conspiracy to submit false claims for unnecessary services to Medicare, Medicaid, and private insurance companies. The relator failed to produce sufficient evidence that he had direct and independent knowledge of the submission of false claims, and thus he was not an “original source” as required by law.

02/13/09 Sutter Health Sacramento Sierra Region v. Leavitt, No. 2:08-CV-03051 (E.D. Cal.). In challenging the proposed termination of Medicare funding for its heart transplant program because of the low volume of heart transplants, the court held that the Sutter Medical Center must exhaust its administrative remedies and dismissed the lawsuit. The court also determined that Medicare had no duty to postpone termination until after administrative appeals are exhausted.

02/19/09 National Renal Alliance LLC v. Blue Cross and Blue Shield of Georgia Inc., No. 1:08-CV-0161 (N.D. Ga.). When it lowered its reimbursement rates for dialysis performed at out-of-network facilities, Blue Cross and Blue Shield of Georgia Inc. did not violate the provisions of the Medicare Secondary Payer Act (MSP) that prohibit insurers from discriminating against individuals with end stage renal disease (ESRD). The reimbursement rates allegedly dropped from $2,900 per treatment to $350 per treatment. The court specifically noted that there was no allegation that Blue Cross paid a different amount for dialysis treatment of non-ESRD than ESRD patients. The court also said that National Renal Alliance could pursue claims that Blue Cross violated the terms of its insureds’ ERISA plans with the reduction, and these ERISA claims preempted any state law claims unless the patient was insured by a non-ERISA plan.

02/26/09 United States ex rel. Roberts v. Sunrise Senior Living Inc., No. CV-05-3758 (D. Ariz.). The court granted the government’s motion to intervene in a qui tam action alleging that Sunrise Senior Living billed Medicare for hospice-related services in violation of the False Claims Act. Specifically, the allegations state that Medicare
was billed for patients who were inappropriately admitted to and re-certified for hospice treatment.

02/26/09 United States ex rel. Fry v. Health Alliance of Greater Cincinnati, No. 1:03-CV-00167 (S.D. Ohio). The court denied interlocutory appeal certification to the Health Alliance of Greater Cincinnati and Christ Hospital in a “pay or play” kickback prosecution because the legal question was not difficult or novel, was not a case of first impression, and did not present an issue that split the federal courts. The hospital allegedly engaged in a cross-referral scheme with the Ohio Heart and Vascular Center Inc. to cause Medicare and Medicaid to pay for illegal kickbacks.

02/27/09 United States ex rel. Sharp v. Eastern Oklahoma Orthopedic Center, No. 05-CV-572 (N.D. Okla.). A federal district court dismissed in part a qui tam action alleging that a medical service provider submitted fraudulent claims by waiving Medicare co-insurance or deductible requirements for certain patients, including employees and members of employees’ families. The court dismissed five of six instances of waived co-insurance because the relator did not plead with the required specificity under Fed. R. Civ. P. 9(b).

03/05/09 United States ex rel. Resnick v. Weill Medical College of Cornell University, No. 04civ3088 (S.D.N.Y.). A federal district court approved the settlement in which Weill Medical College of Cornell University agreed to pay $2.6 million to resolve civil charges that it defrauded the government in connection with federal research funds awarded by the National Institutes of Health and the Department of Defense. The complaint alleged that the principal research investigator for the grants failed to disclose the full extent of her active research projects, thereby depriving the government of its ability to accurately assess the grant applications.

03/06/09 Kumar v. Blue Cross of California Inc., No. BC409095 (Cal. Super. Ct.). A class action complaint alleged that Anthem Blue Cross regularly denied payments for treatments it deemed not medically necessary, even in life-threatening situations, with limited review and little or no input from the prescribing doctor. Furthermore, the complaint also alleged that the insurance company, in violation of the state’s Health and Safety Code, failed to inform enrollees of their right to an independent medical review of coverage denials.

03/06/09 United States ex rel. Baker v. Community Health Systems Inc., No. 1:05-CV-00279 (D.N.M.). The United States intervened in a qui tam lawsuit filed against Community Health Systems Inc. and three of its hospitals, alleging the hospitals knowingly caused false claims to be submitted for federal matching Medicaid funds. In particular, the relator alleged that the hospitals made donations to New Mexico counties which they knew would be used by the counties and the state to obtain triple the amount in federal funding that was then paid to the hospitals.

03/16/09 United States v. Farina, No. 08-CR-10049 (D. Mass.). A federal jury found a former Pfizer sales manager guilty on one count of obstruction of justice by aiding and abetting in the destruction of documents relating to the off-label promotion of a drug. The former manager, who altered documents and ordered others to hide the off-label promotion, faces a maximum sentence of 20 years in prison, to be followed by three years of supervised release, and a $250,000 fine.

03/20/09 United States ex rel. Westfall v. Axiom Worldwide Inc., No. 8:06-CV-571 (M.D. Fla.). The court held that the relators in a qui tam action sufficiently alleged that they were the original source of a public disclosure of alleged violations of the False Claims Act by the maker of a spinal compression device. However, in order to avoid dismissal, the relators had to file an amended complaint to set forth their
claims with additional specificity. The allegations charged that Axiom Worldwide Inc. and several employees caused physicians to submit false billings to federal health care programs with respect to their use of the “DRX” spinal decompression device.

03/20/09  California ex rel. Hunter Laboratories LLC v. Quest Diagnostics Inc., No. CIV 450691 (Cal. Super. Ct.). California Attorney General joined a lawsuit against seven medical testing laboratories, filed under seal, to recover hundreds of millions of dollars in alleged illegal overcharges to California’s Medicaid program, Medi-Cal. The lawsuit alleges that the defendants paid kickbacks to doctors, patients, and hospitals in the form of steep discounts in exchange for patient referrals and overcharging Medi-Cal patients.

03/25/09  United States ex rel. Colucci v. Beth Israel Medical Ctr., No. 06-CIV-5033 (S.D.N.Y.). The court held that the estate of a qui tam relator could be substituted for the relator upon the relator’s death in a False Claims Act suit because the False Claims Act serves both a remedial and punitive purpose.

04/08/09  United States ex rel. Grubbs v. Kanneganti, No. 07-40963 (5th Cir.). The Fifth Circuit reversed a district court decision and held that the relator in a qui tam action satisfied the particularly requirements by describing the fraudulent billing scheme of his colleagues at Memorial Hermann Baptist Beaumont Hospital. The complaint alleged that a psychiatrist and the chairman of the medical staff instructed him to bill face-to-face physician visits that did not occur. Allegations against the hospital ultimately failed because there was no indication that the hospital acted with the requisite intent.

04/10/09  Wahi v. Charleston Area Medical Center Inc., No. 06-2162 (4th Cir.). The Fourth Circuit affirmed summary judgment for the hospital in an action brought by a physician regarding the suspension of his medical privileges. The court affirmed that the hospital was entitled to immunity from damages under the Health Care Quality Improvement Act (HCQIA), even though it failed to afford the physician a hearing before suspending his privileges.

04/10/09  United States v. Urciuoli, (D.R.I.). The former president of Roger Williams Medical Center, a Rhode Island hospital, was sentenced to three years in prison for corruptly employing a former state senator to advance the hospital’s interests in the General Assembly.

04/15/09  United States ex rel. Bierman v. Orthofix International NV, No. 05-10557 (D. Mass.). DJO Inc. and Orthofix International NV announced that they are among several medical device makers named as defendants in a qui tam lawsuit. The relator alleges that the companies made or caused to be made false claims for reimbursement in connection with patients’ use of osteogenesis stimulators. The other medical device makers are Smith & Nephew Corp., Biomet Inc. and its corporate parent, LBV Acquisition Inc., as well as related companies EBI LP, EBI Holdings Inc., EBI Medical Systems Inc., and Bioelectron Inc..

04/28/09  United States ex rel. Bane v. Breathe Easy Pulmonary Services Inc., No. 8:06-CV-00040 (M.D. Fla.). The court refused to grant attorney’s fees and costs to a durable medical equipment company after finding that the False Claims Act lawsuit against the company was not frivolous, vexatious, or brought primarily for purposes of harassment.

05/07/09  United States ex rel. Monahan v. Robert Wood Johnson University Hospital at Hamilton, No. 2:02-CV-05702 (D.N.J.). The court denied a motion to dismiss a qui
tam action seeking recovery of outlier payments from a New Jersey hospital that allegedly submitted fraudulent claims as part of a scheme to defraud Medicare. Based on allegations in the complaint, the court determined that the government pleaded facts that demonstrate nondisclosure and intentional misrepresentation sufficient to meet the heightened pleading requirements of Fed. R. Civ. Pro. 9(b).

05/15/09 Doe v. Central Iowa Health System, No. 07-1017 (Iowa). The court ruled that a hospital employee whose medical and mental health records were accessed by fellow employees may not recover damages for emotional distress because he failed to demonstrate the disclosure of his records actually caused any emotional injury.

05/22/09 United States ex rel. Hobbs v. MedQuest Associates Inc., No. 3:06-1169 (M.D. Tenn.). Federal prosecutors alleged that MedQuest Associates, a Georgia-based medical imaging company, improperly billed Medicare for certain diagnostic tests conducted at centers in Tennessee. According to the complaint, imaging was conducted at the centers without the proper supervision of a qualified doctor.

06/01/09 DeSantis v. Simon, No. 08SA321 (Colo. S. Ct.). In review of a trial court’s holding regarding discovery in a medical malpractice case, the Colorado Supreme Court held that a trial court may consider any expectation of confidentiality the doctor asserts for records listed in a privilege log, and held that the lower court abused its discretion by ordering the doctor to produce all of the documents listed in his privilege log without reviewing the documents in camera and conducting a Martinelli analysis.

06/11/09 United States v. Glaze, No. 1:08-CR-073 (E.D. Va.). The court held that an employee who processed claims for reimbursement from TRICARE failed to prove that she was coerced into pleading guilty to mail fraud for backdating a $1 million claim. Sheridan Glaze, the employee, agreed to backdate a cost report for INOVA, a major health care provider in Fairfax County, Va., in exchange for 20% of the claim.

06/24/09 Life Care Center of Tullahoma v. CMS, Dept. App. Bd., No. CR1964. The ALJ sustained civil monetary penalties of $6,550 per day against Life Care Center of Tullahoma for failure to provide or arrange services that met professional standards of quality in providing care to its diabetic and other residents. The ALJ found that nursing staff failed to comply with written diabetes protocol, failed to comply with physicians’ orders, and failed to consult with treating physicians about potentially life-threatening medical conditions. The penalties totaled over $1 million.

06/26/09 DeBartolo v. HealthSouth Corp., No. 07-1272 (7th Cir.). The court held that a complaint filed by an Illinois physician to prevent his partners from forcing him to liquidate his partnership interest raised a state law contract dispute. According to the court, the complaint did not state a federal cause of action even though he used the Anti-Kickback Act as a defense to the partnership’s attempt to force him to liquify his interest.

06/30/09 United States v. Baig et al., No. 06-CR-916 (N.D. Ill.). The former CEO of a now-closed Illinois psychiatric hospital and a doctor who referred patients there were convicted by a jury of participating in a Medicare beneficiary kickback scheme. According to federal prosecutors, the doctor received bribes disguised as compensation for services to make patient referrals and Medicare beneficiaries were admitted to the hospital for medically unnecessary reasons.

07/02/09 Glaser v. Wound Care Consultants, No. 07-4036 (7th Cir.). The Seventh Circuit
affirmed a district court ruling to dismiss a False Claims Act whistleblower action for lack of subject matter jurisdiction. The court held that relator Carol Glaser’s complaint alleging fraudulent Medicare and Medicaid claims was based upon publicly disclosed allegations and she was not an original source. Four months prior to her action, CMS had contacted Wound Care regarding billing irregularities and was investigating the claims.

07/09/09  
**Arnott v. HCA-HealthOne**, No. 08-CV-2218 (D. Colo.). A federal lawsuit filed by three nurses against their employer, Swedish Medical Center in Denver, is the first known test of a 2007 Colorado law which prohibits termination of health care workers in retaliation for their raising concerns about unsafe patient conditions, insufficient staffing, and other safety matters. The nurses alleged that the intensive care nursing lacked enough “level three” nurses who could medicate, resuscitate and care for premature babies.

07/09/09  
**Longhi v. Lithium Power Technologies Inc.**, No. 08-20306 (5th Cir.). In a *qui tam* suit, a former employee of Lithium Power Technologies alleged that the company engaged in an elaborate pattern of false statements to secure research grants from the federal government under the Small Business Innovation Research program. The Fifth Circuit affirmed the decision of the lower court, which awarded $5 million in damages and penalties in addition to attorney’s fees for the relator.

07/10/09  
**Hospital of the University of Pennsylvania v. Sebelius**, No. 1:08-CV-01665-JDB (D.D.C.). The court held that the CMS administrator’s decision to disregard testimony by three teaching hospitals that they timely mailed forms to the fiscal intermediary for supplemental medical education payments was in error. The court said that the administrator’s rationale for finding that the hospitals had notice that the time limits applied was too cursory to allow for reasoned review, and subsequently remanded the case to the Secretary.

07/17/09  
**American Eyecare v. Department of Human Services**, No. 07-1698 (Iowa). The Iowa Supreme Court held that the Iowa Department of Health and Human Services erred in ruling that American Eyecare improperly upcoded intermediate eye exams as comprehensive exams. Finding that it owed no deference to the agency’s interpretation of “comprehensive ophthalmological services,” the court threw out the agency’s demand that the company repay $26,095 for allegedly upcoded exams.

07/20/09  

07/21/09  
**State of Texas v. Caremark, Inc.**, Nos. 08-50354, 08-50357, 08-50358, 08-50359, 08-50360 (5th Cir.). In a False Claims Act suit by several states and the U.S., the government alleged that Caremark, a pharmacy benefit manager, fraudulently withheld reimbursement payments due to the states under Medicaid. Caremark asserted an affirmative defense that it had actually overpaid and was entitled to recovery, and the states argued that this was a counterclaim and moved to dismiss on the grounds of immunity. The Fifth Circuit held that the district court must address whether the states waived sovereign immunity as against the defendant’s counterclaims by bringing the suit or whether they would still be immune.

07/23/09  
**United States v. Aquillon**, No. 08-CV-789 (D. Del.). The federal court dismissed
one of two Medicare billing fraud charges brought against a Delaware doctor, finding that a recent amendment to the False Claims Act striking the “actual payment” requirement cannot be applied retroactively. The court used a two-part test for whether a federal statute can be applied retroactively, asking first whether Congress unambiguously restrict the law to prospective use only, and second whether retroactive application of the law would cause new legal consequences for the defendant.

07/31/09 United States v. Rodriguez, No. 1:09-CR-20623 (S.D. Fla.). A Florida man was indicted for allegedly paying an ultrasound technician at Miami’s Jackson Memorial Hospital to provide him with confidential patient information that he, in turn, would sell to an unidentified attorney who would use the data to solicit clients. In a separate suit, the ultrasound technician pleaded guilty to wrongful disclosure of individually identifiable health information.

08/05/09 United States v. Khan, No. 2:03-CV-74300 (E.D. Mich.). The court held that the wife of a former owner of a Michigan rehabilitation company convicted of health care fraud was liable for $876,548 for her part in causing false claims to be submitted to Medicare. By signing and certifying Medicare cost reports for three years, the court said that Khan acted with reckless disregard of the falsity of the cost reports and violated the False Claims Act by assisting in causing the government to pay fraudulent claims.

08/07/09 Independent Living Center of Southern California Inc. v. Maxwell-Jolly, No. 08-57016 (9th Cir.). The court ruled that a federal trial court properly issued an injunction to prevent California from cutting Medicaid reimbursement rates solely because of the state's need to reduce expenditures, without complying with the Medicaid Act requirements that the state consider the effect of those cuts on efficient access to economical and high quality care.

08/12/09 United States ex rel. Duxbury v. Ortho Biotech Products LP, No. 08-1409 (1st Cir.). The First Circuit held that the relator in a qui tam action provided factual evidence that the manufacturer unlawfully promoted the sale of the drug Procrit for Medicare reimbursement, and therefore the lower court should not have dismissed the claim. Specifically, the relator alleged the manufacturer caused false claims to be submitted by eight medical providers by providing illegal kickbacks. The manufacturer also allegedly inflated the Average Wholesale Price (AWP) and marketed the spread to induce medical providers to purchase the drug.

08/13/09 United States ex rel. Mason v. State Farm Mutual Automobile Insurance Co., No. 1:07-CV-00297 (D. Idaho). The court dismissed a qui tam action after finding an insurance company did not avoid its legal obligation to reimburse Medicare for its payment of a hospital bill under the Medicare Secondary Payment ("MSP") statute. The hospital was accused of submitting a false claim to Medicare because State Farm was the primary insurer. In applying the MSP statute, the court found that the hospital was entitled to request a contingent payment from Medicare because State Farm had declined to pay other like-bills and had questioned coverage. Therefore, the hospital did not submit a false claim.

08/21/09 Total Renal Care Inc. v. American Renal Associates, No. 08-CV-513 (D. Colo.). In a lawsuit alleging violations of the Sherman Act, the court held that American Renal Associates failed to plead relevant geographic and product markets and failed to allege a shared intent to monopolize by Total Renal Care and other alleged co-conspirators. However, the Court held that the provider should have the opportunity to amend its complaint to cure the deficiencies.
08/24/09  Kansas v. St. Joseph Memorial Hospital Inc., No. 09-CV-61 (Kan. Dist. Ct.). The court granted a temporary restraining order blocking the proposed closing of a nonprofit hospital in rural Kansas. The hospital was built through charitable donations, and the lawsuit charges that the corporate parent’s plan to close the hospital amounted to the waste or misuse of charitable assets.

08/25/09  Director of Health Affairs Policy Planning, University of Connecticut Health Center v. Freedom of Information Commission, No. SC 18286 (Conn.). The Connecticut Supreme Court held that records of a public hospital that would be privileged from discovery under Connecticut’s peer review statute are subject to disclosure pursuant to proceedings before the state’s freedom of information commission. It noted that although a party may gain access to peer review materials through a FOIA request, the privilege statute would still apply to prevent the introduction of those materials into evidence in a civil action.

08/27/09  United States ex rel. Lockyer v. Hawaii Pacific Health, No. 07-17174 (9th Cir.). The Ninth Circuit upheld the dismissal of claims against Hawaii Pacific Health for alleged violations of the False Claims Act. The court found that the relator had presented evidence raising genuine issues of fact as to whether the hospital violated the Medicare “incident to” rules; however, the relator failed to present evidence that the hospital “knowingly” submitted the false claims.

09/04/09  Boca Raton Community Hospital Inc. v. Tenet Healthcare Corp., No. 07-14352 (11th Cir.). The Eleventh Circuit held that a racketeering lawsuit against Tenet Healthcare Corp., was properly dismissed by the lower court because the petitioner offered no evidence of injury, an essential element of the Racketeer Influenced and Corrupt Organizations Act (RICO). The suit alleged that Tenet inflated reimbursement claims for Medicare outlier patients.

09/08/09  United States ex rel. Putnam v. Eastern Idaho Regional Medical Center, No. 4:07-CV-00192 (D. Idaho). The federal district court denied a motion to dismiss a qui tam action alleging that Speech and Language Clinic, Inc., caused fraudulent Medicare and Medicaid billing after finding the allegations were not publicly disclosed. The court held that relator Jennifer Putnam did not publicly disclose the allegations through her communication with the Idaho Department of Health and Welfare (DHW), through the subsequent audit by DHW, or through her deposition testimony; thus, the court did not need to determine whether Putnam was an original source of the allegations.

09/18/09  United States ex rel. Walner v. NorthShore University Health System, No. 1:08-CV-02642 (N.D. Ill.). The court dismissed a qui tam action against NorthShore University Health System for submitting false claims to Medicare because the complaint failed to plead with particularity the circumstances surrounding the alleged fraud as required by Fed. R. Civ. P. 9(b). The claimant did not specify who submitted the allegedly false claim, when it was submitted, or what information it contained.

09/29/09  Four Corners Nephrology Associates PC v. Mercy Medical Center of Durango, No. 08-1231 (10th Cir.). The Tenth Circuit upheld summary judgment in favor of a hospital that closed its medical staff to outside nephrologists in a case alleging antitrust violations brought by a competing nephrology practice that was denied hospital privileges.

09/29/09  United States ex rel. Jamison v. McKesson Corp., No. 2:08-CV-214 (N.D. Miss.). The court denied in part the defendant’s motion to dismiss in a case involving alleged violations of the False Claims Act and the Anti-Kickback Statute by a
durable medical equipment (DME) supplier and several nursing homes. The complaint alleged that the DME supplier submitted claims for DME services in nursing homes under the supplier number of a sham DME company owned by the nursing home, and the homes profited substantially from the Medicare reimbursements. Furthermore, the complaint alleged that the DME supplier and its parent received valuable referrals from the nursing home chain. The court dismissed some of the claims for failure to plead with particularity as required under Fed. R. Civ. P. 9(b).

10/08/09  
Alta Bates Summit Medical Center v. Sebelius, No. 1:08-CV-01015 (D.C.C.). The District Court held that a PRRB decision was not arbitrary or capricious in upholding the fiscal intermediary’s application of a 1984 base year for calculating Medicare reimbursement.

10/09/09  
United States ex rel. Lacy v. New Horizons Inc., No. 08-6248 (10th Cir.). The Tenth Circuit upheld the dismissal of a qui tam action after finding that the claimant failed to plead with particularity her allegations that the operator of LTC facilities submitted false claims to Medicare and Medicaid. Specifically, she failed to allege that any payment was made in exchange for improper referrals she alleged were violations of anti-kickback and self-referral laws. The court noted that False Claims Act claims, which involve averments of fraud, are held to a heightened pleading standard under Fed. R. Civ. P. 9(b).

10/15/09  
United States v. Carell, No. 3:09-CV-445 (M.D. Tenn). The U.S. District Court denied a motion to dismiss and held that the government successfully pleaded facts that, if proved, would establish a valid False Claims Act action. The complaint alleged that the owners of three home health agencies submitted fraudulent cost reports to Medicare for fiscal years 1999, 2000, and 2001. In response to the defendants’ statute of limitations defense, the court held that the government’s knowledge of a “related-party relationship” was insufficient to toll the limitations period. The period was tolled when the government had knowledge of the filing of the fraudulent cost reports which failed to disclose the related-party relationship.

10/16/09  
AstraZeneca v. Alabama, No. 1071439 (Ala.). The Alabama Supreme Court reversed multimillion-dollar verdicts against AstraZeneca, GlaxoSmithKline, and Novartis. The verdicts, totaling $250 million, were originally awarded based on allegations that the companies either published, or allowed to be published, certain pricing information (such as average wholesale price) that induced the Alabama Medicaid Agency to pay too much for drugs when it reimbursed providers. The court held that the State, as a matter of law, could not have reasonably relied on the published prices and could not claim that it did not know that the published AWPs were merely suggested prices, exclusive of discounts and other incentives available to wholesalers and providers.

10/27/09  
TMJ Implants Inc. v. HHS, No. 08-9539 (10th Cir.). The Tenth Circuit upheld an agency decision imposing civil monetary penalties on TMJ Implants, Inc., a company that makes and distributes temporomandibular joint implants, for the knowing failure to submit 17 medical device reports to the FDA. The penalties totaled $170,000, or $10,000 for each report.

10/29/09  

11/04/09  
United States ex rel. Johnson v. Universal Health Services Inc., No. 1:07-CV-00054
The DOJ and Virginia intervened in a *qui tam* action that was filed against Universal Health Services Inc., a health care management company based in King of Prussia, Pa. The defendant allegedly billed Medicaid for therapy sessions conducted by unlicensed therapists without supervision and allowed nonclinical staff to improperly alter the therapists’ records to increase Medicaid reimbursement.

**11/17/09**  
St. John v. Wilcox, No. 08-cv-229 (D.N.M.). The court held that a woman could pursue EMTALA claims against a hospital, alleging that the hospital failed to adequately screen her father and discharged him without stabilizing his emergency medical condition, even though she did not present expert testimony on that issue. No expert testimony was required, the court said, because EMTALA does not hinge on whether the hospital violates the standard of care.

**11/18/09**  
Cell Therapeutics Inc. v. Lash Group Inc., No. 08-35619 (9th Cir.). The Ninth Circuit held that a company that settled its liability under the False Claims Act for allegedly causing insurers and providers to submit claims to Medicare for off-label uses of its cancer drug may pursue claims against the consulting firm that allegedly advised it concerning applicable reimbursement protocols. The consulting firm, Lash Group Inc., advised Cell Therapeutics Inc. in marketing its leukemia drug Trisenox.

**11/24/09**  
Cookeville Regional Medical Center Authority v. Cardiac Anesthesia Services, PLLC, No. M2007-02561-COA-R3-CV (Tenn. Ct. App.). A Tennessee court found that a contract between a hospital and an anesthesia services provider violated the Tennessee fee-splitting statute and was therefore unenforceable. Under the contract, the anesthesia provider agreed to remit 80% of its gross collections to the hospital and to retain 20% as compensation for their efforts. The court held that this arrangement did not fall into either of the statutory exceptions for fee-splitting because there was no consent and the percentage paid was not reasonably related to the value of the goods and services provided.

**11/24/09**  
Little Company of Mary Hospital v. Sebelius, No. 09-1665 (7th Cir.). The court upheld the dismissal of a hospital’s appeal challenging a fiscal intermediary’s failure to reopen an aspect of the disproportionate share hospital payment. In dismissing the case for lack of jurisdiction, the district court upheld the PRRB’s determination that the intermediary’s reopening of a Medicaid fraction issue did not grant the PRRB jurisdiction over an SSI fraction issue.

**12/01/09**  
United States ex rel. Bauchwitz, No. 04-2892 (E.D. Pa.). In this case the court decided two issues of first impression regarding the statute of limitations in a False Claims Act case. First, this case was based on false statements made in a federal research grant application, and the court held that the statute of limitations is triggered by the filing of the application, not by the government’s later payment of the grant. Second, the court held that if the government declines to intervene in a *qui tam* action, the whistleblower does not benefit from the extension of the statute of limitations by up to four years, as provided in the False Claims Act.

**12/01/09**  
United States ex rel. Monahan v. Robert Wood Johnson University Hospital at Hamilton, No. 2:02-cv-05702 (D.N.J., unpublished). The U.S. District Court for the District of New Jersey granted in part the government’s motion to strike certain defenses asserted by the defendant, a nonprofit acute care hospital. In response to the hospital’s claim that the U.S. failed to mitigate damages, the court found that the government has no duty to mitigate damages in fraud actions. The case originated as a *qui tam* suit seeking recovery of outlier payments from the hospital that allegedly submitted fraudulent claims.
12/04/09  Hopper v. Solvay Pharmaceuticals Inc., No. 08-15810 (11th Cir.). The Eleventh Circuit held that whistleblowers failed to identify a specific false claim in alleging that Solvay Pharmaceuticals influenced the government to pay for the off-label use of a drug, and therefore the claim lacked the particularity necessary under Federal Rule of Civil Procedure 9(b).

12/07/09  United States v. Tuomey Healthcare System, No. 3:05-CV-02858 (D.S.C.). A federal case against Tuomey Healthcare System is slated to go to trial in March 2010, alleging that a number of the system’s employment arrangements violated the Stark law and the related False Claims Act. According to the complaint, the arrangements violated the law because the compensation paid was not a fair-market value or commercially reasonable, and because it takes into account the volume or value of referrals.

12/07/09  United States ex rel. Feldman v. Van Gorp, No. 1:03-cv-08135-WHP (S.D.N.Y.). The court held that there were material issues of fact preventing the dismissal of a False Claims Act action against Wilfred van Gorp and Cornell University Medical College in New York. Van Gorp and Cornell allegedly submitted

12/07/09  Thompson v. Quorum Health Resources LLC, No. 06-168 (W.D. Ky.). A former hospital chief executive officer raised genuine issues of material fact as to whether he was discharged in retaliation for conducting an investigation into his employer’s alleged fraudulent activities and filing a qui tam action under the False Claims Act. The former executive filed the suit after becoming concerned about the company’s level of control over decisions usually reserved for the hospital board, such as the selection of vendors.

12/21/09  Nightingale Home Healthcare Inc. v. Anodyne Therapy LLC, No. 09-2523 (7th Cir.). In upholding the dismissal of Nightingale’s fraud claims against Anodyne Therapy, a device maker, the court said the claims had no merit because Anodyne made no material misrepresentation about the approved uses of its device, an infrared lamp designed to relieve pain and improve circulation.

IV. CENTERS FOR MEDICARE & MEDICAID SERVICES PRONOUNCEMENTS

A. ADVISORY OPINIONS

None.

B. OTHER

03/20/09  The government requires self-insured defendants, insurance companies, and plaintiffs’ attorneys to report monetary settlements of Medicare beneficiaries, i.e., when another entity becomes primarily responsible for the costs of the Medicare beneficiary’s health care. These entities are called responsible reporting entities (RREs). In March 2009, CMS announced “interim” threshold amounts that it will deem exempt from the reporting requirement. An RRE must examine the total payment obligation to the claimant (TPOC), and it need not report the following amounts:

- 07/01/2009 – 12/31/2010 = $0 through $5,000
- 01/01/2011 – 12/31/2011 = $0 through $2,000
- 01/01/2012 – 12/31/2012 = $0 through $600
07/23/09 CMS terminated the Medicare provider agreement of Anaheim General Hospital.

08/26/09 CMS advised Medicare providers that do not get accredited and/or obtain a security bond because they do not expect to supply durable medical equipment to beneficiaries in the near future to formally disenroll from the program. By voluntarily disenrolling, the providers will remain in the NSC database with updated information and may continue to provide other Part B products. See MedLearn Matters SE0925.

V. HHS INSPECTOR GENERAL PRONOUNCEMENTS

A. ADVISORY OPINIONS

03/13/09 Advisory Opinion 09-01 (concerning a complimentary local transportation program for friends and family of residents of a skilled nursing facility)

04/02/09 Advisory Opinion 09-02 (concerning an employment contract entered into concurrently with a real estate purchase contract between the employer and new employee)

04/30/09 Advisory Opinion 09-03 (concerning an arrangement whereby three municipalities reciprocally waive otherwise applicable cost-sharing obligations of individuals residing within each other’s borders when providing backup emergency medical services transportation)

05/18/09 Advisory Opinion 09-04 (concerning a nonprofit, tax-exempt, charitable organization’s arrangement to provide financial assistance with cost-sharing obligations associated with certain advanced diagnostic testing owed by financially needy patients, including Medicare and Medicaid beneficiaries)

05/21/09 Advisory Opinion 09-05 (concerning a hospital’s proposal to compensate physicians for on-call services performed on behalf of the hospital’s uninsured patients)

05/26/09 Modification of OIG Advisory Opinion 08-11 (concerning Advisory Opinion No. 08-11, which was issued on 09-04-2008, regarding the waiving of cost sharing obligations for protocol-required clinical services and oxygen therapy provided to Medicare beneficiaries who participate in the Long-term Oxygen Treatment Trial sponsored by the National Heart, Lung, and Blood Institute and the Centers for Medicare and Medicaid Services)

06/30/09 Advisory Opinion 09-06 (concerning an existing arrangement in which a hospital has agreed to share with a cardiology group, a vascular surgical group, and an interventional radiology group a percentage of the hospital’s cost savings arising from the physicians’ implementation of a number of cost-reduction measures in certain cardiac catheterization procedures)

06/30/09 Advisory Opinion 09-07 (concerning a proposal to expand an existing program that provides free oral nutritional supplements to malnourished end-stage renal disease patients who are on dialysis)

07/28/09 Advisory Opinion 09-08 (concerning a proposed institutional patient assistance program that would make certain drug products available to people without prescription drug coverage through the provision of replacement stock to certain participating disproportionate share hospitals)

07/29/09 Advisory Opinion 09-09 (concerning a proposed joint venture involving ownership of
an ambulatory surgery center by a hospital and physicians)

07/31/09  Advisory Opinion 09-10 (concerning the proposed use of a “preferred hospital” network as part of a Medicare Supplemental Health Insurance [“Medigap”] policy)

08/10/09  Advisory Opinion 09-11 (concerning the provision of free blood pressure screenings to walk-in visitors at a hospital)

08/14/09  Advisory Opinion 09-12 (concerning a proposal for a government entity to subsidize copayments for outpatient prescription drugs owed by certain financially needy Medicare Part D enrollees)

08/18/09  Advisory Opinion 09-13 (concerning a proposal for a hospital to provide subsidies to an affiliated ambulance cooperative, to enable the cooperative to provide certain ambulance services currently provided by the hospital)

09/03/09  Advisory Opinion 09-14 (concerning an exclusive contract for ambulance transport services between a township and an ambulance company that provides for reimbursement to the township for the costs of providing emergency dispatch services)

09/03/09  Advisory Opinion 09-15 (concerning an exclusive contract for ambulance transport services between a municipality and an ambulance company that provides reimbursement to the city for the costs of providing emergency dispatch services and for monitoring the quality of the emergency ambulance operation)

09/24/09  Advisory Opinion 09-16 (concerning a proposed arrangement between a professional organization and a referral service)

10/07/09  Advisory Opinion 09-17 (concerning a joint venture to provide EMS and scheduled ambulance transportation services)

B. CIVIL MONETARY PENALTIES ACTIONS

01/06/09  Methodist Health Care-Memphis Hospitals (Methodist), Tennessee, agreed to pay $136,627 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Methodist employed an individual that Methodist knew or should have known was excluded from participation in Federal health care programs.

01/27/09  After it self-disclosed conduct to the OIG, San Jacinto Methodist Hospital (SJMH), Texas, agreed to pay $21,025 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that SJMH entered into an arrangement with a physician for a medical director position that included the physician occupying hospital space for private use and utilizing hospital personnel for clerical assistance related to the physician's private practice patient visits without any contractual entitlement to do so.

02/09/09  After it self-disclosed conduct to the OIG, Jewish Hospital and St. Mary's Healthcare (JHSMH), Kentucky, agreed to pay $130,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that JHSMH entered into an arrangement with a physician for a medical director position that included the physician being paid compensation in excess of his medical director agreement and receiving free nurse services for his private practice without any contractual entitlement to such services.

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02/25/09 After it self-disclosed conduct to the OIG, HealthWorks Rehab & Fitness, (HealthWorks), West Virginia, agreed to pay $8,132 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that HealthWorks inappropriately billed Medicare for the performance of iontophoresis services, which is not a covered service under Medicare because it is deemed experimental.

03/03/09 After it self-disclosed conduct to the OIG, ShopKo Stores, Inc. (ShopKo), Utah, agreed to pay $669,824 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that ShopKo employed an individual that ShopKo knew or should have known was excluded from participation in Federal health care programs.

03/11/09 After it self-disclosed conduct to the OIG, Walgreen Louisiana Co. (Walgreen), Louisiana, agreed to pay $1,053,774 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Walgreen employed an individual that Walgreen knew or should have known was excluded from participation in Federal health care programs.

03/13/09 West Valley Imaging Limited Partnership and two physicians (West Valley), Nevada, agreed to pay $2 million and to enter into a 5-year integrity agreement for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that West Valley performed radiology tests and exams that were not ordered by Medicare beneficiaries' treating physicians.

03/16/09 Ediberto Soto-Cora, M.D., Texas, agreed to pay $534,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Dr. Soto-Cora submitted false or fraudulent claims by using CPT codes that would generate a higher reimbursement than justified by the medical documentation or that he submitted claims without any supporting medical documentation.

03/25/09 After it self-disclosed conduct to the OIG, St. Mary Medical Center (SMMC), Pennsylvania, agreed to pay $172,617 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that SMMC employed an individual that SMMC knew or should have known was excluded from participation in Federal health care programs.

04/21/09 After it self-disclosed conduct to the OIG, National Medicare Recovery Services, Inc. (NMRS), California, agreed to pay $500,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that NMRS presented or caused to be presented claims for Medicare Part B wound care supplies that NMRS knew or should have known would result in greater payment to NMRS's nursing home clients than the code applicable to the items actually provided.

05/14/09 After it self-disclosed conduct to the OIG, Colquitt Regional Medical Center (Colquitt), Georgia, agreed to pay $151,004 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Colquitt billed Medicare and Tricare for services provided by physician-assistants as if they were provided by the actual physicians.

05/27/09 Claxton-Hepburn Medical Center (CHMC), New York, agreed to pay $168,597 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that CHMC employed two individuals that CHMC knew or should have known were excluded from participation in Federal health care programs.

06/02/09 Ravenwood Nursing Home, Inc. (RNH), Maryland, agreed to pay $28,252 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that RNH employed an individual that RNH knew or should have known was excluded from participation in Federal health care programs.
06/26/09 After it self-disclosed conduct to the OIG, Memorial Hospital of Union County (MHUC), Ohio, agreed to pay $31,202 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that MHUC provided excess non-monetary compensation to physicians and the immediate family member of a physician who referred patients to MHUC.

07/31/09 After self-disclosing to the OIG, Kahuku Hospital, Hawaii, agreed to pay $75,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that Kahuku Hospital entered into services agreements with emergency room physicians where payments were made in excess of the amount provided for in the agreement and entered into other arrangements with emergency room physicians that were not in writing.

08/03/09 After it self-disclosed conduct to the OIG, Central Kansas Medical Center (CKMC), Kansas, agreed to pay $50,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that CKMC entered into two lease arrangements, with a referring-physician-owned partnership, that failed to comply fully with the Stark law's requirements for such financial arrangements.

08/11/09 After it self-disclosed conduct to the OIG, Cushing Memorial Hospital (CMH), Kansas, agreed to pay $50,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that CMH's financial relationship with a cardiologist failed to meet Stark Law requirements. Specifically, the cardiologist was engaged to provide medical director services to CMH's cardiac rehabilitation unit. However, the written agreement was not signed. In addition, CMH's office space lease with the cardiologist did not meet the applicable lease exception.

08/12/09 After it self-disclosed conduct to the OIG, Saint Vincent Medical Education and Research Institute, Inc. d/b/a Saint Vincent Medical Group (SVMG), Pennsylvania, agreed to pay $23,436 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that SVMG employed an individual that SVMG knew or should have known was excluded from participation in Federal health care programs.

09/08/09 After it self-disclosed conduct to the OIG, Pocahontas Manor Care Center (PMCC), Iowa, agreed to pay $106,862 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that PMCC employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

09/11/09 After it self-disclosed conduct to the OIG, Medicalodge of Butler (Medicalodge), Missouri, agreed to pay $67,715 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Medicalodge employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

09/17/09 After it self-disclosed conduct to the OIG, Liberty HealthCare System, Inc. (Liberty), New Jersey, agreed to pay $417,675 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks. The OIG alleged that one of Liberty's hospitals failed to reflect an increase in compensation and hours of service in a written pediatric coverage agreement with a physician practice that provided pediatric coverage services to MHMC.

09/25/09 Michael Bakst, the former Executive Director of Community Memorial Hospital (CMH) of Ventura, California, agreed to pay $64,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks. The OIG alleged that
Bakst caused the submission of claims to Medicare in violation of the physician self-referral (Stark) law. During the relevant time period Bakst was also identified as CMH's Compliance Officer.

10/05/09 Former Executive Director for Community Memorial Hospital (CMH) of California, Michael Bakst, Ph.D., agreed to pay $64,000 to resolve allegations that he violated the Civil Monetary Penalties Law and the civil monetary provisions of the Stark law. CMH entered into a $1.5 million civil settlement to resolve the hospital's liability for Dr. Bakst's actions as well as other conduct.

10/15/09 After it self-disclosed conduct to the OIG, ABCM Corporation, Iowa, agreed to pay $40,137 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that ABCM Corporation employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

10/15/09 After it self-disclosed conduct to the OIG, Margaretville Memorial Hospital and Margaretville Nursing Home, Inc., New York, agreed to pay $80,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Margaretville inappropriately billed Medicare Part D and State health care plans for drugs provided by Margaretville Hospital to Margaretville Nursing Home residents when the residents were covered by Medicare Part A.

10/16/09 After it self-disclosed conduct to the OIG, Medina General Hospital (MGH), Ohio, agreed to pay $240,298 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that MGH's financial relationships with a family practice physician, occupational health services physicians, and a cardiologist failed to meet Stark Law requirements. Specifically, the financial relationships were during periods when there were no written service agreements or payments were not made consistent with the contracts.

10/16/09 After it self-disclosed conduct to the OIG, Vascular Specialty Services, Inc. (VSSI), Maryland, agreed to pay $34,182 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that VSSI's financial relationship with four vascular surgeons failed to meet Stark law requirements. Specifically, VSSI added lab referral revenues into a bonus pool that was paid to the vascular surgeons.

10/16/09 After it self-disclosed conduct to the OIG, Coram, Inc., New York, agreed to pay $72,500 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Coram, Inc. employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

10/22/09 After it self-disclosed conduct to the OIG, University Pediatricians, Michigan, agreed to pay $91,782 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that a former physician employee of University Pediatricians failed to follow policies and procedures for claims submitted to Medicare and Medicaid for services provided by Pediatric Gastroenterology Fellows under her supervision. Specifically, the physician employee occasionally instructed Fellows to use pre-printed forms indicating that she accompanied the Fellows during patient visits. The physician employee used these forms at times when she was present during patient visits, as well as at times when she was not present.

11/04/09 After it self-disclosed conduct to the OIG, Allied Health Care Corporation (Allied), Florida, agreed to pay $132,500 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged
that two physicians that were shareholders in Allied made referrals to two home health agencies which were wholly owned subsidiaries of Allied.

11/10/09 After it self-disclosed conduct to the OIG, Heartland Surgical Specialty Hospital (Heartland), Kansas, agreed to pay $33,187 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Heartland employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

C. OTHER

01/23/09 The OIG announced that three former Purdue Frederick Co. executives, who pleaded guilty to misdemeanor misbranding of the painkiller OxyContin in 2007, have been excluded from doing business with Medicare, Medicaid, and all federal health care programs for 15 years. Goldenheim v. Inspector General, Dept. App. Board, Civil Remedies Div., Dec. No. CR1883.

03/29/09 Open Letter to Providers. The Open Letter informed providers that the OIG’s self-disclosure protocol could not be used for self-reporting of Stark Law violations that did not also contain violations of the Anti-kickback Statute and any self-disclosure under the protocol would result in the imposition of a fine of at least $50,000.

VI. EMTALA COURT DECISIONS

03/23/09 Bode v. Parkview Health Sys., No. 1:07-CV-324 (N.D. Ind.). A hospital that deviated from its standard policies to take the blood pressure of emergency room patients and reassess vital signs before discharge may be liable under EMTALA for failing to provide an appropriate medical screening. The court refused to grant the hospital summary judgment on the EMTALA claim because the hospital deviated from standard policies, which is not “de minimis” as a matter of law.

04/23/09 Pina-Figueroa v. Hospital Metropolitano Dr. Susoni, No. 08-1373-JAF (D.P.R.). The court found no liability under the Emergency Medical Treatment and Labor Act (EMTALA) when a hospital failed to treat an insured patient because there was no gastroenterologist available, and subsequently set up a transfer to another facility. The patient died during the transfer. The court noted that the hospital did not intend to “dump” the patient as he was not uninsured, and there was no issue of material fact to impose liability on the hospital.

09/02/09 Torretti v. Main Line Hospitals, Inc. d/b/a Paoli Memorial Hospital, No. 08-1525 (3d Cir.). A federal appeals court ruled that the Emergency Medical Treatment and Labor Act (EMTALA) did not apply to a pregnant woman who was directed to a hospital after an outpatient appointment at another facility, and whose condition became emergent only after being admitted at the hospital. EMTALA does not apply to outpatients and, furthermore, there was no evidence that the initial referring facility knew that she was in imminent danger.

09/04/09 Alvarez-Torres v. Ryder Memorial Hospital, No. 08-2351 (1st Cir.). A federal court in Puerto Rico properly dismissed a claim brought by the decedents of a man whose condition, they claimed, was not stabilized in violation of EMTALA, noting that the patient was never transferred. The court also affirmed that EMTALA applies only to hospitals and cannot be used to impose liability on individual providers.
VII. OTHER NOTEWORTHY DEVELOPMENTS

04/23/09 Coast Independent Review Board (Coast IRB), a company paid to oversee the safety of clinical trials, shut down after a government sting operation revealed that Coast IRB approved a fake medical device and, in the process, violated several major FDA regulations regarding institutional review boards.

07/01/09 Colorado announced a 2% across the board cut for Medicaid provider reimbursements beginning on July 1, 2009. The affected areas include: physician services (all specialties), transportation, dental services, inpatient hospitals, outpatient hospitals, laboratory and x-ray, durable medical equipment, home health, home and community based services, private duty nursing, hospice, and single entry points.

07/09/09 California legislation requiring health organizations to report unlawful or unauthorized access or use or disclosure of patients' medical information yielded the reporting of some 823 data breaches to the California Department of Public Health in the first five months of 2009.

07/16/09 A Kaiser Permanente hospital, Bellflower Hospital of Los Angeles County, was fined $187,500 by the California Department of Public Health for patient privacy violations. The fine is the second in two months at the hospital, which was fined $250,000 after the medical records of Nadya Suleman, known primarily for being a single mother of octuplets, were accessed.

12/07/09 The Connecticut Attorney General asked federal criminal authorities to investigate the alleged loss of a disk drive with private data on nearly 1.5 million individuals on the theory that the disk, reported lost by Health Net Inc., may have actually been stolen. The company said that the data cannot be read without special software, and they have had no confirmed reports of misuse of the information.