I. LEGISLATION

A. FEDERAL

07/15/08 Medicare Improvements for Patients and Providers Act of 2008. The 2008 Medicare Physician Fee Schedule, which included a rate reduction of 10.6 percent, was retroactively replaced with a schedule which reflected a 0.5 percent increase from 2007 rates. The law also reinstated the therapy cap exceptions process.

10/08/08 Health Care Safety Net Act. President Bush signed legislation (H.R. 1343) that reauthorizes the community health centers program and will provide for $13 billion in funding during the next five years. The Act also reauthorizes the National Health Services Corps. and the Rural Health grants program.

10/15/08 Ryan Haight Online Pharmacy Consumer Protection Act of 2008. The law amends the Controlled Substances Act to counter the growing sale of controlled substances over the internet without adequate medical oversight. Specifically, it bars the sale or distribution of all controlled substances via the internet without a valid prescription, increases the penalties for illegal distributions of Schedule III, IV or V substances, and creates a new cause of action that would allow a state attorney general to shut down a rogue site selling controlled substances in any state.

B. COLORADO

01/01/08 Michael Skolnik Medical Transparency Act. The law requires doctors in Colorado to disclose certain information including malpractice settlements, professional disciplinary action, and ownership of health care businesses. This information will be made public, via a Web site, by the Board of Medical Examiners. This law took effect January 1, 2008.

06/06/08 Increased Transparency To Consumers. The law directs the creation of an “apples-to-apples” consumer shopping guide for health insurance and requires insurance brokers to tell customers how much commission they make on each policy they sell. This law took effect January 1, 2009.
06/06/08  **SB 160** expanded eligibility for Child Health Plan Plus, the state's version of SCHIP, to include children in families with incomes up to 225% of the federal poverty level. The act also will expand mental health benefits for children enrolled in the program. A companion bill (SB 161) will remove some administrative barriers to applying for Medicaid and Child's Health Plan Plus.

### FRAUD AND ABUSE SETTLEMENTS

01/09/08  **Dey LP and Takeda Pharmaceuticals North America Inc.** agreed to pay Alabama $4.75 million and $2 million, respectively, to settle allegations that they and 71 other pharmaceutical companies fraudulently inflated the prices of their drugs, causing the Alabama Medicaid to overpay for the drugs.

02/04/08  **Bayonne Medical Center** in New Jersey agreed to pay $2.5 million to resolve allegations that it improperly increased charges to Medicare patients to obtain enhanced Medicare outlier payments.

02/07/08  **Merck & Co.** agreed to pay more than $650 million to the federal government and states to resolve allegations in two separate lawsuits that the pharmaceutical manufacturer failed to pay proper rebates to Medicaid and other government health care programs. The settlement agreements also resolved allegations that Merck paid illegal remuneration to health care providers to induce them to prescribe the company's products.

02/14/08  **CVS Caremark Corp.** agreed to pay 28 states and the District of Columbia $41 million to settle civil charges it encouraged physicians to switch patients to different brand-name prescription drugs.

03/04/08  **Cathedral Healthcare System** of New Jersey agreed to pay $5.3 million, plus interest, to settle allegations that the Newark-based hospital system improperly increased the charges to Medicare patients in order to receive enhanced outlier reimbursement from the federal program.

03/05/08  **Besler & Company Inc.**, a health care consulting company in North Brunswick, N.J., agreed to pay the United States almost $2.9 million to settle charges that the company improperly counseled hospital clients to increase charges to Medicare patients to obtain enhanced outlier payments from Medicare.

03/07/08  **Yale-New Haven Hospital** agreed to pay the federal government $3.7 million to settle charges that it violated the False Claims Act. The settlement resolved allegations of improper billing for infusion therapy, chemotherapy administration, and blood transfusion services.

03/07/08  **Eleven drug companies** agreed to pay $125 million to consumers and insurance companies to settle a class action lawsuit charging that the drugmakers inflated average wholesale prices for certain products, resulting in overcharges to patients and payers.

03/12/08  **The Federal Government** agreed to pay 650 hospitals across the country treating low-income patients $666 million to settle a dispute over Medicare disproportionate share hospital payments.

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03/27/08 Bristol-Myers Squibb Co. agreed to pay $4 million to resolve allegations it violated the False Claims Act by engaging in off-label marketing of the antipsychotic drug Ability.

03/28/08 HealthEssentials Solutions, a nationwide in-home nursing service based in Louisville, KY, agreed to pay the government $3.1 million in criminal restitution for submitting false claims to Medicare.

04/09/08 Medicaid Dental Center (MDC), a privately owned chain of dental clinics in North Carolina, agreed to pay more than $10 million to resolve allegations it violated the False Claims Act through improper Medicaid billing.

04/14/08 Fred Steinberg and his University MRI-related entities, which provide radiology services in Palm Beach County, Fla., agreed to pay $7 million to resolve a False Claims Act *qui tam* action which alleged that the doctor billed Medicare and other federal health care programs for computed tomography (CT) scans that were never performed.

04/17/08 Touro Infirmary, New Orleans, agreed to pay $1.75 million to resolve False Claims Act allegations that it disguised kickbacks to a physician in the form of consultant and medical directorship contracts.

04/24/08 Memorial Health, Inc., the parent company of a hospital in Savannah, Ga., agreed to pay $5.08 million to resolve allegations the hospital defrauded Medicare by violating the Stark Law.

05/13/08 Baptist Health South Florida Inc. agreed to pay more than $7.7 million to settle claims that it overpaid an oncology group that was a source of patient referrals to two of its hospitals.

05/22/08 Kyphon, Inc., now known as Medtronic Spine LLC, agreed to pay the United States $75 million to resolve allegations that the spinal device manufacturer caused the submission of false claims for its kyphoplasty procedure to Medicare.

05/27/08 Express Scripts Inc., a St. Louis-based pharmacy benefits manager, agreed to pay $9.5 million to settle the state’s claims that it improperly encouraged physicians to switch patients to different brand-name prescription drugs.

06/04/08 Walgreen Co. agreed to pay $35 million to resolve allegations that it improperly switched patients to different versions of three prescription drugs to receive more money from Medicaid.

06/18/08 North East Medical Services, a federally-qualified health clinic, agreed to pay almost $5 million to resolve allegations it submitted false claims to California Medicaid.

07/08/08 Saint Louis University agreed to pay $1 million to settle charges that its School of Public Health committed fraud in charging the federal government for supplemental pay for faculty members.
07/08/08 Ohio General Hospital agreed to pay $2.2 million to settle allegations involving the alleged fraudulent billing for wound ointment, double-billing for patients treatments and billing for emergency room visits for patients who were actually treated at the hospital’s wound center, which carried a lower rate of payment.

07/22/08 Amerigroup Corp. agreed to pay $225 million (plus $9 million in attorney fees) to resolve *qui tam* litigation against it relating to certain marketing practices of the company’s former Illinois health plan. The settlement resolves allegations that it violated the False Claims Act by not enrolling pregnant women or sick people to keep costs down.

07/22/08 Lester E. Cox Medical Centers, Springfield, MO, agreed to pay the United States $60 million to resolve allegations it violated the False Claims Act, the Stark Law, and the Anti-Kickback Statute by entering into financial arrangements with a physician group and inducing physicians to refer patients to the hospital.

08/05/08 St. Elizabeths Hospital agreed to pay $11.3 million to resolve allegations it received reimbursement for inadequately documented or non-covered services the hospital claimed under the Medicare Part B program. CMS suspended payments on St. Elizabeths’ Part B outpatient claims amounting to more than $10.3 million, which CMS will retain as payment, the settlement agreement said. St. Elizabeths also agreed to forego $998,095 in Part A claims for inpatient services that CMS withheld.

08/11/08 BlueCross BlueShield of Tennessee, d/b/a Riverbend Government Benefit Administrators, agreed to pay $2.1 million to settle allegations of violating the False Claims Act that resulted in excessive outlier payments by Medicare to many New Jersey hospitals.

08/15/08 Caritas Carney Medical Group agreed to pay $347,456 to the federal government to settle allegations under the False Claims Act that it improperly billed federal government programs for services over a period of nearly seven years. The group submitted claims using physician provider numbers for services provided at nursing homes when the services were actually provided by nurse practitioners.

08/26/08 Rotech Healthcare, Inc., a durable medical equipment supplier, agreed to pay $2 million to the United States to resolve allegations it submitted false claims to Medicare.

09/08/08 Abbott Laboratories Inc. agreed to pay $28 million to settle an enforcement action alleging it falsely reported drug prices to the Texas Medicaid program because it failed to obtain Certificates of Medicaid Need.

09/15/08 Staten Island University Hospital agreed to pay $89 million to settle claims that it defrauded federal and state health care programs, through alcohol and detox billing. The hospital agreed to pay just over $74 million to the United States and $14.9 million to New York.

09/16/08 Carlson Therapy Network agreed to pay $1.88 million to settle allegations that it violated the False Claims Act. The government alleged the company billed government health programs for direct one-on-one therapy when the therapist was providing therapy services to multiple patients at one time.
09/24/08  **Bristol-Myers** agreed to pay 43 states a total of $389 million dollars to Medicaid fraud allegations. The settlement is based on 9 whistleblower lawsuits filed in federal courts across the country.

09/24/08  **Cooper University Hospital** agreed to pay the United States $3.8 million plus interest to resolve allegations that it defrauded the Medicare program by inflating charges to qualify for higher outlier reimbursements. The civil settlement resolved allegations against the hospital violated the False Claims Act by improperly increasing its charges for inpatient and outpatient care to Medicare patients between January 2001 and August 2003.

09/29/08  **Cephalon Inc.** agreed to pay $444 million to resolve claims of marketing three of its drugs for uses that were not approved by the FDA. The government alleged that as a result of the off-label marketing campaign by Cephalon, false claims for reimbursement were submitted to Medicare, Medicaid, and other government insurance programs.

09/30/08  **Walgreen Co.** agreed to pay the United States $9.9 million to settle allegations that its pharmacies in four states falsely billed the Medicaid Program. According to the lawsuit, the Medicaid programs reimbursed Walgreens in an amount equal to the difference between what the third-party insurance paid when the claims were submitted and what the participating states' Medicaid programs would have paid in the absence of third-party insurance.

10/21/08  **St. Joseph Healthcare System** agreed to pay $1.75 million to the federal government to resolve a False Claims Act *qui tam* lawsuit alleging Medicare fraud by improperly inflating its Medicare reimbursement claims. The whistleblower alleged that St. Joseph excessively billed for “outlier” payments.

10/21/08  **West Jefferson Medical Center** agreed to pay $3.3 million to the federal government and the state of Louisiana to resolve a False Claims Act *qui tam* suit alleging the hospital overcharged the Medicaid program. The lawsuit alleged that the hospital falsely billed Medicaid the median per diem reimbursement rate for services provided in a Level I facility, but the hospital did not meet the service requirements of a Level I facility.

10/31/08  **Schering-Plough** agreed to pay the state of Missouri $31 million to settle charges that it defrauded the state Medicaid program by manipulating the price-reporting mechanism used by Medicaid to establish reimbursement rates.

11/07/08  **Harris County Hospital District** agreed to pay an additional $2.2 million dollars to the Medicare and Medicaid programs after a compliance audit found the agency had allegedly improperly filed claims for the treatment of motor vehicle accident victims without proper checks for other payment sources. This amount is an addition to the $15.4 million dollars that the agency has to pay pursuant to a settlement agreement it entered into in June, 2007.

11/24/08  **St. Vincent Health System Inc.** agreed to pay the United States $1.9 million to settle a whistleblower’s allegations that it defrauded the Medicare program by inflating charges to qualify for higher outlier reimbursement.
11/24/08  Centennial HealthCare Corp. agreed to pay $2 million to resolve allegations of fraudulent Medicare and Medicaid billing. The government alleged that Centennial violated the False Claims Act by seeking reimbursement for skilled nursing services and other services that were not provided or were so inadequate that they amounted to worthless services.

11/25/08  Bayer HealthCare LLC agreed to pay $97.5 million, plus interest, to settle allegations it paid illegal kickbacks to 11 diabetic supply companies between 1998 and 2007. The settlement resolves allegations that Bayer’s actions caused the suppliers to submit false claims to the federal government for Medicare-covered diabetic supplies manufactured by Bayer and settles allegations that Bayer paid the medical supply companies more than $3 million in a so-called cash-for-patient scheme in which the suppliers received payment incentives to switch patients to Bayer products from competing products.

11/25/08  Manchester Community Hospital agreed to pay $712,166 to settle allegations that it improperly billed Medicare for chemotherapy and infusion therapy services.

12/01/08  MedQuist, Inc. agreed to pay $6.6 million to the federal government to resolve allegations that it knowingly overbilled several government agencies. According to the government, MedQuist overbilled the Veterans Administration, the Department of Defense, and the Public Health Service for medical transcription services by allegedly inflating the number of lines transcribed.

12/01/08  Condell Health Network agreed to pay $36 million after voluntarily disclosing that it received improper Medicare and Medicaid payments. The federal government will receive $33 million and Illinois will receive $2.8 million. The settlement resolves allegations of improper financial relationships with physicians, including below FMV rent, improper loans, and payment for services without a written agreement.

12/01/08  Milan General Hospital and Jackson Madison General Hospital agreed to pay a total amount of $7.8 million to settle allegations related to inpatient services at Milan General Hospital and claims for non-emergency ambulance transportation to Jackson Madison General Hospital.

12/24/08  Boulder Valley IPA agreed to enter into a consent order with the Federal Trade Commission, to settle charges the physician group engaged in unlawful agreements to raise fees it received from health plans in violation of the Federal Trade Commission Act. The complaint alleged that the IPA, acting as a combination of its competing physician members and in conspiracy with its members, acted to restrain competition in fee-for-service contracts by, among other things, entering agreements to fix prices at which its physician members would contract with payers, threatening to terminate contracts with payers who refused to deal with the IPA, and having its members refrain from negotiating individually with payers.
III. COURT DECISIONS

02/08/08 United States ex rel. Digovanni v. St. Joseph’s/Chandler Health System Inc., No. CV 404-190 (S.D. Ga.). While the court declined to dismiss the complaint for failure to plead fraud with particularity, the court found that the alleged fraudulent activities were immaterial to the government’s payment of any claims. According to the court, even if the relator proved that Saint Joseph’s had improperly charged for reusable equipment in inpatient claims submitted to Medicare, such submissions would not impact the hospital’s Medicare inpatient PPS reimbursement.

02/25/08 United States v. Prabhu, No. 2:04-CV-00589 (D. Nev.). A federal district court held that the government must pay a physician $542,495 to cover his attorneys’ fees and costs after he prevailed in a False Claims Act case charging him with Medicare fraud. The district court found that the government failed to demonstrate that special circumstances would make the award unjust.

03/31/08 Atlantic Urological Associates PA v. Leavitt, No. 1:08-CV-00141 (D.D.C.). A federal district judge blocked CMS temporarily from enforcing a provision in a November 2007 rule that would have made substantial changes to the way physicians bill for anatomic pathology diagnostic testing services. A preliminary injunction enjoined the enforcement of a provision in the anti-markup rule that applied to anatomic pathology diagnostic testing services provided in a centralized building, as defined in physician self-referral regulations.

04/01/08 Mendiondo v. Centinela Hospital Medical Center, No. 06-55981 (9th Cir.). A nurse who claimed that a California Hospital fired her for protesting “civil and criminal violations” in reference to a possible Medicare fraud, was entitled to proceed with her lawsuit under the False Claims Act, even though her complaint was vague and “inartfully drafted.” The Ninth Circuit found that the nurse’s complaint was adequate under federal court rules, and the trial court erred in dismissing her claims under the False Claims Act, the California False Claims Act, and the California Safety Code. The Ninth Circuit concluded that an employee claiming retaliation under the False Claims Act need only claim a suspicion that a defendant submitted a false claim—“not that the defendant actually submitted one.”

04/01/08 United States ex rel. Fry v. Health Alliance of Greater Cincinnati, No. C-1-03-167 (S.D. Ohio). DOJ intervened in a qui tam action alleging that a hospital’s scheduling of physicians at its outpatient testing unit based on the physician’s procedure volume for the previous year constituted a violation of the Anti-Kickback Statute.

04/08/08 United States v. Solinger, No. 3:03-CV-519 (W.D. Ky.). A qui tam realtor pursuing a False Claims Act lawsuit against an academic medical center failed to show that the defendants did not qualify for the academic medical center exception under the Stark Law. The district court interpreted the academic medical exception using a goal and purpose oriented perspective rather than a hyper-technical one. The court noted that such an approach reflected the recognition of the important relationships between physicians, hospitals and medical instruction.
04/21/08  Triad at Jeffersonville I LLC v. Leavitt, No. 08-329 (D.D.C.). The District Court determined that the current owner of certain nursing homes knowingly accepted assignment of the existing provider agreements from the previous nursing home operator, and thus was responsible for a $2 million overpayment made to the prior owner of the facilities.

05/16/08  Fresenius Medical Care v. United States, No. 07-2299 (8th Cir.). A federal appeals court held that Fresenius Medical Care was not immune from further investigation of its administration of a drug because of an earlier settlement agreement of allegations that the company submitted false claims to Medicare for the same drug.

05/23/08  Alameda County Medical Center v. Leavitt, No. 1:08-CV-00422 (D.D.C.). The U.S. District Court for the District of Columbia vacated regulations issued by the Department of Health and Human Services related to Medicaid reimbursement because HHS acted improperly and the rule was contrary to Congress’s plain intent to prohibit the reimbursement change.

06/09/08  Allison Engine Co. v. United States ex rel. Sanders, No. 07-214 (U.S.). In a unanimous decision, the U.S. Supreme Court held that, while presentment is not required for liability under two provisions of the False Claims Act, it must be proved that the false statement was made with the intent of getting a false claim paid or approved by the government.

06/18/08  Zurich American Insurance Co. v. O’Hara Regional Center for Rehabilitation, No. 06-1357 (10th Cir.). The Tenth Circuit held that a nursing home’s general and professional liability policies did not cover potential False Claims Act liability that was based upon quality of care allegations against the nursing home.

07/14/08  United States v. Bourseau, No. 06-56741 (9th Cir.). The presidents of two hospital management companies must pay the government almost $15.7 million for submitting false statements in three annual Medicare cost reports. The Ninth Circuit held that none of the disputed costs in the 1997, 1998, and 1999 cost reports for Bayview Hospital, owned by California Psychiatric Management Services (CPMS), were allowable. The court found that the government sustained actual damages of more than $5.2 million and was entitled to treble damages of $15.7 million and $31,000 in civil penalties under the False Claims Act.

07/24/08  Di Carlo et al. v. St. Mary Hospital et al., No. 06-3579 (3d Cir.). The court dismissed a class-action lawsuit against a local hospital for allegedly charging uninsured patients higher rates than patients who are insured or covered by publicly funded health care programs.

07/25/08  United States ex rel. Serrano v. The Oaks Diagnostics Inc., No. CV 03-2131 (C.D. Cal.). The court dismissed a False Claims Act qui tam action alleging a diagnostic clinic defrauded Medicare, after finding the intervening complaint failed to allege the charges with sufficient particularity, but the court granted to leave to amend the complaint.
United States ex rel. Roberts v. Aging Care Home Health Inc., No. 3:02-cv-02199 (W.D. La.). A federal district court in Louisiana held that the husband of the owner of a home health agency was responsible for paying almost $4.7 million in damages and fines after finding he knowingly violated the False Claims Act by signing false cost certifications. The Court found that the owners had sufficient knowledge or reckless disregard of the truth to warrant his liability under the FCA. The Court found that the defendants had signed four of the five cost certifications submitted to Medicare that were false and material to the Medicare program's decision to pay.

United States ex rel. Hopper v. Solvay Pharmaceuticals Inc., No. 8:04-CV-2356 (M.D. Fla.). A magistrate judge recommended dismissal of a False Claims Act action because the whistleblowers failed to provide specific allegations that a pharmaceutical company's marketing scheme for unapproved uses of a drug caused submission of false claims to any government health program.

United States ex rel. Baker v. Rehabilitation Specialists of Livingston County Inc., No. 2:00-CV-74410 (E.D. Mich.). A federal district held that a jury, not the court, should decide whether a physical therapist and his company knowingly submitted false claims to Medicare by signing two cost reports that relied on an employee's fraudulent information.

Kuhn v. LaPorte County Comprehensive Mental Health Council, No. 3:06-CV-317 (N.D. Ind.). The federal trial court refused to dismiss a lawsuit brought by two employees of a medical center who allegedly were fired for disclosing medical record problems to government officials. The court rejected the contention that the False Claims Act protections did not apply because the altered documents were never submitted to the government in support of a request for payment. The court held that the False Claims Act protects employees from retaliation “while they are collecting information about possible fraud, before they have put all the pieces together.” The court held that the whistleblowers are not required to show that the entity was subsequently liable for its actions in order to have been engaged in protected activity, instead, the whistleblowers are only required to show sufficient evidence to establish that their ‘investigatory conduct' was motivated by a good faith belief, consistent with that of a reasonable person in the same or similar circumstances.

United States ex rel. Pogue v. Diabetes Treatment Centers of America, No. 1:99-CV-03298 (D.D.C.). The court held it will not reconsider a July decision that refused to dismiss a False Claims Act lawsuit brought against Diabetes Treatment Centers of America because the court found that the company provided no new evidence or justification for the court to retreat from its prior determination that proof of false claims could be based on circumstantial evidence. The court also held that evidence of claim submission as to a subset of physicians can create a genuine issue of material fact as to a related subset of physicians.
09/24/08  U.S. ex rel. Foster v. Bristol-Myers Squibb Co., 9:05-CV-00084 (E.D. Tex.). The court determined that even under a relaxed pleading standard, the whistleblower failed to set forth the factual basis for his “information and belief” that Bristol-Myers Squibb Co. submitted false claims in a kickback scheme. The whistleblower provided no facts to support his belief that physicians at an HMO prescribed Bristol-Myers drugs instead of its competitor’s drugs and, therefore, failed to satisfy a relaxed Federal Rule of Civil Procedure 9(b) pleading standard.

09/30/08  United States ex. rel. Sterling v. Health Insurance Plan of Greater New York Inc., No. 06 civ. 1141 (S.D.N.Y.). Claims brought by a woman who alleged a health insurer she worked for defrauded the United States in violation of the False Claims Act were dismissed because the allegedly false statements were not made with the intent of securing a government payment. The court held that the qui tam relator could not pursue her False Claims Act allegations against the insurer because the allegedly false statements were made to secure accreditation from the National Committee for Quality Assurance and were not made to receive federal money.

10/02/08  United States ex rel. Conner v. Salina Regional Health Center Inc., No. 07-3033 (10th Cir.). A federal appeals court dismissed a lawsuit after finding no basis in either law or logic to adopt an express false certification theory that turns every violation of a Medicare regulation into the subject of a False Claims Act qui tam action. The court upheld a district court’s decision finding that the whistleblower cited no regulations or case law indicating that the government normally seeks retroactive recovery of Medicare payments for services actually performed on the basis that the noncompliance rendered them fraudulent. The court held that the government has established a detailed administrative mechanism for managing Medicare participation and that although the government considers substantial compliance a condition of ongoing Medicare participation, it does not require perfect compliance as an absolute condition to receiving Medicare payments for services rendered.

10/07/08  United States ex rel. Bane v. Breathe Easy Pulmonary Services Inc., No. 8:06-CV-00040 (M.D. Fla.). A federal district court denied dismissal of a False Claims Act qui tam action alleging a durable medical equipment company conspired with independent diagnostic testing facilities to submit fraudulent claims to Medicare. The court overruled the defendant’s objections because it found that none of the litigation documents from an unrelated case constituted a “public disclosure of allegations or transactions” that the defendant engaged in a scheme to defraud Medicare.

10/10/09  United States ex rel. Hebert v. Dizney, No. 07-31053 (5th Cir.). A federal court upheld the dismissal of a False Claims Act qui tam action alleging against a hospital, its owner, and the owner’s executives, saying that the complaint failed to adequately allege the nature of the underlying fraud. The court held that the whistleblowers failed to point with specificity to the what, when, or where of any individual false claim in their complaint against the hospital and its executives. The court stated that the whistleblowers “do not make, even on information and belief, particularized allegations of any false claim having been submitted and pleading on information and belief does not otherwise relieve a qui tam plaintiff from the requirements of Rule 9(b).”
Alabama v. CMS, M.D. Ala., (No. 2:08-CV-00881). Alabama filed an action in the U.S. District Court for the Middle District of Alabama seeking to prevent CMS from implementing a policy related to the federal share of state Medicaid recoveries. The complaint requests that the court set aside CMS's Oct. 28 letter and permanently enjoin CMS from implementing its requirements.

United States ex rel. Thomas v. Bailey, No. 4:06-CV-00465 (E.D. Ark.). The court held that an amended False Claims Act qui tam complaint failed to state a claim that a company selling spinal surgery devices and its salesman knowingly caused hospitals to present false or fraudulent claims for payment to Medicare, Medicaid, and TRICARE. The court, however, found the amended complaint, filed by the whistleblower did state a claim upon which relief could be granted under the False Claims Act, insofar as it alleged that the defendants caused a physician to submit false claims to the government for payment. The court determined that the whistleblower could file the amended complaint, so long as it was limited to the claim that defendants violated the False Claims Act by knowingly causing the physician to present to the government false claims for payment or approval.

United States ex rel. Ben Bane v. Life Care Diagnostics, No. 8:06-CV-00467 (M.D. Fla.). A federal judge dismissed a False Claims Act qui tam complaint alleging a diagnostic testing laboratory caused Medicare to pay for medically unnecessary and redundant services because the allegations in the complaint were nearly identical to an earlier False Claims complaint by the same relator. The court dismissed the complaint against Life Care Diagnostics for lack of jurisdiction under the False Claims Act "first-to-file" bar.

United States ex rel. Kennedy v. Aventis Pharmaceuticals Inc., No. No. 1:03-CV-02750 (N.D. Ill.). A federal district court dismissed for lack of particularity a False Claims Act qui tam action filed by two former sales representatives in which they alleged a pharmaceutical manufacturer marketed a drug for off-label use, thereby inducing hospitals to submit fraudulent claims to Medicare. The court found that the relators/whistleblowers failed to identify any particular cost report submitted to CMS that contained a claim for an off-label use of the drug as a covered expense. Because the relators did not tie the cost reports to particular claims, they failed to allege an individual hospital's cost reports were material to the payment of any given claim, the court found.

IV. CENTERS FOR MEDICARE & MEDICAID SERVICES PRONOUNCEMENTS

A. Advisory Opinions.

05/28/08 Advisory Opinion 08-01. CMS concluded that a hospital system's proposal to pay for development of customized software that allows the hospital's electronic health records system to communicate with similar systems owned by staff physicians does not constitute a compensation arrangement under physician self-referral laws. As such, the hospital would not have to meet a so-called Stark Law exception in order to pay for the development of the custom "interfaces."

06/11/08 Advisory Opinion 08-02. Physician owners of a diagnostic center can refer patients to the facility without running afoul of physician self-referral laws because the center meets the criteria for a rural provider.
B. Other.

02/12/08 CMS announced it is making publicly available the names of all 136 nursing homes targeted in its Special Focus Facilities (SFF) program for underperforming nursing homes. This list expands upon the list of 54 poor-performing nursing homes announced in November 2007.

04/23/08 CMS informed North Carolina it would withhold about $175 million in Medicaid reimbursement claims. CMS wrote state regulators that approximately $175 million in reimbursement for community support services the state sought for the fourth quarter of 2007 may not be allowable. The matter stems from certain community-based mental health services that audits found to be not medically or clinically necessary. A series of state audits over the past year found inconsistencies in the quality of care provided and a misunderstanding of the service by some providers and recipients.

05/08 CMS published a report stating that Medical Integrity Group has developed algorithms that will allow its contractors to complete far more audits than possible with traditional audit methods. MIG has already developed 50 algorithms, and more will be completed in the next six to nine months. The algorithms allow auditors to zero in on potential billing errors quickly and efficiently.

06/27/08 CMS published a final rule that modifies how the agency will determine extended payment schedules for providers that were overpaid by the Medicare program. The final rule makes no changes to the proposed rule that CMS published in November 2006. 73 Fed. Reg. 36443.

06/27/08 Medicare providers and suppliers as of August 26, 2008, will have expanded abilities to appeal the denial of their rights to bill the federal health program. CMS finalized the regulations that entitle providers and suppliers to a hearing before an administrative law judge and the right to appeal ALJ decisions to the Departmental Appeals Board. 73 Fed. Reg. 36448.

09/29/08 CMS issued several clarifications on payments of routine costs in clinical trials in the September 29, 2008 edition of Medicare Learning Network Matters. CMS stated that a research sponsor could create a fraud and abuse problem, if it pays for the co-payments of Medicare beneficiaries enrolled in clinical trials. CMS also clarified that if a research sponsor agrees in writing to pay for routine costs for which an insurance company—including Medicare—will not provide reimbursement, then the sponsor must absorb those charges.

10/28/08 CMS issued a letter regarding its policy regarding the refunding of the federal share of Medicaid overpayments, damages, fines, penalties, and any other component of a legal judgment or settlement when a state recovers pursuant to a legal action under the state’s false claims act. CMS asserted that the amounts recovered by a state through the state false claim action are to refunded at the Federal Medical Assistance Percentage (“FMAP”) rate and also demands that a state return not only the federal amount originally paid attributable to fraud or abuse, but also the FMAP-rate proportionate share of any penalties recovered. CMS asserted that neither a whistleblower’s share nor legal expenses paid by the state, may be deducted from the federal portion of the litigation’s proceeds.
V. INSPECTOR GENERAL PRONOUNCEMENTS

A. Advisory Opinions.

01/03/08 Advisory Opinion 07-18 (concerning the management by a health care industry consultancy of a charitable organization's arrangements to subsidize patient cost-sharing and premium obligations).

01/03/08 Advisory Opinion 07-19 (concerning an arrangement whereby a radiology group practice prepares written reports of its interpretations of radiology tests for a critical access hospital without charge to the hospital).

01/03/08 Advisory Opinion 07-20 (concerning an investment by a physician in an imaging center in a medically underserved area devastated by Hurricane Katrina).

01/14/08 Advisory Opinion 07-21 (concerning an arrangement in which a hospital has agreed to share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures).

01/14/08 Advisory Opinion 07-22 (concerning an arrangement in which a hospital has agreed to share with a group of anesthesiologists a percentage of the hospital's cost savings arising from the anesthesiologists' implementation of a number of cost reduction measures related to anesthesia services provided during cardiac surgical procedures).

02/01/08 Advisory Opinion 08-01 (concerning a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage).

02/05/08 Advisory Opinion 08-02 (concerning a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage).

02/08/08 Advisory Opinion 08-03 (concerning a proposed arrangement by which a health care system would provide prompt pay discounts to Federal health care program beneficiaries and other insured patients in connection with both inpatient and outpatient care).

02/12/08 Advisory Opinion 08-04 (concerning a proposal to offer a free trial prescription program to hemophilia A patients who are Federal health care program beneficiaries).

02/22/08 Advisory Opinion 08-05 (concerning a pharmaceutical company's proposal to place in certain physicians' offices electronic kiosks that offer patients free disease state screening questionnaires).
05/09/08 Advisory Opinion 08-06 (concerning a laboratory’s proposal to provide services consisting of the labeling of test tubes and specimen collection containers at no cost to dialysis facilities).

07/07/08 Advisory Opinion 08-07 (concerning a proposal for a health care system to provide $10 gift cards to patients whose service expectations were not met).

07/25/08 Advisory Opinion 08-08 (concerning an investment in an ambulatory surgery center by a group of surgeons and a health care corporation that owns hospitals).

08/07/08 Advisory Opinion 08-09 (concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center’s cost savings arising from the surgeons’ implementation of a number of cost reduction measures in spine fusion surgical procedures).

08/26/08 Advisory Opinion 08-10 (concerning a proposal for a physician practice group to provide space, equipment and personnel to other physician practice groups through block leases).

09/04/08 Modification of OIG Advisory Opinion No. 04-13 (concerning Advisory Opinion No. 04-15, which was issued on 11/05/04, regarding proposed modifications to the nonprofit, charitable organization’s existing program to provide grants to financially-needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies).

09/24/08 Advisory Opinion 08-11 (concerning 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).

09/26/08 Advisory Opinion 08-12 (concerning a proposed arrangement under which a newly formed legal entity would provide purely administrative insurance preauthorization processing and submission services for various radiology and imaging centers).

10/02/08 Advisory Opinion 08-13 (concerning the use of a “preferred hospital” network as part of a Medicare Supplemental Health Insurance (“Medigap”) policy).

10/02/08 Advisory Opinion 08-14 (concerning a substance abuse treatment center’s use of motivational incentives to reward a patient’s achievement of certain treatment-related goals).

10/14/08 Advisory Opinion 08-15 (concerning an existing multiple-year arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital’s cost savings arising from the cardiologists’ implementation of a number of cost reduction measures in certain procedures).
10/14/08  **Advisory Opinion 08-16** (concerning a proposed arrangement by which a hospital would share with a physician-owned entity certain performance-based compensation available to the hospital under a quality and efficiency agreement with a private insurer).

10/21/08  **Advisory Opinion 08-17** (concerning a nonprofit, tax-exempt, charitable organization’s proposed arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with a certain disease).

10/28/08  **Advisory Opinion 08-18** (concerning a proposal whereby a medical center providing emergency medical services transportation in a county would not bill bona fide county residents for applicable cost-sharing amounts, but would instead be paid such amounts by the county from a fund consisting of tax revenue).

11/05/08  **Advisory Opinion 08-19** (concerning an Internet advertiser’s proposal to extend its “pay per call” or “pay per lead” advertising business to the chiropractic industry).

11/26/08  **Advisory Opinion 08-20** (concerning a proposal whereby two suppliers of durable medical equipment, prosthetics, orthotics and supplies will (i) place inventory in consignment closets on-site at certain hospitals and (ii) have licensed personnel on-call or on-site at the hospitals to train and educate patients who have been prescribed respiratory equipment and have selected one of the companies as their supplier upon discharge to their homes).

12/08/08  **Advisory Opinion 08-21** (concerning a multiple-year arrangement in which a hospital has agreed to share, with cardiology groups and a radiology group, a percentage of the hospital’s cost savings arising from the physicians’ implementation of cost reduction measures in certain cardiac catheterization procedures).

12/15/08  **Advisory Opinion 08-22** (concerning certain part-time physician employment arrangements).

12/19/08  **Advisory Opinion 08-23** (concerning a proposal for a county, which provides emergency medical services (EMS) transportation through its fire department, to treat revenue received from taxes as payment of otherwise applicable cost-sharing amounts owed by bona fide county residents for EMS transportation to hospitals).

**B. Civil Monetary Penalties Actions.**

01/04/08  After it self-disclosed conduct to the OIG, Shands at Alachua General Hospital (Shands), Florida, agreed to pay $119,838 and to enter into a 3-year certification of compliance agreement for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Shands employed an individual that Shands knew or should have known had been excluded from participation in Federal health care programs.

02/01/08  Newton Memorial Hospital (NMH), New Jersey, agreed to pay $89,279.70 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that NMH employed an individual that NMH knew or should have known was excluded from participation in Federal health care programs.
After it self-disclosed conduct to the OIG, Caritas Christi, Massachusetts, agreed to pay $250,060 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Caritas Christi employed or contracted with five individuals that Caritas Christi knew or should have known were excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Biotronic West, LLC, NeuralWatch, LLC, and The Regents of the University of California, for its University of California Davis Medical Center (collectively, Respondents), agreed to pay $41,488.24 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the Respondents employed an individual that the Respondents knew or should have known had been excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Sabine County Hospital District, Texas, agreed to pay $82,341, for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Sabine fraudulently included a physician recruiting fee on its cost report as a reimbursable expense.

After it self-disclosed conduct to the OIG, Sparks Health System, Sparks Medical Foundation, and Sparks Regional Medical Center (collectively, Respondents), Arkansas, agreed to pay $1,142,973 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the Respondents billed Medicare for medically unnecessary hospital services.

Southern Illinois Healthcare Foundation (SIHF), Illinois, agreed to pay $562,021 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that SIHF employed an individual that SIHF knew or should have known was excluded from participation in Federal health care programs.

St. Barnabas Hospital, New York, agreed to pay $132,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the hospital employed three individuals that the hospital knew or should have known were excluded from participation in Federal health care programs.

Whole Health Pharmacy (WHP), Colorado, agreed to pay $100,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that WHP employed an individual that WHP knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, FutureCare Irvington, LLC (FutureCare), Maryland, agreed to pay $36,290.79 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that FutureCare employed an individual that FutureCare knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Courtyard Manor of Farmington Hills (Courtyard Manor), Michigan, agreed to pay $1.7 million for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Courtyard Manor received federal health care program funds while the entity was excluded. Courtyard Manor also agreed to be excluded from Medicare, Medicaid, and all other Federal health care programs for two years in addition to its original 10-year period of exclusion.
After it self-disclosed conduct to the OIG, Briarcliff Nursing and Rehabilitation Center LP (Briarcliff), Texas, agreed to pay $1,833 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Briarcliff and its management company, Skilled Healthcare LLC, employed an individual that Briarcliff knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Pacific Healthcare and Rehabilitation Center, LLC (Pacific), California, agreed to pay $4,657.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Pacific and its management company, Skilled Healthcare LLC, employed an individual that Pacific knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Rossville Healthcare and Rehabilitation Center, LLC (Rossville), Kansas, agreed to pay $46,216.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Rossville and its management company, Skilled Healthcare LLC, employed an individual that Rossville knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Town & Country Manor LP, Texas (Town & Country), Texas, agreed to pay $4,383 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Town & Country and its management company, Skilled Healthcare LLC, employed an individual that Town & Country knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, St. Elizabeth Healthcare and Rehabilitation, California, agreed to pay $6,223 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that St. Elizabeth and its management company, Skilled Healthcare LLC, employed an individual that St. Elizabeth knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Hallmark Rehabilitation, California, agreed to pay $68,055 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Hallmark employed an individual that Hallmark knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Royalwood Care Center, California, agreed to pay $1,054.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Royalwood employed an individual that Royalwood knew or should have known was excluded from participation in Federal health care programs.
09/30/08 After they self-disclosed conduct to the OIG, Eureka Healthcare and Rehabilitation Center, LLC (Eureka) and Grenada Healthcare and Rehabilitation Center, LLC (Grenada), California, agreed to pay $58,323 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Eureka and Grenada and their management company, Skilled Healthcare LLC, employed an individual that Eureka and Grenada knew or should have known was excluded from participation in Federal health care programs.

11/18/08 After it self-disclosed conduct to the OIG, City of Chicago, Illinois, agreed to pay $6.9 million for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the City of Chicago submitted claims to Medicare for ambulance services that were not medically necessary, billed at the wrong level of service, and submitted claims without the patient's or other appropriate person's signature as required by CMS regulations.

C. Other.

03/26/08 Revision to the OIG Advisory Opinion Process. The OIG revised the terms and process for obtaining an advisory opinion. Requesters still are required to pay a fee equal to the cost of preparing an advisory opinion, but the OIG no longer will require an initial payment at the time of the request.

04/15/08 Open Letter to Providers. According to the OIG, providers that resolve fraud matters using the OIG's Provider Self-Disclosure Protocol generally will no longer be required to enter into corporate integrity agreements. An open letter to providers said that accurate and complete disclosures, timely responses to OIG requests for additional information, and accurate audits by disclosing providers all indicate “effective compliance measures,” ruling out the need for corporate integrity agreements or certification of compliance agreements in most cases.

07/08 OIG Policy Statement on Retroactive Medicare Rate Increase. The OIG issued a policy statement assuring providers, practitioners, and suppliers affected by retroactive increases in Medicare payment rate increases under the Medicare Improvements for Patients and Providers Act of 2008 will not be subject to OIG administrative sanctions if they waive Retroactive Beneficiary Liability.

VI. OTHER NOTEWORTHY DEVELOPMENTS

05/23/08 The Department of Health and Human Services announced the beginning of Sentinel Initiative, a program which would allow the FDA to use information on Medicare claims to assess the risks of drugs already on the market. FDA officials will be able to monitor almost immediately how drugs affect health.

07/10/08 The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a revised version of the PhRMA Code on Interactions with Healthcare Professionals (the “PhRMA Code”). The PhRMA Code sets industry standards for pharmaceutical marketing practices.
08/28/08  The U.S. Department of Justice revised its *Principles of Federal Prosecution of Business Organizations*, published in the United States Attorneys' Manual. The Principles specifies the DOJ policy concerning how it will measure a corporation's cooperativeness in a criminal investigation and how the DOJ determines whether an entity should be charged with a crime.

09/15/08  New Marking Rules for Medicare Advantage Plans and Part D Plans. New marketing and sales agent compensation rules for Medicare Advantage and Part D prescription drug plans were finalized to protect beneficiaries from high-pressure sales tactics by insurance agents. Plans will be prohibited from providing meals at sales and marketing events for beneficiaries, from conducting unsolicited telemarketing and door-to-door sales campaigns, from cross-selling of non-health care related products, from conducting sales activities in health care provider locations and at pharmacy counters, and from conducting sales activities at educational events. 73 Fed. Reg. 54208; 73 Fed. Reg. 54226.

11/04/08  CMS was required to impose an automatic stay in the contract work of the Recovery Audit Contractors (“RAC”) program. The automatic stay will stop work for all four RAC regional awards. The action is the result of protests filed by two unsuccessful bidders for the RAC program.

11/12/08  Amendment to Federal Acquisition Regulations (“FAR”). The government published an amendment to FAR to require mandatory disclosure of what would otherwise be voluntary disclosures of fraud related matters. The new rule expands the scope of contractors who are required to have a code of business ethics and conduct and an internal control system. The rule also mandates disclosure to the government of certain violations of criminal law, violations of the civil False Claims Act, and significant overpayments.

12/18/08  AdvaMed issued a major update of its Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”). The revised AdvaMed Code clarifies and distinguishes between appropriate and inappropriate activity between health care professionals and medical device manufacturers.