AMERICAN HEALTH LAWYERS ASSOCIATION

Year in Review
2006-2007
American Health Lawyers Association  
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ANITRUST

U.S. Court In New York Declines To Dismiss Radiology Practice’s Antitrust Claims Against NYU School Of Medicine
A radiology practice and a radiologist terminated from a radiology provider network that has an exclusive contracting arrangement with the New York University School of Medicine (NYU) had antitrust standing and alleged antitrust injury sufficient to survive a motion to dismiss filed by NYU and one of its professors, a federal district court in New York has ruled. New York Medscan, LLC, a facility providing state-of-the-art diagnostic imaging services, and one of its radiologists filed an antitrust action against NYU, radiology provider network CareCore National LLC (CCN), which controls the PET/CT services for roughly 3.5 million New York City subscribers, and one of the university’s professors who also serves as CCN’s chairman of the board. Medscan alleged that defendants engaged in an unlawful group boycott and per se unreasonable restraint of trade, and in a course of dealing that restrained, eliminated, and suppressed competition in the market for PET/CT scanning services.

Refusing to grant defendants’ motion to dismiss, the U.S. District Court for the Southern District of New York found plaintiffs alleged the type of injuries the antitrust laws were intended to prevent—i.e. that defendants harmed their business, decreased the quality and output of the provision of diagnostic imaging services, and increased the price for such services. The court also concluded that, while physicians may not be the most efficient enforcers of the antitrust laws, they may nonetheless serve as an appropriate party to assert injury under the antitrust laws where their interest coincides with that of the patient. New York Medscan LLC v. New York Univ. Sch. of Med., No. 05 Civ. 4653 (S.D.N.Y. May 1, 2006).

D.C. Circuit Affirms Dismissal Of Medical Resident Lawsuit
The D.C. Circuit affirmed June 1, 2006 a district court’s dismissal of a lawsuit by medical residents alleging that the National Resident Matching Program illegally restrained competition. Because the suit falls squarely within an antitrust exemption carved out by Congress in the Pension Funding Equity Act of 2004, plaintiffs cannot prevail on their claims, the appeals court said. Jung v. Association of Am. Med. Colleges, No 04-7023 (D.C. Cir. Jun. 1, 2006).

Four Class Action Suits Filed Against Major Hospital Systems Alleging Conspiracy To Depress Nurse Wages
In June, 2006 four class action lawsuits were filed in federal courts in Albany, Chicago, Memphis, and San Antonio alleging that a number of major hospitals have conspired to keep their nurses’ wages at artificially low levels. Among the many hospitals named in the suit are Ascension Health, Inc., Northeast Health, Inc., Advocate Health Care, Evanston Northwestern Healthcare, Baptist Memorial Healthcare Corporation, and Hospital Corporation of America, Inc. According to the suits, the hospitals have “agreed to regularly exchange detailed and non-public information about the compensation each is paying or will pay to its RN employees,” which has “facilitated the formation, implementation, and enforcement of defendants’ wage-fixing conspiracy” in violation of
§ 1 of the Sherman Act, 15 U.S.C. § 1. Absent such conspiracy, the suit alleged, hospitals in the four areas would have substantially increased RN compensation in order to attract a sufficient number of nurses to their facilities, the suits alleged. Instead a nationwide nursing shortage remains, the complaints said.

Subsequently, in December 2006, six hospitals in the Detroit area also became the subject of a class action filed alleging they unlawfully conspired to depress nurses’ wages. The hospitals named in the suit, filed in the U.S. District Court for the Eastern District of Michigan, are Bon Secours Cottage Health Services, Detroit Medical Center, Henry Ford Health System, McLaren Health Care Corp (d/b/a Mount Clemens Regional Medical Center), Oakwood Healthcare Inc., and St. John Health Partners. The complaint contends the hospitals conspired, in violation of federal antitrust law, to keep wages low by agreeing “to regularly exchange detailed and non-public information about the compensation each is paying or will pay to its RN employees” though meetings, telephone conversations, and written surveys. The complaint adds that, absent the alleged conspiracy, hospitals in the Detroit area would have responded to the national nursing shortage by “substantially increasing RN compensation.”

U.S. Court In Oregon Rejects Physician’s Antitrust Claims Against Hospital
An anesthesiologist whose privileges at an Oregon hospital were not renewed failed to show a conspiracy between the hospital and anesthesiology service to support his antitrust claims, a federal district court in Oregon ruled June 29. Theodore R. Ford, M.D, who is Asian and African-American, was a member of the medical staff at Redmond, Central Oregon District Hospital (CODH) where he served as the Medical Director of its Anesthesia Department. CODH subsequently merged with St. Charles Medical Center to form Cascade Health Services (CHS). Bend Anesthesiology Group, P.C. (BAG) had provided anesthesiology services for St. Charles and signed an agreement with CHS to provide physician anesthesiology services at the Redmond hospital. Ford then announced his plans to form a competing physician anesthesia group. Subsequently, CODH informed Ford that his privileges would not be renewed, citing complaints from staff members and hospital management about Ford’s behavior.

The U.S. District Court for the District of Oregon granted defendants summary judgment on Ford’s antitrust claims, finding he failed to present evidence of a conspiracy to support his Sherman Act § 1 claim and holding no reasonable factfinder could conclude that BAG had monopoly power over the provision of anesthesia services in Central Oregon to allow his § 2 claim for monopolization or attempted monopolization to go forward. In so holding, the court refused to define the relevant market more narrowly to consist of M.D. anesthesiology services alone, finding instead competition between certified registered nurse anesthetist and physicians evident.

The court did allow the physician’s claim for racial discrimination against the hospital and various other physicians to proceed, noting that other Caucasian physicians had not been subject to the same adverse employment actions for similar complaints made against them. *Ford v. Cascade Health Servs.*, No. 03-6256-TC (D. Ore. June 29, 2006).
U.S. Court In Georgia Allows Claims Of Interference With Competing Dialysis Center to Proceed
On June 29, 2006, a judge in the Middle District of Georgia dismissed in part and allowed in part claims, including economic credentialing claims, that the former hospital employer of a nephrologist interfered with the nephrologists' attempts to operate a competing dialysis center. Plaintiff Mark G. Wood, the former Director of Defendant Archbold Medical Center's inpatient and outpatient dialysis units, filed an antitrust complaint challenging allegedly anticompetitive actions aimed at eliminating competition from his dialysis facilities. According to the complaint, after a falling-out with Archbold's administration, Wood resigned his position and began plans to build and operate a competing dialysis unit. Archbold allegedly offered to pay Wood not to open a competing unit upon learning of Wood's plans, but Wood refused Archbold's offer and subsequently opened both home care and onsite dialysis facilities. In response, Archbold purportedly interfered with Wood's operation of his dialysis facilities (resulting in their eventual sale) and used its peer review authority to harass him and to revoke his staff privileges at Archbold. Wood then sued Archbold and certain of its administrators and staff on behalf of both himself and his former dialysis facility, alleging: (1) Sherman Act violations; (2) state law tort claims; and (3) state law deceptive practices claims. Archbold moved to dismiss the complaint.

After finding that defendants were not immune under the Health Care Quality Improvements Act or the Georgia Peer Review statute, the district judge held that Wood and the facility each had shown sufficient antitrust standing. Further, the district judge found that plaintiffs had pled sufficient facts to make out their claims for refusal to deal, tortious interference, and intentional infliction of emotional distress. The district judge dismissed plaintiffs' deceptive practices claims, however. Wood v. Archbold Med. Ctr., No. 6:05-CV-53 (M.D. Ga. June 29, 2006).

U.S. Court In Missouri Says Medical Group’s Antitrust Suit Against Hospital Failed To Allege Relevant Geographic Market
A federal court in Missouri dismissed August 8, 2006 a medical group’s antitrust claims against a nearby hospital saying the relevant geographic market alleged by the group was “implausible” and drawn so as to exclude the hospital’s competitors. Ferguson Medical Group, L.P. (FMG) is comprised of limited partner-physicians who practice family medicine, general internal medicine, and a variety of medical specialties and subspecialties in the Scott County, Missouri area. FMG competes with Missouri Delta Medical Center (MDMC) in the market for ancillary medical services and outpatient diagnostic and surgical services such as medical laboratory, testing, and imaging services, minor urgent care services, and limited ambulatory surgical procedures. FMG sued MDMC and others alleging defendants had conspired to eliminate competition for these services in Sikeston, Missouri and certain surrounding areas.

The U.S. District Court for the Eastern District of Missouri held FMG failed to allege a relevant market to support its claims of attempted monopolization and conspiracy to monopolize under § 2 of the Sherman Act and under Missouri antitrust law. According to the court, FMG’s proposed geographic market was “artfully pled to exclude competitors”
in nearby areas. The area encompassed by FMG’s proposed geographic market “makes sense only if one were attempting to artificially boost MDMC’s market power. The law, however, does not permit such gerrymandering,” the court said. According to the court, FMG made the mistake of basing its geographic market on where MDMC’s customers actually go for services, not where they could practically turn for services. *Ferguson Med. Group, L.P., v. Missouri Delta Med. Ctr.*, No 1:06CV8 CDP (D. Mo. Aug. 2, 2006).

**FTC Announces Proposed Consent Order With Kansas City IPAs**

On August 24, 2006, the Federal Trade Commission (FTC) announced that it had entered into an agreement and proposed consent order with two Kansas City independent physician associations (IPAs), their constituent physician practices, and four current or former officials of the IPAs. The consent order settles a complaint (disclosed on the same day) challenging the IPAs' joint contracting practices. According to the complaint, the two IPAs provided a forum for individual physicians to share financial risk and contract with payors on a capitated basis. In addition to these capitated services, each physician offered and sold their medical services to patients and payors on a fee-for-service basis. When payors attempted to purchase medical services on a fee-for-service basis, however, the individual physician practices allegedly agreed among themselves that they would only sell those services to payors through capitation contracts between payors and the IPAs. Unlike many other FTC complaints, the Kansas City complaint did not allege unlawful collective negotiations due to an inaccurately implemented messenger model. Here, the FTC did not challenge the risk contracting by the IPA, which should be permissible under the FTC/Department of Justice (DOJ) healthcare guidelines.

Instead, the complaint alleged an unlawful concerted refusal to deal on a fee-for-service basis. Under the FTC/DOJ healthcare guidelines, an agreement by a group of physicians to contract exclusively through an IPA on a risk basis is not suspect in the absence of market power. The FTC apparently viewed the Kansas City IPA has having market power, but it was not clear from the complaint what the group's share of any particular relevant market is and how its high share of a particular payor's provider network enters into assessment of its market power.

To remedy the complaint's allegations, the proposed consent order imposes a number of restrictions on the IPAs, the constituent practices, and the named officials. First, the order prohibits the constituent practices (except where necessary to form or participate in a legitimate risk-sharing or clinically-integrated joint arrangement) from entering into, or facilitating, any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) regarding on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving the IPAs. The constituent practices also may not facilitate exchanges of information between or among physicians concerning whether, or on what terms, to contract with a payor. The order further requires the IPAs to notify the FTC before contracting with payors on behalf of individual physicians, and bars the named officials from negotiating payor contracts or advising on such contracts (except in risk-sharing or clinically-integrated situations, or where the negotiation involves only the practice in which the official participates) for a

**U.S. Court In Pennsylvania Dismisses Disgruntled Doctor's Antitrust Suit**

On August 30, 2006, the U.S. District Court for the Western District of Pennsylvania dismissed an antitrust suit brought by a disgruntled doctor against hospitals that previously had terminated his privileges and doctors involved in the peer review processes that led to the terminations. Plaintiff claimed in his complaint that the hospitals and the doctors had conspired to terminate his privileges and shut him out of the surgical market in the Johnstown, Pennsylvania area.

The court began its analysis by noting the complicated history of the case. Plaintiff had begun his medical career in New Jersey, where his medical staff privileges were suspended; at least four state and federal lawsuits followed the suspension. After a brief stay in New York, plaintiff moved to the Johnstown area in late 1994 and eventually was granted privileges at three hospitals: UPMC Lee Regional Hospital (Lee), Conemaugh Memorial Medical Center (Conemaugh), and Windber Medical Center (Windber). In 1999, in response to plaintiff's reapplication for surgical privileges at Lee, Lee instituted a peer review process that found plaintiff had displayed poor judgment in two of nine cases reviewed, both of which resulted in fatalities, and required plaintiff to have a second surgeon present whenever certain surgeries (pancreatic or liver resections) were performed. Plaintiff challenged this action in state court, and Lee subsequently granted him unrestricted clinical privileges for a two-year period retroactive to February 1, 1999. During that period, however, an outside physician was selected to monitor six to ten of plaintiff's major abdominal surgeries. After this monitoring period, the outside physician recommended that a second surgeon be involved with all of plaintiff's major abdominal procedures, and Lee's Medical Staff Executive Committee voted to condition a grant of clinical privileges to plaintiff on the second surgeon requirement. Plaintiff appealed this decision through both Lee's peer review process and through state and federal courts, and his staff privileges at Lee eventually were terminated.

While this dispute was ongoing, the plaintiff was in the process of reapplying for privileges at both Conemaugh and Windber. Although he fully documented the Lee proceedings to Conemaugh and Windber, both hospitals reappointed him without restrictions. Conemaugh revoked his privileges in December 2002, however, when his "poor judgment" resulted in the death of a patient and he subsequently attempted to shift the blame for the death to anesthesiologists and others (plaintiff appealed the revocation decision through Conemaugh's internal peer review process). Moreover, plaintiff voluntarily resigned his Windber privileges in August 2002. He subsequently filed suit in May 2003 against Lee, Conemaugh, and assorted physicians, alleging Sherman Act violations, § 1983 civil rights violations, tortious interference with prospective economic advantage, negligence, perjury, and defamation. Defendants promptly filed moved to dismiss.

After disposing of certain claim and issue preclusion arguments posed by defendants, the court dismissed plaintiff's Sherman Act claims due to his inability to show either antitrust
standing or antitrust injury. In support of dismissal, the court found plaintiff could offer no evidence other than bare allegations to support the requisite conspiracy, that Lee and Conemaugh terminated the plaintiff's privileges for independent reasons, and that the plaintiff at all times could have competed in the market by retaining his Windber privileges. The court then dismissed the remainder plaintiff's claims. Untracht v. Fikri, Case No. 3:03-cv-00199 (W.D. Pa. Aug. 30, 2006).

**Tenth Circuit Rules Excluding Optometrists From Provider Panel Does Not Violate Sherman Act**

Optometrists who were refused admission to the provider panel for the largest managed care company in Utah failed to prove allegations that their exclusion constituted an unlawful group boycott, tying, or monopoly under the Sherman Act, the Tenth Circuit ruled on September 6, 2006. The optometrists applied to the provider panel of Intermountain Health Care (IHC), estimated to represent 60% of total managed care enrollees in the relevant Utah market. IHC provided eye care services to its enrollees through a panel of ophthalmologists, who perform the same services as optometrists in addition to exercising hospital eye surgery privileges. The ophthalmologists on the IHC provider panel had a long and well-documented history of opposing optometrists' admission to the panel.

After IHC denied their application, the optometrists sued IHC and two panel ophthalmologists, arguing that the denial violated the Sherman Act. Affirming summary judgment in favor of defendants, the Tenth Circuit found the optometrists failed to show IHC and the ophthalmologists engaged in a concerted action to harm competition. Further, because the optometrists relied on circumstantial evidence, that evidence must tend to exclude the possibility that IHC and the ophthalmologists acted independently. In this case, the court determined, it did not. Specifically, the appeals court agreed that, "it is clear that IHC excluded optometrists because of the actions of its panel ophthalmologists." Nevertheless, this undisputed fact was not sufficient to prove an illegal conspiracy under the Monsanto test, the appeals court ruled. Although admitting optometrists to the panel might have reduced the cost of eye care, the appeals court found other pro-competitive justifications supported IHC's decision to admit only ophthalmologists. Abraham v. Intermountain Health Care, No. 05-4043 (10th Cir. Sept. 6, 2006).

**FTC Says Non-Profit Institution Act Applies To Health System’s Drug Purchase And Distribution Program**

The Non-Profit Institutions Act (NPIA) applies to a health system’s plan to provide pharmaceuticals to patients at an affiliated hospital and clinic through hospital-owned pharmacies, according to an advisory opinion issued by the Federal Trade Commission (FTC) staff September 15, 2006. The NPIA exempts from the Robinson-Patman Act “purchases . . . of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit.” St. John’s Health System is a nonprofit Missouri corporation that operates an integrated health services delivery system. Within that system are two nonprofit Missouri corporations and fully owned subsidiaries—St. John’s Regional Health Center (hospital)
and St. John’s Clinic (clinic). St. John’s Health System, which is currently receiving preferential price treatment in its purchase of pharmaceuticals for treatment of hospital inpatients as permitted under the NPIA, asked whether it could extend the use of NPIA-discounted pharmaceuticals for use by hospital outpatients and by clinic patients filling prescriptions at three hospital-owned pharmacies.

Under the proposed program, safeguards would be instituted to ensure that the preferentially priced pharmaceuticals are not dispensed to the pharmacies’ walk-in customers, who are not current hospital or clinic patients. Moreover, St. John's Health System plans to “establish a separate accounting system to track non-exempt transactions and avoid improper sales,” according to the FTC’s press release.

The FTC staff concluded that “pharmaceuticals used in the ways outlined in the request letter could be distributed by St. John’s Health System to Hospital outpatients and to Clinic patients through the hospital-owned pharmacies without violating the NPIA.” According to the advisory opinion, “[t]hough not explicitly enumerated as eligible institutions in the NPIA’s statutory language, non-profit integrated health delivery systems, such as St. John’s, appear to be a type of non-profit charitable institution that Congress intended to exempt in the statute.”

**Seventh Circuit Rejects Anesthesiologist's Antitrust Challenge To Exclusive Contract Between Hospitals And Anesthesiology Group Practice**

An anesthesiologist whose privileges to practice at the only two hospitals in Lafayette, Indiana were denied after the hospitals merged and entered into exclusive contracts with a competing provider of anesthesia services cannot bring antitrust claims against the hospitals, the Seventh Circuit ruled September 12, 2006. The appeals court affirmed a federal trial court’s decision to grant summary judgment in favor of the hospitals based on its findings that the anesthesiologist lacked antitrust standing and also failed to establish her claims alleging violations of both Sherman Act §§ 1 and 2.

From 1985 through 1993, the anesthesiologist, Carolyn Kochert, M.D., provided anesthesiology services at both of the two hospitals located in Lafayette, Indiana—Home Hospital and St. Elizabeth’s Medical Center (SEMC). In 1998, these hospitals merged to form Greater Lafayette Health Services (GLHS), which subsequently operated both hospitals. Kochert became board certification in pain management in 1999, and by mid-2000, was practicing pain management full time; currently, she provides pain management services at both Home Hospital and SEMC. In 2001, GLHS decided to contract with a competing anesthesia group, of which Kochert was not a member, for exclusive services at SEMC.

On appeal, the Seventh Circuit found Kochert did not suffer an antitrust injury because at the time the alleged anticompetitive conduct began in 2001, Kochert was no longer a practicing anesthesiologist but rather specializing in pain management. The Seventh Circuit went on to say that “[e]ven if Kochert could establish antitrust injury, she would fail to establish antitrust standing because she is not the party ‘who can most efficiently
vindicate the purposes of the antitrust laws’ in this case.” Kochert v. Greater Lafayette Health Servs. Inc., No. 05-1196 (7th Cir. Sept. 12, 2006).

Eighth Circuit Holds Drug Companies Not Liable Under Antitrust Laws For Allegedly Suppressing Importation Of Drugs From Canada
Drug companies may not be sued under federal antitrust laws for alleged anticompetitive conduct in suppressing drug importation from Canada, the Eighth Circuit held November 30, 2006. Because importation is illegal, consumers lacked standing to sue, the appeals court said. Plaintiffs, consumers and organizations who have purchased prescription drugs from the defendant drug companies, sued the companies alleging they violated § 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring to suppress the importation of Canadian prescription drugs for personal use. According to the complaint, the conduct was anticompetitive because it eliminated a legal source of prescription drugs and caused American consumers to pay higher drug prices.

Affirming a lower court ruling, the Eighth Circuit concluded drugs dispensed in Canada are “misbranded” under federal law, and thus are prohibited from being imported into the U.S. The appeals court rejected plaintiffs’ argument that even if personal importation of drugs from Canada is illegal, they nonetheless may pursue legal action based on defendants’ anticompetitive conduct. According to appeals court, plaintiffs lacked an antitrust injury, noting that the “absence of competition from Canadian sources in the domestic prescription drug market . . . is caused by the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants.” In re: Canadian Import Antitrust Litigation, No. 05-3873 (8th Cir. Nov. 30. 2006).

FTC Says Physicians Groups Engaging In Price Fixing
Several organizations representing more than 2,900 independent Chicago-area physicians agreed to fix prices in violation of federal antitrust laws, the Federal Trade Commission (FTC) alleged in a complaint against Advocate Health Partners (AHP) and other related parties. FTC’s complaint challenged AHP’s conduct in collectively negotiating prices during a nine-year period ending in 2004. The complaint alleged that AHP negotiated contracts on behalf of its physician members who could then either opt in or out of the negotiated contract. In addition, FTC alleged that AHP terminated its members’ contracts with a health plan that rejected proposals for higher fees and forced the hospital to agree to a group contract. The group contract included fees 20% to 30% higher than the health plan’s individual physician contracts, FTC said. A consent order agreed to by the parties would prohibit AHP from engaging in such anticompetitive conduct in the future.

FTC Commissioner Says FY 2006 Saw Increase In Anticompetitive Patent Settlements
There has been a substantial increase in pharmaceutical settlements involving payments to generic manufacturers to restrict generic drug entry on the market, Federal Trade Commission (FTC) Commissioner Jon Leibowitz said in testimony January 17, 2007 before the Senate Judiciary Committee. Such patent agreements—called exclusion or reverse payments—are anticompetitive because they delay the market entry of cheaper generic drugs at consumers’ expense, Leibowitz said. An FTC study released the same
day as the hearing showed a “disturbing new trend” in drug settlements, Leibowitz added. According to the study, half of all patent settlements in fiscal year 2006 involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for a period of time.

“[T]here is every reason to expect the upsurge in these settlements to continue, and early entry under Hatch-Waxman to decline,” because exclusion payments are highly profitable for both the band-name manufacturer and the generic manufacturer, Leibowitz told the panel. And recent court cases have made it more difficult for FTC to bring antitrust suits to stop exclusion payments. In one such case, Schering-Plough Corporation entered into settlement agreements with two generic drug manufacturers, which effectively delayed entry of generic competitors to one of Schering-Plough's drugs. FTC filed an administrative complaint against the companies that was tried before an administrative law judge (ALJ). The ALJ ruled that both agreements were lawful settlements of legitimate patent lawsuits and dismissed the case. The FTC then issued an opinion reversing the ALJ and finding both agreements to be anticompetitive. The Eleventh Circuit subsequently vacated the FTC's decision with respect to both agreements, finding the agreements not anticompetitive. See Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056 (11th Cir. 2005). The U.S. Supreme Court refused to review the Eleventh Circuit’s decision.

**U.S. Court In D.C. Finds FTC’s Settlement Of Antitrust Challenge With One Company Does Not Moot Case Against Second Company**

The Federal Trade Commission’s (FTC's) settlement of an antitrust challenge with one pharmaceutical company did not moot its case against a second pharmaceutical company just because the challenged conduct was no longer taking place, a federal district court held January 22. Because FTC challenged not only the current conduct but also sought to prevent future conduct in its complaint, there was still relief available to FTC, the court found.

Defendant Warner Chilcott acquired Ovcon 35, an oral contraceptive, in 2000. Ovcon is one of the company’s most lucrative products, earning it approximately $71.5 million a year. In 2001, Barr Pharmaceuticals announced its decision to market a generic version of Ovcon and filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA). According to the FTC, on September 10, 2003, Warner Chilcott and Barr executed a letter of intent, which provided that Warner Chilcott would pay Barr $20 million and that Barr would agree not to compete in the United States with its generic Ovcon for five years after receiving final FDA approval of its ANDA, but instead would agree to be available as a second supplier of Ovcon to Warner Chilcott upon request.

The FTC alleged that the final agreement prevented Barr from selling generic Ovcon in the United States until May 2009, whereas otherwise “Barr would have started selling generic Ovcon shortly after receiving final FDA approval in April 2004.” The FTC further asserted that the introduction of generic Ovcon would have “quickly and significantly” reduced the sales of Warner Chilcott’s brand-name counterpart and led to a significant reduction in the average price purchasers paid for Ovcon.
Subsequently, Warner Chilcott waived its exclusive license with Barr and Barr announced that it would introduce a generic version of Ovcon in October 2006. Barr then moved to dismiss FTC’s action, arguing the case was moot and no relief remained for the FTC. In addition, while the motion was pending, Warner Chilcott settled with the FTC.

The U.S. District Court for the District of Columbia denied Barr’s motion to dismiss, finding the case was not moot because FTC had sought not only to enjoin enforcement of the final agreement between Barr and Warner Chilcott, but also to prevent similar conduct from occurring in the future. Although Warner Chilcott was constrained by its agreement with FTC not to engage in similar conduct in the future, “Barr faces no such constraint,” the court said. The court noted, however, that it specifically did not reach the issue of whether "FTC will be able to demonstrate an entitlement to injunctive relief aimed at conduct 'similar and related' to the exclusivity provisions of the final agreement." Federal Trade Comm’n v. Warner Chilcott Holdings Co. III, Ltd., No. 05-2179 (D.D.C. Jan. 22, 2007).

Eighth Circuit Affirms Dismissal Of Medical Device Manufacturer’s Antitrust Action

The Eighth Circuit affirmed the dismissal of a medical device manufacturer's lawsuit against another manufacturer alleging violations of the Sherman Act, finding the defendant did not possess monopoly power in the relevant product market and finding the plaintiff failed to prove any anticompetitive conduct. Plaintiff HDC Medical, Inc. (HDC) and defendant Minntech Corporation (Minntech) both manufacture a medical device called a dialyzer reprocessing machine and a reprocessing solution to go with it. HDC sued Minntech after Minntech modified its machine alleging that the modifications rendered HDC’s reprocessing solution incompatible with Minntech’s machines. HDC claimed Minntech’s actions violated the Sherman Act, 15 U.S.C. §§ 1, 2.

The Eighth Circuit first noted that a “prima facie claim of monopolization under the Sherman Act requires a plaintiff to show that the defendant ‘possessed monopoly power in the relevant market’ and ‘willfully acquired or maintained that power.’” Amerinet, Inc. v. Xerox Corp., 972 F.2d 1483, 1490 (8th Cir. 1992). At issue was the dispute between the parties about the relevant market. The district court found that single-use and multiple-use dialyzers are competitors in the same market and concluded that Minntech did not possess monopoly power in that market. HDC argued, however, that single-use and multiple-use dialyzers do not compete in the same product market. According to HDC, the district court ignored case law suggesting that significant price differences between identical-use products can establish reasonable interchangeability, and thus support a jury's inference that two separate product markets exist. The appeals court disagreed with this argument, finding instead that a price differential alone is insufficient to infer two separate product markets.

Turning to HDC’s attempted monopolization claim, the appeals court found HDC did not present evidence of predatory or anticompetitive conduct. The appeals court explained that Minntech’s policy of not honoring its device’s warranty if a competitor’s
reprocessing solution were used had a legitimate business justification and was not anticompetitive. The appeals court also found that HDC did not present any evidence that Minntech’s modifications to its device were anticompetitive. *HDC Med., Inc. v. Minntech Corp.*, No. 06-1638 (8th Cir. Jan. 25, 2007).

**Fifth Circuit Dismisses Physician’s Antitrust Claims Against Hospital**

The Fifth Circuit held February 6, 2007 in an unpublished opinion that a physician who lost his privileges at a hospital did not allege harm to competition sufficient to support his Sherman Act claim against the hospital. David Taylor began working as a gastroenterologist at Christus St. Joseph’s Medical Center (St. Joseph’s) and with the private practice of Drs. Daryl Dickey and David Stewart in 1998. In 1999, St Joseph’s acquired McCuistion Regional Medical Center. Taylor alleged that St Joseph's recruited him in order to compete with McCuistion and after the acquisition, St. Joseph’s “no longer had any need to support [his] practice” and accordingly began conspiring with Dickey and Stewart to drive him out of the market. During the same time, Taylor was involved in two medical malpractice lawsuits. In its investigation, St Joseph’s discovered that Taylor had been rejected as an approved physician by a federally funded health insurer. Based on this discovery, St. Joseph’s disqualified Taylor from its staff and removed his privileges to admit patients to the hospital. Taylor also alleged that during this time, Dickey and Stewart made comments that he was a “bad doctor” and a “problem doctor.”

Affirming the lower court’s dismissal of Taylor’s lawsuit, the Fifth Circuit held he failed to show any competitive injuries as required to maintain a Sherman Act claim. “He alleged only that his ejection might have ‘allowed the remaining doctors . . . to engage in monopoly pricing’” and stated that “the remaining market providers could now easily reduce services,” the appeals court noted. *Taylor v. Christus St. Joseph Health Sys.*, No. 06-40775 (5th Cir. Feb. 6, 2007).

**U.S. Court In California Dismisses Sherman Act Claims Finding Plaintiff Failed To Prove Antitrust Injury**

The U.S. District Court for the Southern District of California held March 7, 2007 that a pediatric radiologist failed to show she suffered an actionable antitrust injury as a result of an agreement between a competing radiology group and local hospitals. In so holding, the court granted the group and several of its shareholders summary judgment on plaintiff’s Sherman Act claims.

Plaintiff, Saskia Hilton, a pediatric and general radiologist, applied for staff privileges at defendant Children’s Hospital (CHSD) after the hospital where she was currently on staff (USCD) decided to decrease the size of its pediatric facility. CHSD granted plaintiff privileges for general diagnostic radiology, fluoroscopy, and neurosonography, but did not grant computerized tomography (CT) and ultrasound privileges. After almost a year of asking CHSD to modify her privileges and getting no response, plaintiff sued CHSD, San Diego Diagnostic Radiology Medical Group, Inc. (SDDR), which provided professional radiology services for both adult and pediatric patients, and several physician-shareholders of SDDR. Plaintiff alleged CHSD’s delay in processing her
application was in bad faith and was intended to further a horizontal market conspiracy designed to prevent her from competing in the market. Defendants moved to dismiss, claiming plaintiff’s claims were barred by the Health Care Quality Improvement Act (HCQIA). The trial court granted the motion.

Plaintiff appealed the dismissal to the Ninth Circuit, which reversed and remanded the case. After remand, plaintiff filed an amended complaint alleging violation of §§ 1 and 2 of the Sherman Act and violation of the Cartwright Act against defendant SDDR. Plaintiff contended that there was a Market Division Agreement whereby SDDR agreed with UCSD that SDDR pediatric radiologists would not practice at UCSD and UCSD pediatric radiologists would not practice at CHSD. SDDR and the physician defendants moved for summary judgment.

Granting the motion as to the Sherman Act § 1 claim, the court found while plaintiff presented evidence of an agreement between SDDR and UCSD that would prevent UCSD pediatric radiologists from working at CHSD, she failed to show any resulting injury to competition, “a defining element of an antitrust violation.” Namely, plaintiff did not “come forward with evidence showing that other pediatric radiologists have been excluded from the marketplace or that patients are unable to find alternatives to the defendants for their radiological needs, or that plaintiff is incapable of competing in the relevant market or that there is a diminishment in the quality of care or that there is an anti-competitive increase in the price of pediatric radiology.” Without a proven antitrust injury, defendants are entitled to summary judgment, the court held. The court also dismissed plaintiff’s Sherman Act § 2 monopolization claim, again finding she failed to show an antitrust injury. Hilton v. Children’s Hosp.—San Diego, No. 02-CV-1080-L(CAB) (S.D. Cal. Mar. 7, 2007).

California Appeals Court Upholds Exclusive Arrangement Between Blue Cross PPO Plan And Group Of Physical Therapy Providers

An exclusive preferred provider arrangement between Blue Cross of California and a group of physical therapy practices that imposes territorial restrictions on its members is authorized under California statutes immunizing certain conduct from antitrust liability, a state appeals court ruled March 23, 2007. The California Court of Appeal, Second District, affirmed a trial court’s judgment finding that the conduct at issue was authorized by statute, and that plaintiffs had failed to allege an antitrust violation under California’s Cartwright Act or under the state’s unfair competition laws.

Defendant-provider group PTPN, Inc. is allegedly the largest group of physical therapy providers in California. PTPN limits its membership based in part upon geographic considerations; it does not allow new members whose practices are located within a certain radius of an existing member’s practice. The other defendant, Blue Cross of California (Blue Cross), is allegedly the largest provider of preferred provider organization (PPO) coverage in California. Under the arrangement at issue, members of PTPN are, for the most part, the exclusive preferred providers of physical therapy for Blue Cross. Under Blue Cross’ PPO plan, a member of PTPN who provides physical therapy services to a Blue Cross subscriber receives the negotiated rate of payment as a
preferred provider directly from Blue Cross. If the subscriber chooses an out-of-network provider for services, then he or she must pay for that treatment.

Plaintiffs Lori Rubenstein Therapy, Inc. and One on One PT are providers of physical therapy who are not members of PTPN and not preferred providers for Blue Cross’ PPO plan. Plaintiffs brought an action alleging that PTPN and Blue Cross violated California antitrust and unfair competition laws by engaging in an improper market allocation (via PTPN’s geographic restrictions) and a group boycott (via Blue Cross’ exclusive contract with PTPN). Plaintiffs also asserted that the exclusive arrangement unlawfully restrained competition resulting in higher prices to patients, less innovation, less variety in service offerings, and lower quality in physical therapy services.

The appeals court noted two markets in which plaintiffs competed with PTPN and/or its members: (1) the market to provide physical therapy services to patients, including Blue Cross PPO plan subscribers, and (2) the market to become Blue Cross preferred providers. As to the first market, the appeals court acknowledged that the contractual relationship between Blue Cross and PTPN inhibited plaintiffs’ ability to compete, but said such a competitive disadvantage was expressly authorized by the state’s insurance laws, which allow insurers to contract for alternative rates with any provider and offer the benefit of those rates to their insureds. Likewise, with respect to the second market, defendants’ conduct was authorized by a state statute that requires an insurer to consider proposals by providers wishing to become preferred providers only if the existing preferred providers do not adequately serve the geographic area proposed to be served by the other providers. Lori Rubenstein Physical Therapy, Inc. v. PTPN, Inc., No. B187172 (Cal. Ct. App. Mar. 23, 2007).

ARBITRATION/MEDIATION

**Mississippi Supreme Court Finds Arbitration Agreement Precludes Wrongful Death Action Against Surgeon**

The beneficiaries of a patient who died following multiple surgeries were bound by the valid and enforceable arbitration agreement signed by the patient and therefore could not bring a wrongful death action against the patient's surgeon and affiliated clinic, the Mississippi Supreme Court has ruled. John Mann signed a clinic-physician arbitration agreement before he underwent a hernia repair to be performed by Dr. Kenneth Cleveland. Mann suffered complications from the surgery and later died. Plaintiffs, as wrongful death beneficiaries of Mann, sued Cleveland, the surgical clinic (i.e., group practice) with which he was affiliated, and the hospital where Mann’s surgeries were performed for medical malpractice. The state trial court refused to compel arbitration, holding the agreement “fell within the realm of adhesion” and therefore was unconscionable.

Reversing, the Mississippi Supreme Court found the agreement was not procedurally or substantively unconscionable. As to the procedural aspect, the high court noted the agreement contained a bolded, all-cap paragraph clearly stating that those signing the agreement agree to arbitrate any negligence or medical malpractice claim and to give up
their rights to a jury or court trial. Moreover, Mann had initialed the agreement in several places, including beside a statement indicating he was not in need of emergency care or under immediate stress. Mann also had fifteen days between the time he signed the agreement and the surgery to rescind or amend it.

The high court said the agreement was not substantively unconscionable because it provided Mann with a “fair opportunity and a proper forum in which to dispute his claims.” The agreement did not limit his damages or legal rights, nor did it limit Cleveland’s and the clinic’s liability, the court said. *Cleveland v. Mann*, No. 2005-CA-00924-SCT (Miss. Aug. 31, 2006).

**Florida Appeals Court Compels Arbitration Under Nursing Home Admissions Agreement Even Though Portions Were Unconscionable**

A Florida appeals court upheld a trial court’s grant of a motion to compel arbitration under a nursing home resident’s admissions agreement even though some portions of the agreement were severed because of unconscionability. Betsy L. Bryant sued Alterra Healthcare Corporation (Alterra) and others (defendants) seeking damages for common law negligence and for violations of the Florida Assisted Living Facilities Act (ALFA), which allegedly occurred while she was a resident at two different nursing facilities owned by Alterra. Alterra moved to compel arbitration for both cases pursuant to the arbitration clause in the admissions agreement executed by Bryant and her husband, Bryant’s attorney-in-fact pursuant to her durable power of attorney. The trial court found portions of the arbitration agreement unconscionable, but granted defendants’ motion to compel arbitration after severing the stricken provisions of the arbitration agreement.

Affirming, the Florida District Court of Appeal, Fourth District, found the portions of the agreement requiring waiver of punitive damages and a $250,000 cap on non-economic damages void as against public policy. The appeals court noted that arbitration agreements containing provisions that defeat the ALFA’s remedial purpose are not enforceable. The appeals court also agreed with the lower court that the problematic portions of the agreement did not render the remainder unenforceable given the severance clause contained in the arbitration agreement. *Alterra Healthcare Corp. v. Bryant*, No. 4D05-4409 (Fla. Dist. Ct. App. Sept. 13, 2006).

**Tennessee Appeals Court Rules Physicians Must Arbitrate Claims Against BlueCross**

Two physicians who alleged that a health insurer systematically and arbitrarily denied payments to them and other similarly situated doctors had to submit their claims to binding arbitration in accordance with their participating provider agreements, a Tennessee appeals court ruled November 29, 2006. Zachary Rosenberg, M.D. and Dewayne P. Darby M.D. (plaintiffs) entered into participating provider agreements with BlueCross BlueShield of Tennessee (BCBST) that required binding arbitration of disputes in accordance with the Tennessee Uniform Arbitration Act. Plaintiffs sued BCBST, alleging breach of contract, unfair or deceptive business practices, and other claims based on fourteen different types of allegedly improper conduct, including bundling, downcoding, and physician profiling. BCBST moved to compel arbitration.
Plaintiffs argued that the arbitration procedure contained in their participating provider agreements was unenforceable because the cost of arbitrating the physicians’ small individual claims was prohibitive thus denying them a viable remedy.

The Court of Appeals of Tennessee noted the party seeking to avoid arbitration bears the burden of proving that arbitration is cost prohibitive. In the case at bar, plaintiffs asserted that their claims were of minimal value, even if aggregated over two years. If that were the case, the appeals court reasoned, “it would be easy enough to say on very limited proof that arbitration was cost prohibitive. The complaint, however, asserts no such small claims but rather alleges a pattern of improper and deceptive conduct and business practices,” costing millions of dollars, plus punitive damages, fees, and permanent injunctive relief. “What might be prohibitive when a $4,000 claim is in issue would certainly not be prohibitive when millions of dollars and vast injunctive relief are actually in issue,” the appeals court determined. Because federal and state law strongly favor arbitration, and the participating provider agreement required all disputes to be subject to binding arbitration, the appeals court agreed with the trial court, which had granted the motion to compel arbitration. *Rosenberg v. BlueCross BlueShield of Tenn.*, No. M2005-01070-COA-R9-CV (Tenn. Ct. App. Nov. 29, 2006).

**California Appeals Court Finds Arbitration Provision In Health Insurer’s Plan Enrollment Form Unenforceable Because Not Prominently Displayed**

The absence of a “prominently displayed” arbitration provision in a health insurer’s plan enrollment form signed by an enrollee rendered that provision and any subsequent arbitration agreement between the enrollee’s employer and the plan unenforceable, a California appeals court ruled December 27, 2006. The California Court of Appeal, First Appellate District, found that the insurer’s failure to prominently display an arbitration disclosure provision in its enrollment form violated Cal. Health and Safety Code § 1363.1.

Mark Zembsch, an attorney employed by the city of Berkeley, California, was eligible for group health insurance coverage under a group hospital and professional service agreement between the city and the health insurer, Health Net of California Inc. (Health Net). Zembsch signed an enrollment form to enroll himself and his family in a Health Net plan that offered health maintenance organization (HMO) coverage but provided most primary care services to the Zembschs through a contracting physician group, Alta Bates Medical Group (Alta Bates). The Zembschs sued Health Net and Alta Bates, alleging breach of contract and other causes of action for refusing to approve a referral to a specialist for their son.

Reversing a lower court decision compelling arbitration of the dispute, the appeals court concluded the arbitration disclosure on Health Net’s enrollment form did not comply with Cal. Health and Safety Code §1363.1 and therefore was unenforceable. The appeals court noted the plan enrollment form signed by Zembsch in 2002 contained an arbitration disclosure provision but the 2002 contract between the city (i.e., Zembsch’s employer) and Health Net contained no such requirement. Although acknowledging that Health Net had produced evidence of a 2005 city-Health Net arbitration agreement requiring both the
group and members to arbitrate their disputes with Health Net, the appeals court determined this did not alter its conclusion that any arbitration agreement relevant to this case was unenforceable. “Even if Health Net has met its burden of proof with respect to the 2005 agreement, it is undisputed that the only arbitration disclosure signed by Zembsch appeared on the 2002 enrollment form,” which did not meet the prominence requirements of Cal. Health and Safety Code § 1363.1. Zembsch v. Superior Court of Alameda County, No. A114157 (Cal. Ct. App. Dec. 27, 2006).

**Oklahoma High Court Finds Arbitration Provision In Nursing Home Admissions Contract Unenforceable Under State Nursing Home Care Act**

Pursuant to Oklahoma’s Nursing Home Care Act, which invalidates any waiver of the right to commence an action against a nursing home or licensee for any intentional or negligent act or omission, an arbitration provision in a nursing home admission agreement was unenforceable as applied to a plaintiff’s wrongful death lawsuit, that state’s high court ruled December 12, 2006. Significantly, the Oklahoma Supreme Court also found that the nursing home care at issue in the case did not involve interstate commerce and therefore the Federal Arbitration Act (FAA) was inapplicable.

Plaintiff Detra L. Bruner filed a lawsuit in state court on behalf of her deceased mother against the Timberlane Manor L.P. and its successor in interest, Timberlane Manor LLC d/b/a Grace Living Center (GLC) in Edmund, Oklahoma. Plaintiff alleged that GLC’s negligent care caused her mother’s death. Upon admitting her mother to the nursing home, plaintiff signed on her mother’s behalf a nursing home admissions contract that contained an arbitration provision requiring the nursing home resident to submit any resident-nursing home dispute to neutral binding arbitration and waive any right to trial in a court of law or equity. Plaintiff sought actual and punitive damages for the wrongful death of her mother, alleging that her death was caused by GLC’s negligence and its violation of the Patients’ Bill of Rights in the Oklahoma Nursing Home Care Act. GLC contended that the anti-arbitration provisions of Oklahoma’s Nursing Home Care Act are preempted in this case by the FAA, and its state counterpart, the Oklahoma Uniform Arbitration Act (OUAA), which both favor arbitration.

“[T]he evidence in this case is insufficient to connect the nursing home admissions contract with interstate commerce under extant jurisprudence from the United States Supreme Court,” the state high court concluded. Thus, the FAA did not apply, the court concluded. Moreover, the court determined that Oklahoma’s Nursing Home Care Act trumped the OUAA. The high court acknowledged a conflict between the OUAA § 1857(a), which provides that arbitration agreements shall be valid, enforceable, and irrevocable except upon a ground that exists at law or in equity for revocation of a contract, and the Oklahoma Nursing Home Care Act, which clearly rejects arbitration agreements between nursing homes and their residents. “Although the United States Supreme Court has decided that the FAA preempts and displaces a state anti-arbitration statutes, we have not decided that the OUAA controls over anti-arbitration statutes such as § 1-1939 in the Nursing Home Care Act,” the high court said. Rather, here the more specific statute, the Nursing Home Care Act, governed over the more general statute

**U.S. Court In Mississippi Declines To Compel Arbitration In Wrongful Death Suit Against Nursing Home Owners**

Defendant nursing home owners in a wrongful death action brought by a deceased resident’s daughter failed to establish the existence of a valid arbitration agreement, and therefore their motion to compel arbitration should be denied, a federal district court in Mississippi ruled December 29, 2006. In reaching this conclusion, the U.S. District Court for the Southern District of Mississippi found defendants had failed to establish that the daughter, the plaintiff in the case, was acting as her mother’s agent when signing the subject arbitration agreement.

Plaintiff Bonita Buie signed an arbitration agreement along with an admission agreement and other forms when her mother, Magdaline McKnickles, was admitted to Countrybrook Living Center in Brookhaven, Mississippi. Buie signed the arbitration agreement on a line designated “Legal Representative (if signing on behalf of Resident).” Within ten days of her admission to Countrybrook, McKnickles died. Buie filed a wrongful death lawsuit in the district court against the nursing home and its owner and operator (defendants), alleging that McKnickles’ death was proximately caused by Countrybrook’s negligence and gross negligence. Defendants moved to dismiss, asserting that all of Buie’s claims were subject to an arbitration agreement and requesting an order to compel arbitration.

The district court, which had jurisdiction based on diversity of citizenship, denied the motion, concluding the arbitration agreement was invalid because Buie lacked the authority to sign the agreement on her mother's behalf. Under Mississippi agency law, the court continued, the decedent in this case (i.e., the principal) would only be “bound by the actions of [her] agent within the scope of that agent’s real or apparent authority,” which may be expressed or implied. The court found defendants failed to show Buie “was empowered, either by court or statute, to make legal decisions regarding McKnickles’ affairs.” *Buie v. Mariner Health Care, Inc.*, No. 3:06cv499-WHB-JCS (S.D. Miss. Dec. 29, 2006).

**California Appeals Court Finds Arbitration Provision In Health Plan Benefits Election Form Unenforceable**

The benefits election form that an employee signed to enroll in a group health insurance plan offered by his employer failed to comply with the disclosure requirements for arbitration provisions set forth in applicable state statutes and therefore the provision was unenforceable, a California appeals court ruled January 16. In reaching this conclusion, the California Court of Appeal, Second District, rejected the health insurer’s contention that the disclosure requirements did not apply to the “benefits election form,” and would only have been triggered if the employee had been required to sign an “enrollment form” to enroll in the plan.
Mary Medeiros, a deputy sheriff employed by the County of San Bernardino, sued Health Net of California (Health Net), which had a group service agreement with the County. Among other claims, the lawsuit alleged breach of contract and bad faith. Health Net moved to compel arbitration, citing the arbitration provision in its group services agreement with the County. Health Net does not obtain individual applications from County employees who elect to enroll in the group service plan offered through the County, but rather such employees notify the County of their desire to become a plan member and the County then sends a copy of a County-prepared benefits election form to Health Net. In this case, Mary’s husband Lee Medeiros, also a deputy sheriff with the County, signed the County’s Benefits Election Agreement indicating that he wanted to enroll himself and his family in the Health Net Plan. That agreement stated that an employee enrolling in one of Health Net’s plans agreed “[t]o abide by the rules of binding arbitration as described in the Evidence of Coverage (EOC) and Disclosure brochures” for Health Net plans. The EOC contains a detailed six-paragraph arbitration clause under a bold-faced “Binding Arbitration” heading.

According to the Medeiros, they never received the EOC until Mary Medeiros requested a copy after their family had been enrolled as plan members for over three years. Moreover, they argued the arbitration provision in the benefits election form signed by Lee Medeiros was unenforceable because it did not comply with the disclosure requirements of Cal. Health & Safety Code § 1363.1 (i.e., that the provision be prominently displayed and located immediately before the signature line). Health Net argued that the disclosure requirements of § 1363.1 apply only to the application for group service agreement and the group service agreement with the County, and not the benefits election form.

Vacating a lower court order compelling arbitration, the appeals court concluded that neither the benefits election agreement signed by Lee Medeiros nor the EOC complied with the disclosure requirements of § 1363.1. The appeals court rejected Health Net’s argument that, regardless of the benefits election form's noncompliance with applicable disclosure requirements, Mary Medeiros was bound by the arbitration provisions found in the group service agreement between Health Net and the County. In these circumstances, “the group health plan that has a binding arbitration provision as a term must include a disclosure to the employee-subscribers which meets the requirements of § 1363.1,” the appeals court said. “We interpret section 1363.1 to provide protection in the form of certain disclosures to all consumers, not just consumers who individually subscribe to a health plan,” the appeals court noted. Medeiros v. Superior Court of Cal., No. B193042 (Cal. Ct. App. Jan. 16, 2007).

Ohio Appeals Court Upholds Nursing Home Arbitration Agreement Finding Procedural But Not Substantive Unconscionability
An Ohio appeals court January 26 upheld a nursing home arbitration agreement, finding the agreement was procedurally but not substantively unconscionable. After being discharged from the emergency room, Patricia Manley went to Personacare of Ohio, d/b/a. Lake Med Nursing Home and Rehabilitation Center. Upon her arrival, she signed both an admissions agreement and a document entitled “alternative dispute resolution
agreement between resident and facility.” According to plaintiff—personal representative of Manley’s estate—Manley fell several times while at Lake Med and eventually died as a result of the treatment she received there. Plaintiff sued Personacare and Personacare moved to stay the proceedings and have the matter referred to arbitration.

Affirming the trial court’s order to arbitrate, the appeals court concluded all factors taken together, including that Manley was under stress at the time of admission and was having bouts of confusion, pointed to a finding that the agreement was procedurally unconscionable. But the appeals court also found the agreement was not substantively unconscionable because it contained a warning that the resident was giving up his or her right to a jury trial by signing the agreement and provided the resident thirty days to reject the agreement. Because a contract must be both procedurally and substantively unconscionable to be unenforceable, the appeals court affirmed the trial court’s ruling that arbitration must proceed in the case. *Manley v. Personacare of Ohio*, No. 2005-L-174 (Ohio Ct. App. Jan. 26, 2007).

**California High Court Finds Chiropractor-Patient Arbitration Agreement Remains Effective Despite Two-Year Gap Between Treatments**

The arbitration agreement that a patient signed when he was first treated for back pain by a chiropractor remains valid and applicable to a medical malpractice claim arising from the patient’s treatment for a different condition two years later, the California Supreme Court ruled February 8. When Terry Reigelsperger sought treatment from chiropractor James M. Siller in August 2000, he was suffering from severe lower back pain. At the conclusion of this treatment, Reigelsperger paid in full and said he did not expect to return. Reigelsperger did not consult Siller until two years later when, in September 2002, he sought treatment for his cervical spine and shoulder. Reigelsperger was not satisfied with the results of this treatment and sued Siller for medical malpractice. Siller sought to stay litigation and compel arbitration pursuant the agreement Reigelsperger signed at his initial treatment.

Finding that the agreement as a whole, complied with all the requirements of Cal. Civ. Proc. Code § 1295, whose purpose is to encourage and facilitate arbitration of medical malpractice disputes, the high court concluded that the agreement governed “all subsequent open-book account transactions for medical services for which the contract was signed.” In any event, the high court said, “[r]egardless of whether the parties had an open-book account relationship,” their obligation to arbitrate under the agreement, which specifically stated it applied to current and future treatments, “would stand on its own.” The lower court in refusing to compel arbitration concluded that the arbitration agreement could not reasonably be construed to bind the parties “in perpetuity.” But the high court said “like other contracts, arbitration agreements that do not specify a term of duration are terminable at will after a reasonable time has elapsed.” Here, Reigelsperger did not try to terminate the arbitration agreement. The high court also cited the consent agreement, which stated it applied “not only to the ‘entire course of treatment for my present condition,’ but also to ‘any future condition[s] for which I seek treatment,’” as additional evidence that the parties contemplated the possibility of future transactions. *Reigelsperger v. Siller*, No. S131664 (Cal. Feb. 8, 2007).

Although a state trial court properly struck down certain provisions of a Mississippi nursing home’s admissions agreement as substantively unconscionable, it erred in striking down the agreement’s arbitration provisions on that basis, the Mississippi Supreme Court ruled February 22, 2007. Barbara Brown, Sharon Goss, and Margaret Grace brought a wrongful death lawsuit on behalf of their deceased mother against Covenant Health Rehab of Picayune, L.P. and its successor in interest, Picayune Partners, L.P. (collectively Covenant), doing business as Picayune Convalescent Center (PCC) in Picayune, Mississippi. Plaintiffs alleged their mother had been grossly neglected while a resident at PCC before her death. Covenant moved to compel arbitration pursuant to the arbitration provisions in the admissions agreement. Plaintiffs then moved to declare the admissions agreement invalid, alleging it was procedurally and substantively unconscionable.

On appeal, the Mississippi high court agreed with the trial court that the agreement was not procedurally unconscionable since decedent’s daughter, Sharon Goss, signed the agreement on her mother’s behalf, even if at the time decedent lacked the capacity to understand the agreement. Under applicable state law (Miss. Code Ann. § 41-41-211), a surrogate has authority to sign a nursing home admissions agreement on behalf of a decedent, who at the time of admission, does not have an appointed agent or guardian, and has been determined by her primary care physician to lack capacity, the high court noted.

The high court also affirmed the lower court’s ruling that a number of the agreement’s provisions were substantively unconscionable and therefore invalid, including those limiting actual damages and waiving punitive damages; those allowing the care facility to bring suit in court on payment issues but prohibiting residents from doing so, and a provision limiting the statute of limitations for a resident to bring a legal action to one year following the event giving rise to a grievance. Despite the problems with these provisions, the trial court should not have struck down the arbitration portion of the agreement, the high court found. Citing Vicksburg Partners, L.P. v. Stephens, 911 So. 2d 507 (Miss. 2005), as controlling, the high court noted the arbitration provisions at issue were nearly identical to those upheld in Vicksburg, a case that also involved an admissions agreement with other unconscionable provisions. Thus, the high court concluded the remainder of the admissions agreement without the unconscionable provisions was enforceable and remanded the case with directions to compel the parties to submit to arbitration. A lengthy dissenting opinion argued that the admissions agreement, as “a contract for illegal services,” should be found wholly void as a matter of law. Covenant Health Rehab of Picayune, L.P. v. Brown, No. 2005-CA-02220-SCT (Miss. Feb. 22, 2007).

California Appeals Court Says Daughter With Healthcare Power Of Attorney Could Bind Mother To Nursing Home Arbitration Agreement
A daughter with a statutory healthcare power of attorney had the authority to enter into an arbitration agreement on her mother's behalf during the admissions process at a nursing home, a California appeals court ruled March 1, 2007. Reversing a lower court decision refusing to compel arbitration of a subsequent elder abuse action brought against the nursing home, the appeals court found the decision to sign an arbitration agreement during admissions is part of the healthcare decision-making process and therefore within the healthcare power of attorney’s scope of authority.

Barbara Hogan and her brothers (plaintiffs) sued Country Villa Health Services, which owned and operated the skilled nursing facility where their mother Sarah had resided, for wrongful death, elder abuse, and violation of patient rights. At the time of Sarah’s admission, Barbara, who had a statutory healthcare power of attorney, signed two arbitration agreements—one related to medical malpractice claims and the other related to violations of California’s elder abuse law. County Villa moved to compel arbitration of plaintiffs’ claims pursuant to the arbitration provisions, but the trial court refused, stating that the healthcare power of attorney did not authorize Barbara to enter into the arbitration agreements on her mother’s behalf.

The California Court of Appeal, Fourth District, reversed, holding the healthcare power of attorney allowed Barbara to execute admissions forms, including arbitration agreements, for her mother. Citing its decision in Garrison v. Superior Court, 132 Cal.App.4th 253 (2005), as controlling precedent, the appeals court noted that the healthcare power of attorney gave Barbara the authority to “make health care decisions” for her mother. In Garrison, the court held under similar facts that the arbitration agreements a plaintiff executed were enforceable because they were part of the healthcare decision-making process for which the plaintiff was authorized to act. Agreeing with this analysis, the appeals court here added that Cal. Health and Safety Code §§ 1599.60 et seq. sets forth the specific contract requirements for long term care admission agreements, including arbitration. Thus, the appeals court said, it follows that a healthcare power of attorney may be faced with the decision to sign an arbitration agreement as part of the admissions contracts package at a nursing home. Hogan v. Country Villa Health Servs., No. G036406 (Cal. Ct. App. Mar. 1, 2007).

California Appeals Court Finds Arbitration Provision In Plan Subscriber Agreement Unenforceable
The arbitration provision in a health plan’s subscriber agreement failed to comply with the requirements set forth in California’s Knox-Keene Health Care Services Plan Act of 1975 and therefore was unenforceable, a California appeals court ruled March 1, 2007. The California Court of Appeal, Fourth District, affirmed a lower court’s order denying the health insurance company’s petition to compel arbitration of the lawsuit brought against it by subscribers accusing the company of breaching their contract and engaging in bad faith insurance practices. The subscribers, George and Shirley Ogle, sued PacifiCare Life and Health Insurance Company and PacifiCare of California (collectively, PacifiCare) in state trial court, seeking damages and declaratory relief. PacifiCare petitioned to compel arbitration, relying on two separate documents: the
enrollment form signed by the Ogles in 2003, and the 2003 subscriber agreement booklet the Ogles received in the mail.

The enrollment form contained an arbitration provision printed in all capital letters and appearing just before the signature line, in accord with the disclosure requirements set out in the Knox-Keene Act. However, the enrollment form also stated that it was an application, not a contract. The subscriber booklet consisted of thirty-seven small-print pages, with an unnumbered arbitration provision appearing in the introductory “General Provisions” section. This provision did not explain the costs of arbitration, the location of the arbitration, or set forth the procedures to be utilized, according to the trial court. In refusing to compel arbitration, the trial court concluded that the arbitration provision in the enrollment form was irrelevant, because the form was not a contract, and the subscriber agreement did not comply with the Knox-Keene Act, which requires plans using arbitration to settle disputes to have contracts that “set forth the type of disputes subject to arbitration, the process to be utilized, and how it is to be initiated.” The appeals court affirmed. Ogle v. PacifiCare, No. G037319 (Cal. Ct. App. Mar. 1, 2007).

**California Appeals Court Refuses To Compel Arbitration Where Spouse Signed Nursing Home Arbitration Agreement**

A California appeals court affirmed March 13, 2007 a lower court’s denial of a skilled nursing facility’s motion to compel arbitration of a negligence action where a husband signed the admission agreement for his wife, finding the spousal relationship alone is insufficient to confer authority to agree to an arbitration provision in a nursing home admissions contract. In May 2004, Josephina Flores was admitted to Evergreen at San Diego, LLC’s skilled nursing facility. Her husband, Luis Flores, signed various admissions documents, which included two arbitration agreements. At the time he signed the documents, Luis did not have a power of attorney to act for Josephina, nor had he been declared her conservator or guardian.

Josephina and Luis later sued Evergreen, alleging negligence and several other causes of action in connection with a fall Josephina took that resulted in a leg fracture. Evergreen petitioned to compel arbitration. The trial court denied the petition. Evergreen appealed. Affirming, the California Court of Appeal, Fourth District, noted that while an agency relationship can arise, even in the absence of a written agency authorization, by oral consent or by implication from the conduct of the parties, Evergreen presented no evidence that this was the case here. The mere fact that Luis signed the admissions agreement was insufficient to show agency without evidence of Josephina’s conduct at the time of admission, the appeals court said. “Although we agree that spouses are fiduciaries and owe a duty of support in the family law context, these duties do not create a power to contractually bind each other in the agency context,” the appeals court held.

The appeals court next addressed Evergreen’s contention that Luis' authority to admit Josephina to the nursing facility and to make medical decisions for her gave him the authority to agree to arbitration on her behalf. This argument, the appeals court said, hinges on “whether, independent of agency principles, there is a statutory basis for the authority to agree to arbitration based solely on kinship.” Finding no such statutory basis,
the appeals court said, “[a]lthough the Legislature has specifically conveyed authority
over medical decision making and enforcement of rights to family members, it has not
conveyed authority over the arbitration decision to family members.” After reviewing
relevant statutes, the appeals court found it could not “conclude the Legislature intended
to include the arbitration decision as among the matters that may be decided by next of
kin when signing a nursing home admission contract.” *Flores v. Evergreen at San Diego,

**Massachusetts High Court Requires Son To Arbitrate Dispute Against Nursing
Home Where Father Died**
A son was bound by the valid arbitration agreement he signed on behalf of his father
during the admissions process at a nursing home, the Massachusetts high court held
recently. Reversing a lower court decision, the high court found judicial economy was
not a sufficient reason to refuse to compel arbitration of a valid agreement, even if
plaintiff would have to proceed in different forums against the defendants named in his
lawsuit.

Plaintiff Charles Miller, Jr. signed an arbitration agreement on behalf of his father as part
of the admission’s process at Birchwood Care Center (Birchwood). Plaintiff had a
durable power of attorney and a valid healthcare proxy for his father. The admissions
agreement included a separate document, which plaintiff signed, requiring binding
arbitration of disputes. Plaintiff’s father died while a patient at Birchwood. Plaintiff sued
physician Eric Cotter who attended his father at the nursing home, Birchwood, and three
Birchwood employees, alleging negligence and wrongful death. Birchwood moved to
dismiss the complaint and compel arbitration. Cotter was not a Birchwood employee or a
party to the arbitration agreement so he did not join in the motion. The trial court denied
Birchwood’s motion, saying it would be “inequitable” and “inefficient” to require
arbitration of only some of plaintiff’s claims.

The Massachusetts Supreme Judicial Court reversed. The high court noted the
Massachusetts Arbitration Act favors arbitration, except where fraud, duress, or
unconscionability is involved. The high court also said the similarly worded Federal
Arbitration Act (FAA) applied because the arbitration agreement involved interstate
commerce—i.e. the hospital purchased out-of-state medicine and accepted Medicare
payments. The high court found no evidence that the arbitration agreement at issue was
procedurally or substantively unconscionable, and rejected “judicial economy”—i.e. that
plaintiff would have to proceed in different forums against Cotter (court) and Birchwood
(arbitration proceedings)—as an inadequate ground for setting aside an otherwise valid

**Florida Appeals Court Reverses Order Compelling Arbitration Of Nursing Home
Dispute**
A Florida appeals court held March 30, 2007 that an arbitration agreement was void as
against public policy and therefore a lower court erred in compelling arbitration of a
nursing home dispute. Tamera Fletcher, in her capacity as the personal representative of
Betty Nickless’ estate, appealed a trial court order compelling arbitration of her claim
against Huntington Place Limited Partnership, d/b/a Huntington Place Rehabilitation and Nursing Center (Huntington). The Florida District Court of Appeal, Fifth District, reversed, citing its decision in *SA-PG-Ocala, LLC v. Stokes*, 935 So. 2d 1242 (Fla. Dist. Ct. App. 2006), as controlling. In *Stokes*, the court found an arbitration provision void as against public policy because it contained certain provisions in the Alternative Dispute Resolution Service Rules of Procedure for Arbitration of the American Health Lawyers Association that “had the effect of superseding or dismantling the protections afforded patients by the legislature in the Nursing Home Resident’s Act.”

The appeals court said the contractual language here was very similar to that at issue in *Stokes* and declined Huntington’s urgings to deviate from that holding. Huntington also argued the admissions agreement had a severability clause that allowed the court to sever the language requiring that the arbitration be “administered by the American Health Lawyers Association,” thereby salvaging the rest of the agreement. “Based on our analysis of the agreement, however, it appears clear that the arbitration agreement reflects an intent that the parties arbitrate specifically with the AHLA,” the appeals court found. The appeals court added that a nursing home should be expected “to proffer form contracts that fully comply with [the Nursing Home Resident’s Act], not to revise them when they are challenged to make them compliant. Otherwise nursing homes have no incentive to proffer a fair agreement.” The appeals court also found the way the arbitration agreement was executed precluded its enforcement. Specifically, the appeals court noted that Fletcher did not sign the admissions agreement in her capacity as her mother’s representative; but rather, signed only after the provision providing for financial notices to the person who controls funds or assets that could be used to pay the resident’s charges. *Fletcher v. Huntington Place Ltd. Partnership*, No. 5D06-580 (Fla. Dist. Ct. App. Mar. 30, 2007).

**CORPORATE GOVERNANCE**

**GAO Releases Survey Results On Executive Compensation**

On July 28, 2006, the Government Accountability Office (GAO) released the results of the survey it undertook on executive compensation policies and practices at nonprofit hospital systems. In January of 2006, the GAO, at the request of then Chairman Bill Thomas (R-CA) of the House Ways and Means Committee, sent questionnaires to 100 selected nonprofit hospital systems to review certain executive compensation issues and to gain an understanding of the policies and practices related to the salaries, benefits, travel, gifts, and entertainment expenses paid by these hospital systems.

The GAO said it received responses from 65 of the 100 nonprofit hospital systems notified. The survey results indicated that these hospital systems reported many similarities in certain governance and compensation policies and practices. Many of the hospital systems indicated having an executive compensation committee or entire board with primary responsibility for approving executives' base salary, bonuses, and perquisites, in addition to a conflict of interest policy that covers members of the executive compensation committee and compensation consultants. It was also common among the respondents to rely upon comparable market data of total compensation and
benefits prior to making compensation determinations. A range of practices, however, was noted with respect to perquisites and entertainment and travel expenses for the hospital systems' executives and the related internal controls for these payments.

CRIMINAL LAW

Seventh Circuit Says Dentist May Not Withdraw Guilty Plea To Medicaid Fraud
A dentist was not entitled to withdraw his guilty plea to Medicaid fraud based on his assertion that he was coerced into making the deal, the Seventh Circuit ruled July 19, 2006. The appeals court concluded that the dentist could not show the “package deal”—in which the government agreed to dismiss charges against his wife in exchange for his guilty plea—resulted from duress. Bryan Spilmon, a dentist, pleaded guilty to defrauding Medicaid by submitting claims for work that he had not performed, billing for unnecessary procedures, and concealing overpayments. As part of the plea agreement, the government dismissed charges against his wife. Spilmon subsequently moved to withdraw his plea, but the district court judge refused and instead sentenced him to a fifty-seven-month prison term (per the plea agreement) and ordered him to pay over $2.4 million in restitution. On appeal, the Seventh Circuit rejected Spilmon’s argument that the plea was coerced and that he only admitted his guilty so his wife could avoid charges. United States v. Spilmon, No. 05-3750 (7th Cir. July 19, 2006).

Fifth Circuit Affirms Fraud Convictions Of Home Health Agency Owners, But Vacates Their Sentences
The Fifth Circuit upheld June 12, 2006 a jury’s conviction of a married couple who owned a home healthcare agency and another individual for conspiracy to commit Medicare fraud, but reversed the three defendants’ sentences, finding the trial court failed to follow the guidance set forth in United States v. Booker, 543 U.S. 220 (2005). Hames and his wife, Lesa Hames, an attorney, owned and operated Alternate Nursing Care (ANC), a Medicare-funded home healthcare agency. According to the federal government, the Hameses, in 1996, discovered that their reportable expenses were $600,000 less than what they had already received through estimated advances. Instead of repaying this amount, however, the couple padded their expenses to keep the money. The government alleged that the Hameses and a family friend, James Michael Davis, operated various schemes until 1998, when auditors discovered and disallowed the fraudulent expenses. The government eventually found that between 1996 and 1998 Medicare overpaid the Hameses and Davis $2.2 million, of which Davis received approximately $500,000.

A jury found the Hameses and Davis guilty on all counts charged. The U.S. District Court for the Northern District of Texas sentenced Lesa Hames to 102 months imprisonment and Pete Hames and Davis to seventy months imprisonment each. The court also ordered Lesa Hames and Davis to serve three years of supervised release. In addition, the court ordered the Hameses and Davis to pay, jointly and severally, $2,885,020 in restitution. According to the Hameses, their sentences violated the Sixth Amendment because they were based in part on facts that were neither admitted by them nor found beyond a
reasonable doubt by the jury. In addition, contrary to Booker, the trial court sentenced them pursuant to a mandatory application of the United States Sentencing Guidelines.

Although the defendants were all sentenced pre-Booker, the government conceded that they preserved their Booker objections at the trial court level by citing the previous Supreme Court case, Blakely v. Washington, 542 U.S. 296 (2004). Therefore, because the government could not demonstrate that the Booker error was harmless, the sentences must be vacated and the case remanded for resentencing, the Fifth Circuit held. United States v. Hames, No. 05-10045 (5th Cir. June 12, 2006).

First Circuit Vacates Three-Month Prison Sentence For Executive Convicted Of Conspiring To Defraud Medicare Of Over $5 Million

A federal district court’s decision to impose only a three-month prison term for an executive at a clinical laboratory testing company who was convicted of conspiring to defraud Medicare of over $5 million was too lenient and therefore must be vacated, the First Circuit held. The appeals court remanded the case to the district court for resentencing, cautioning that a sentence of fewer than thirty-six months’ imprisonment for a fraud offense carrying a statutory maximum penalty of sixty months’ imprisonment would fail a reasonableness review.

William Thurston was indicted in 1988 for conspiring to commit Medicare fraud. As an executive at Damon Clinical Laboratories (Damon), Thurston conspired with others to induce physicians to order “rarely needed” laboratory tests for Medicare beneficiaries by making them part of a “battery of frequently ordered tests” and then falsely informing physicians that these tests did not cost extra. The government offered plea agreements to each of the defendants. Joseph Isola, Damon’s president, accepted the government’s offer, and was sentenced to a three-year term of probation but Thurston declined and was convicted by a jury. At the sentencing hearing, the trial judge acknowledged the sentencing guidelines called for a sentencing range of sixty-three to seventy-eight months’ imprisonment, and that the applicable statute’s maximum penalty was sixty-months’ imprisonment. Nonetheless, the judge sentenced Thornton to three months’ imprisonment and twenty-four months’ supervised release, finding a sixty-month sentence would result in an “untoward disparity” between Thurston’s sentence and the probationary sentence imposed on Isola.

The First Circuit affirmed Thurston’s conviction, but remanded for resentencing, concluding that Thornton should have been sentenced to sixty months' imprisonment under the mandatory sentencing guidelines. After granting Thurston’s writ of certiorari petition, the U.S. Supreme Court subsequently vacated the First Circuit’s decision, and remanded to that court for further consideration in light of its recent decision in United States v. Booker, 543 U.S. 220 (2005), which replaced the mandatory sentencing guideline regime with an advisory system. The First Circuit then remanded back to the district court to determine whether any enhancements should be applied to Thurston’s sentencing guideline range. The district court, under a different judge, imposed essentially the same three-month prison sentence on Thurston.
Although evaluating the record in light of the *Booker* decision, the First Circuit still concluded that the district court had erred by imposing an excessively lenient sentence on Thurston. The district court’s reasoning placed too much emphasis on the disparities in sentencing Isola and Thurston, without giving adequate consideration to a key rationale underlying the sentencing guidelines—to encourage “nationwide uniformity in sentencing,” the appeals court concluded. Moreover, Isola and Thurston “were not so similarly situated that nearly identical sentences were warranted,” the First Circuit reasoned. “Thurston’s decision to go to trial entailed the risk of a stiffer post-conviction punishment . . . [and upon electing] . . . to go to trial, he was no longer situated similarly to Isola,” the appeals court explained. The First Circuit also rejected the lower court’s conclusion that the plea bargain offered to the defendants by the government was “evidence that even a probationary sentence would adequately reflect the seriousness of the offense” at issue. When sentencing Thurston, the government’s lenient pretrial plea bargain did not diminish the sentencing court’s obligation to independently consider the sentencing factors outlined in 18 U.S.C. § 3553(a), including the seriousness of the offense. *United States v. Thurston*, No. 05-2271 (1st Cir. July 26, 2006).

**Fourth Circuit Vacates Physician’s Drug Trafficking Conviction Citing Improper Jury Instruction**

A district court erred in instructing a jury not to consider a physician’s good faith in prescribing large quantities of pain medication to patients and therefore his conviction for drug trafficking must be vacated and the case remanded for a new trial, the Fourth Circuit held August 22, 2006. The appeal arose after a jury convicted physician William E. Hurwitz of multiple counts of drug trafficking for prescribing high doses of prescription pain medication to patients. The district court sentenced him to twenty-five years in prison.

The government presented evidence at trial that Hurwitz “was little more than a common drug dealer” operating out of a medical office. At the same time, Hurwitz and his witnesses argued that “the high-dose protocol was a proper medical procedure for treating patients with intractable pain,” the opinion noted.

The Fourth Circuit found the district court incorrectly concluded that a “good faith” instruction was not relevant to the charges that Hurwitz violated the Controlled Substances Act (CSA), 21 U.S.C.A. § 841(a)(1), by engaging in drug trafficking. According to the appeals court, the good faith issue was relevant to the jury’s determination of whether Hurwitz violated the CSA by acting outside the bounds of accepted medical practice or without a legitimate medical purpose when he prescribed narcotics to his patients. The appeals court rejected, however, the good faith instruction Hurwitz offered at trial, which defined “good faith” subjectively—i.e. whether the “doctor acted according to what he believed to be proper medical practice.” The appropriate standard when prosecuting a physician under § 841, as found by other courts considering the issue, is an objective one, said the appeals court. Thus, the district court properly rejected Hurwitz’s good faith instruction, but at the same time it erred by affirmatively informing the jury that good faith was relevant only to the healthcare fraud charges, the appeals court held. *United States v. Hurwitz*, No. 05-4474 (4th Cir. Aug. 22, 2006).
Eleventh Circuit Vacates Sentences Imposed On Consultant And Home Health Agencies For Conspiring To Submit False Claims To Medicare
The Eleventh Circuit vacated September 5, 2006 sentences imposed on an individual healthcare consultant and two home healthcare agencies (HHAs) convicted of conspiracy to submit false claims and cost reports to Medicare, finding they were based on “clearly erroneous” determinations that the criminal activity was not extensive and that no loss resulted from the conspiracy. In September 1997, the consultant, Mahendra Pratap Gupta, along with his healthcare consulting company, Allegheny Management Company (Allegheny), and HHAs controlled by Gupta, were indicted for their involvement in a scheme to defraud Medicare based on violations of the “related party” regulation, 42 U.S.C § 413.17. The government alleged that Gupta created Allegheny and put a figurehead owner in place for the purpose of charging the HHAs he controlled with consulting fees and then collecting additional reimbursable costs from the Medicare program which, in turn, increased the reimbursable costs of the HHAs so that they were closer to Medicare’s “cost caps.”

The Eleventh Circuit affirmed Gupta's and the HHAs' convictions, concluding that the HHAs conspired to submit false costs reports to Medicare in violation of 18 U.S.C. § 286 by failing to disclose in their costs reports that Gupta was providing consulting services as a related party. The appeals court also found sufficient evidence that the HHAs, Allegheny, and Gupta conspired “to conceal their relationship” by using “dummy employment contracts, false and misleading corporate minutes, straw owners, forged contracts, backdated correspondence, and false invoices that were cosmetically altered to make them look older.”

The Eleventh Circuit agreed with the government’s argument that it was “clear error” for the lower court not to make a finding that Gupta’s criminal activity was extensive, as required to impose a Sentencing Guidelines enhancement. “The record shows extensive [and complex] criminal activity, involving seven corporations, numerous straw owners, Medicare reimbursements of over $15 million, and repeated failure to disclose related party status of a seven-year period,” the appeals court said. The appeals court also agreed with the government’s argument that the lower court erred in concluding that no loss resulted from the conspiracy between Gupta, Allegheny, and the HHAs because the reimbursement amounts did not exceed Medicare “cost caps.” Instead, the appeals court reasoned that the appropriate measure of damages in this case is the amount the government paid in response to the false claims submitted by defendants, which should have been taken into account in calculating loss. United States v. Gupta, No. 04-16091 (11th Cir. Sept. 5, 2006).

Eleventh Circuit Finds Sufficient Evidence To Support Florida Physician’s Convictions For Conspiracy And Healthcare Fraud
The evidence presented against a Florida physician convicted of conspiracy and healthcare fraud was sufficient to support his convictions, the Eleventh Circuit held November 27, 2006. The appeals court affirmed a jury’s conviction of the physician for one count of conspiracy to defraud the United States and eight counts of healthcare fraud,
and the subsequent thirty-nine-month prison sentence imposed on the physician by the U.S. District Court for the Southern District of Florida. The jury concluded that the physician, Jose Humberto Forcada, participated in a scheme to defraud Medicare by claiming reimbursement for costly intravenous infusion drug treatment allegedly administered to patients at two Miami Beach HIV clinics. The drugs, Neupogen and Procrit, were diluted with saline and then administered to patients who did not need the drugs in the first place.

The appeals court noted that “Forcada, an experienced physician who had previously worked in HIV clinics, demonstrated his awareness of the conspiracy on numerous occasions, but nonetheless continued to participate in and benefit from it.” The appeals court also said that establishing intent through circumstantial evidence was permissible, “so long as there is enough evidence from which a jury could reasonably infer that the defendant acted with the specific intent to defraud.” United States v. Forcada, No. 05-14448 (11th Cir. Nov. 27, 2006).

DOJ Revises Thompson Memorandum On Privilege Waiver, Advancement Of Legal Fees
The Department of Justice (DOJ) is placing new restrictions on federal prosecutors that seek privileged information from companies under corporate charging guidelines. The announcement, made by U.S. Deputy Attorney General Paul J. McNulty December 12, 2006 involves the Thompson Memorandum, which outlines nine factors for DOJ prosecutors to consider in deciding whether to bring criminal charges against a company. One of the factors cites the “timely and voluntary disclosure of wrongdoing and [the corporation's] willingness to cooperate in the investigation . . . including, if necessary, the waiver of corporate attorney-client and work product protection.” The Department’s stance on privilege waiver in the Thompson Memorandum, which was issued in 2003 by then Deputy Attorney General Larry D. Thompson, has raised the ire of the defense bar and other attorneys who argue the policy poses ethical concerns.

Under the revisions, federal prosecutors must comply with new approval requirements before asking companies to waive their attorney-client privilege or work product protections. The new guidance also cautions that prosecutors should not consider a corporation’s refusal to provide attorney-client communications against it in their charging decisions. At the same time, the new guidance provides that prosecutors “may always favorably consider a corporation’s acquiescence to the government’s waiver request in determining whether a corporation has cooperated in the government’s investigation.” This language has prompted some commentators to question whether the new guidance in practice will still result in many organizations waiving their privileges in exchange for cooperation credit. In addition, the new guidance instructs prosecutors not to consider a corporation’s advancement of attorneys’ fees to employees when making a charging decision, except in the rare instance where the circumstances show it was intended to impede the government's investigation.

Seventh Circuit Affirms Psychologist’s Conviction For Medicaid Fraud
The Seventh Circuit affirmed September 7, 2006 the conviction of a psychologist who a jury found guilty of defrauding the Indiana Medicaid program. Thomas Davis is a psychologist licensed in Indiana as a “health service provider in psychology” (HSPP) and enrolled as a provider under the state’s Medicaid program. According to the indictment against Davis, by September 2002 he accounted for more Medicaid spending in the state than any other individual HSPP. A jury found Davis guilty on one count of healthcare fraud in connection with three alleged schemes: billing for services actually provided by others, known as “substitute-billing”; overbilling for hours of work not actually performed; and miscoding procedures to avoid pre-authorization requirements. At trial, Davis contended that he lacked a specific intent to defraud because he believed that all three practices were legal.

Affirming the conviction, the Seventh Circuit concluded that substitute-billing is illegal under Indiana’s Medicaid regulations, which state that “Medicaid reimbursement is available for mental health services provided by psychologists endorsed as a [HSPP].” Davis argued that even though certain psychological tests were administered by other people, he still “provided” the services because he paid the rent and utilities at his clinics, trained the staff, and acquired the necessary licenses. Noting the issue was one of first impression, the Seventh Circuit found the plain meaning of the word “provided” as used in the regulations required the HSPP to be the person actually performing the test in order to bill Medicaid. Finally, the appeals court held the indictment was not impermissibly duplicitous because it alleged “an ongoing and continuous course of conduct” over a “discrete period of time.” United States v. Davis, No. 05-3481 (7th Cir. Dec. 15, 2006).

Third Circuit Vacates Healthcare Fraud Conviction, Finding Clinic Employee Made No Misrepresentations
The Third Circuit found that an employee of a healthcare provider who committed theft should not have been charged under the federal healthcare fraud statute because the employee’s actions did not meet the statute’s misrepresentation requirement. Aimee Jones worked at a methadone clinic operated by Progressive Medical Specialists, Inc. The clinic did not accept insurance and patients generally paid cash for services. A clinic project director discovered a $451,000 discrepancy between the amount received from patients and the amount of money deposited into the clinic’s bank account over a four-year time period. Further investigation implicated Jones and she was indicted and found guilty on one count of healthcare fraud in violation of 18 U.S.C. § 1347(2). Jones was sentenced to twenty-four months in prison. The district court also ordered restitution to Progressive of $240,076.33, and ordered forfeiture of $199,716.25 and a Honda motorcycle. Jones appealed, arguing that the government did not establish the elements of healthcare fraud under § 1347(2).

The Third Circuit agreed and reversed Jones’ conviction. According to the appeals court, the plain language of the statute prohibits healthcare fraud by knowingly or willfully using “false or fraudulent pretenses, representations, or promises” to obtain the money or property of a healthcare benefit program in connection with the delivery of, or payment for, healthcare benefits, items, or services. See 18 U.S.C. § 1347(2). The government did not meet all of these required elements, the appeals court said, because it did not establish
any type of misrepresentation by Jones in connection with the delivery of, or payment for, healthcare benefits, items, or services. “[I]t cannot be the case that Congress intended § 1347 to be interpreted so broadly as to convert an instance of simple theft into health care fraud merely because the theft was perpetrated by an employee of a health care benefit program.” Thus, the court reversed Jones’ conviction and vacated her sentence. United States v. Jones, No. 05-4898 (3d Cir. Dec. 28, 2007).

Fifth Circuit Vacates Sentencing And Restitution Orders For Two Healthcare Executives Convicted Of Medicare Fraud
The Fifth Circuit vacated January 16, 2007 the sentencing and restitution orders for two healthcare company executives convicted of Medicare fraud based on its conclusion that the U.S. government had submitted insufficient evidence of actual loss to Medicare. One of the executives in the case, Jedd Jones, was a principal of Health One Management, Inc. (Health One), a healthcare management company. After incorporating Health One, Jones served as the company’s secretary-treasurer, while the other executive, William Clark, served as the company’s president and part owner.

For Medicare purposes, Health One was “related to” Riverbend Rehabilitation Hospital (Riverbend) in Covington, Louisiana, through common ownership and control. Riverbend paid fees to Health One pursuant to a full-service management contract, and Jones and Clark pursuant to a management and consulting agreement. Under Medicare regulations, 42 C.F.R. § 413.17(c), healthcare providers must disclose the goods and services purchased from a “related party” because reimbursements are limited to the provider’s actual cost or the cost of similar providers on the open market, whichever is the lesser amount, for related organizations. Jones and Clark failed to do this on the cost report they submitted to the Medicare fiscal intermediary.

Jones and Clark each pled guilty to one count of Medicare fraud, but objected to the pre-sentence report on the question of whether Medicare suffered a loss as a result of their offense. The report listed the full amount of Medicare’s reimbursements to Riverbend for payment to Health One, as well as payments to Jones and Clark, individually. The district court nonetheless accepted the pre-sentence report as evidence regarding the actual costs incurred by Riverbend, and then used this amount to calculate the amount of loss to Medicare. Based on this calculation, the district court added enhancements to the sentences imposed on both Jones and Clark. Both were sentenced to prison time as well as ordered to pay jointly nearly $1.5 million in restitution; Clark was ordered to individually pay additional restitution of more than $1.2 million.

The Fifth Circuit concluded that Jones and Clark “should not be liable for the entire amount of Medicare reimbursements because Medicare would have paid Health One’s actual costs notwithstanding disclosure of the relationship between Health One and Riverbend.” Moreover, the government failed to present evidence showing either the differential between Medicare’s reimbursements and Health One’s actual costs or the reasonable value of Health One’s services. While the pre-sentence report “usually provides sufficiently reliable evidence for the district court’s consideration,” such is not the case on the present facts, the Fifth Circuit concluded.
As to the reasonable value of Health One’s services, the Fifth Circuit noted that the only evidence the government provided on this issue was the salary ($178,000) of the chief operating officer (COO) at another hospital. The district court erred in relying solely on this evidence to arrive at a valuation of $150,000 a year for all of the services provided by Health One, Jones, and Clark to Riverbend, the appeals court concluded. “Nothing in the record, neither the district court opinion nor the government witnesses’ testimony, establishes that the St. Francis COO position was comparable to the work performed by Clark, Jones, and Health One, collectively,” the appeals court said. The appeals court remanded the cases to the district court for resentencing, emphasizing that Jones and Clark should not receive any enhancement from the base offense level and restitution order. *United States v. Jones*, No. 05-30942 (5th Cir. Jan. 16, 2007).

**Fifth Circuit Vacates Restitution Order In Medicare Fraud Case Citing Loss Calculation Error**

In sentencing the owner and operator of two home health agencies (HHAs) for Medicare fraud, a federal district court erred in calculating the loss to Medicare because it failed to credit over $643,000 in pension plan benefits the HHAs funded long before the fraud was detected, the Fifth Circuit ruled February 13, 2007. The appeals court affirmed the defendant’s sentence in part, but remanded the case for resentencing with regard to restitution. The defendant in the case, Howard Douglas Austin, and his wife, owned and operated two HHAs—one in Lafayette, and the other in Baton Rouge (Louisiana)—which provided services to Medicare beneficiaries. Austin pled guilty to filing cost reports on behalf of the HHAs in 1997 and 1998 that included improper expenses and misrepresented actual costs. By Austin’s sentencing date, however, $1.5 million of the approximately $1.7 million in overpayments claimed by Medicare already had been recouped by Medicare. In addition, the balance due was secured by Austin’s own personal assets worth more than the amount owed.

Under the circumstances, Austin asked the district court to reduce his sentence based on the repayments and assets pledged. He argued that regardless of whether the court applied the 2004 Sentencing Guidelines (which were in effect at sentencing) or the 1998 Guidelines (in effect when the offense occurred), the repayments and pledged assets should reduce the amount of loss. In addition, Austin argued that the amount of loss must be reduced by $643,388 in pension plan benefits that the HHAs funded well before the fraud was detected. The U.S. District Court for the Middle District of Louisiana rejected these arguments, and determined a loss to Medicare totaling over $2 million, basing its calculation on the improper and untimely costs reported. Applying the 1998 Guidelines, the district court sentenced Austin to twenty-seven months’ imprisonment, restitution equal to Medicare’s loss “with credit for any payments previously made,” a fine of $50,000, and an assessment of $100.

On appeal, Austin reiterated arguments he made before the district court, including that the commentary in the 2004 Guidelines regarding credits against loss (§ 2B1.1, note 3(E)) lacked an explicit time by which the collateral must be provided in order to be factored into a loss calculation. Therefore, according to Austin, collateral provided any
time before sentencing, “even on the eve thereof,” reduces the loss. In rejecting that argument, the Fifth Circuit said that allowing a loss reduction via the pledge of collateral after discovery of the offense “would alter the long-standing, well-recognized rule that post-detection repayments or pledges of collateral do not reduce the loss.” The appeals court explained that “[s]uch payments are considered at sentencing, but with regard to restitution and acceptance-of-responsibility reductions.” The Fifth Circuit also rejected Austin’s argument that he should receive credit towards the loss calculation for the assets personally pledged. “Austin fails to explain why he did not repay or arrange to pledge assets to satisfy the amount owed to Medicare,” instead of causing the HHAs to initiate bankruptcy proceedings and then later pledging assets as part of that process, the appeals court said. As for Austin’s argument that he should receive credit towards the loss calculation for the amount repaid by “withholds” from Medicare, the appeals court emphasized that these repayments were post-detection of Austin’s fraud.

The Fifth Circuit next turned to the lower court’s failure to give credit in the loss calculation to $643,388 in pension plan benefits actually funded by the HHAs before Austin’s fraud was detected. “The failure to recognize this credit during the sentencing proceedings resulted in a total offense level of 17 rather than 16 and restitution in the amount of $2,020,653.60 rather than $1,377,265.60,” the appeals court explained. Although acknowledging that the restitution order stated that Austin pay "$2,020,653.60 less any payments,” the appeals court determined that the "less any payments" language was ambiguous and did not cure the error in ordering restitution in an amount greater than the loss. United States v. Austin, 05-30602 (5th Cir. Feb. 13, 2007).

Fifth Circuit Vacates Sentence For Healthcare Fraud Imposed On Owner Of Physical Therapy Clinics

The Fifth Circuit partially reversed the healthcare fraud conviction of a former owner of a number of physical therapy clinics located in Houston, Texas, and therefore vacated the owner’s sentence and remanded for resentencing. The appeals court affirmed the conviction and sentence of Clemis Laraine Jackson, a physician who managed one of the physical therapy clinics. Although the appeals court also affirmed the conviction of Wesley Alford Boyd Jr. for conspiracy and payment of illegal kickbacks, it ultimately concluded that the government had failed to present sufficient evidence to convict Boyd for healthcare fraud.

According to the government’s allegations, the physical therapy clinics at issue knowingly engaged in a scheme to fraudulently bill Medicare and Medicaid. At one clinic where Boyd served as a consultant, the owners followed Boyd’s recommendations to hire individuals to recruit Medicare and Medicaid patients to the clinic; these “marketers” targeted areas with a high concentration of elderly residents, and were paid $100 to $300 for each patient referral. Jackson, who was the physician at this particular clinic, intentionally misdiagnosed patients in order to receive maximum payments from Medicare and Medicaid, the government alleged. The clinic also billed these programs for services that were never performed. In addition, under Boyd’s management, the clinic allegedly ignored requirements pertaining to direct physician supervision under Medicare and Medicaid laws by billing these programs for therapy performed while Jackson was
not at the clinic. After this clinic closed, Boyd opened with co-owners two other physical therapy clinics, each of which employed “marketers” who were paid to recruit patients, and engaged in other fraudulent activities, the government contended.

A grand jury indicted Boyd and Jackson, along with several other individuals, on charges of violating the federal False Claims Act (FCA) by conspiring to pay kickbacks, committing healthcare fraud, and money laundering. The jury convicted Boyd and Jackson on all of the charges specified against them in the indictment, and the district court sentenced them in accordance with the federal Sentencing Guidelines.

The Fifth Circuit agreed, concluding that a “rational jury could not have found that the government proved every element [of the healthcare fraud count] beyond a reasonable doubt.” Because “the government wholly failed to present evidence that Boyd engaged in a scheme to defraud Medicare by submitting claims for services that were never performed,” the appeals court said, “the jury’s verdict on cannot stand, and we reverse Boyd’s conviction for health care fraud.” The appeals court rejected, however, Boyd’s attempt to challenge his conviction for conspiring to pay illegal kickbacks based on his assertion that the government lacked sufficient evidence to show that two checks he wrote to one clinic employee were for patient referrals, and not for payroll. United States v. Jackson, No. 04-20600 (5th Cir. Mar. 2, 2007).

U.S. Court In Mississippi Refuses To Dismiss Healthcare Fraud Indictment Based On Trial Delays
The U.S. District Court for the Southern District of Mississippi refused March 5, 2007 to dismiss a healthcare fraud indictment based on defendant’s argument that a thirty-five month delay in the start of the trial violated his statutory and constitutional rights to a speedy trial. On March 17, 2004, defendant Wilson N. Ellis was indicted on one count of healthcare fraud and nine counts of false statements related to healthcare matters. According to the government, Ellis defrauded Medicare by inappropriately coding chelation therapy provided at his clinics in Mississippi, which would not have been paid by Medicare, as intravenous infusion treatment, causing Medicare to pay over $100,000. Defendant, who was arraigned on April 26, 2004, filed three continuances, all of which were granted. The indictment was later dismissed, without prejudice, on December 21, 2005. The government then re-indicted Ellis on November 20, 2006. Ellis moved to dismiss the second indictment, alleging violations of the Speedy Trial Act and the Sixth Amendment.

The Speedy Trial Act requires that a criminal defendant’s trial begin within seventy days, less excludable time, from the later of the filing of the indictment or the date of arraignment. The court found no violation of the Speedy Trial Act because the “ends of justice” were served by granting the requested continuances given the complexity of the case and the need for additional trial preparation. According to the court, excluding the time granted under the continuances and the time between indictments, the seventy-day “speedy trial clock” had not yet elapsed.
The court also found no violation of Ellis' constitutional right to a speedy trial under the Sixth Amendment, analyzing the case under the factors cited by the U.S. Supreme Court in *Barker v. Wingo*, 407 U.S. 514 (1972). The court acknowledged that the thirty-five month delay between the filing of the first indictment and the date for the scheduled trial was “presumptively prejudicial” and that at least part of the delay (between the filing of the first and second indictment) was attributable to the government. But, at the same time, the court noted that Ellis was responsible for twenty-one months of the total delay because of his continuance requests and the length of time between the date he was first indicted (March 17, 2004) and the date on which he first asserted his rights to a speedy trial (January 25, 2007) “cuts against finding prejudice.” Thus, the court concluded that defendant’s allegations did not “rise to the requisite level of actual and substantial prejudice necessary to support dismissal” of the second indictment. *United States v. Ellis*, No. 3:06cr199-WHB-LRA (S.D. Miss. Mar. 5, 2007).

**Seventh Circuit Says Sentence Imposed On Cardiologist Convicted Of Committing Medicare Fraud Was Too Light**

A federal district court judge erred in imposing a sentence of five years’ probation and issuing a restitution order of less than $1,500 on a Chicago-area cardiologist found to have committed Medicare fraud on a large scale, a federal appeals court ruled April 9, 2007. “[A]ny loss estimate lower than $1.4 million would be clear error inviting summary reversal . . . and most of the mitigating factors that persuaded the district judge to sentence below the applicable guidelines range were irrelevant and must not influence the sentence that he imposes on remand,” the Seventh Circuit said.

The cardiologist, Dr. Krishnaswami Sriram, billed Medicare approximately $17 million over a five-year period, according to the appeals court. After an investigation, Sriram pleaded guilty to healthcare fraud and tax fraud, admitting that he had received “substantial payments” for fraudulent claims (estimated at between $5 and $10 million in a presentence report) and had defrauded the government of more than $550,000 in income tax. Judge John W. Darrah of the U.S. District Court for the Northern District of Illinois ruled that the only loss the government had proven was the face amount ($1,258) of two checks that Sriram admitted having received for medical services he had not actually performed. However, in his plea agreement, Sriram had admitted to a host of fraudulent activities, including knowingly creating fraudulent records, billing insurers for tests and other procedures that were never performed, and receiving insurance payments for services allegedly rendered when he was not in the United States, as well as for services he did not perform. “[Sriram] did not admit in the plea agreement to a specific amount of loss that his frauds had inflicted on insurers, but it is inconceivable that the amount was as slight as the district judge thought,” the appeals court said. Judge Darrah sentenced Sriram for five years’ probation for both the healthcare fraud and the tax fraud (sentences to run concurrently) plus restitution of $1,258.

The appeals court acknowledged that the government’s expert witness committed some errors in attempting to add up the fraudulent payments that Sriram had received, and that, because of these errors, “the judge found himself unable to calculate the exact amount of the fraudulent payments.” Although the judge’s inability was genuine, it “did not justify
“[his] loss calculation,” the appeals court said. The appeals court found the evidence would have supported a finding that Sriram had caused a total loss of at least $5 million, making the judge’s $1,258 not just clearly erroneous but “incomprehensible.” According to the appeals court, the “district judge dipped far below even his erroneously calculated guidelines range to take account of what he considered to be mitigating factors,” such as the fact that the prosecution had been so protracted and had stigmatized Sriram and potentially caused him to lose his medical license. However, “probation was too light a sentence,” the appeals court determined, noting that these mitigating factors would justify only a “limited” reduction to a prison term or fine. United States v. Sriram, No. 05-2752 (7th Cir. Apr. 9, 2007).

EMPLOYMENT AND LABOR

Discrimination Actions

Eighth Circuit Says ADA Protects “Employees,” Not Physician Practicing At Hospital As Independent Contractor

A member of the hospital's medical staff could not bring claims under the Americans with Disabilities Act (ADA) or the Rehabilitation Act because he was an independent contractor and not an employee, the Eighth Circuit held June 9, 2006. Paul A Wojewski was a cardiothoracic surgeon who became a member of the medical staff at Rapid City Regional Hospital (RCRH), but leased separate office space, scheduled his time in the hospital’s operating room, and hired, maintained, and paid his own staff. Wojewski also billed his patients directly, and they remitted payment directly to him. As RCRH did not pay Wojewski for his services, it did not issue him a form W-2 or 1099 nor did it pay his social security taxes or provide him benefits such as health and malpractice insurance. Wojewski was diagnosed with bipolar disorder and took a leave of absence. RCRH later reinstated Wojewski to the active medical staff subject to certain conditions that were outlined in a Letter of Agreement. Citing patient safety concerns, RCRH eventually terminated Wojewski’s staff privileges.

Although Wojewski’s asserted the terms of his reinstatement to RCRH’s medical staff as outlined in the Letter of Agreement subjected him to “more control . . . than most doctors and perhaps rendered him the most controlled doctor in America,” this heightened control did not convert his relationship with the hospital into that of employer and employee, the Eighth Circuit concluded. The conditions RCRH placed on Wojewski constituted “reasonable steps to ensure patient safety and avoid professional liability while not attempting to control the manner in which . . . Wojewski performed operations,” the appeals court found. Wojewski v. Rapid City Reg'l Hosp. Inc., No. 05-2952 (8th Cir. June 9, 2006).

U.S. Court In California Finds Physician’s History Of Alcohol Dependency Does Not Constitute “Disability” Under ADA

A federal court in California dismissed August 31, 2006 a lawsuit brought by a physician who alleged a hospital unlawfully discriminated against him in denying his application for staff privileges because of his history of alcoholism. According to the court, the
physician failed to demonstrate that his condition constituted a disability under the Americans with Disabilities Act (ADA) or the Rehabilitation Act of 1973 (Rehabilitation Act). Dr. Ronald Roger Ward began working as a head and neck surgeon at Kaiser Foundation Hospital in San Francisco in 1979. He was appointed Chief of the Otolaryngology/Head and Neck Surgery for the hospital in 1992 and held this position until 1999.

In September 1997, Ward voluntarily asked for a leave of absence from KFH to seek alcohol dependency treatment. After his privileges were reinstated, Ward applied for privileges at another KFH facility. The credentialing committee at that facility denied Ward’s application, citing his past history of alcohol dependency and his participation in an extended alcohol rehabilitation program. This decision was later upheld at two separate appeal hearings, after which KFH filed an adverse action report on Ward with the National Practitioner Data Bank.

The U.S. District Court for the Northern District of California dismissed Ward’s action against KFH, finding he failed to state a claim that he was discriminated against based either on an actual disability or a perceived impairment under the ADA or the Rehabilitation Act. Ward neither alleged any facts nor produced any evidence to demonstrate that his alcohol dependency impaired a “major life activity,” the court noted. To the contrary, Ward specifically alleged that his alcohol dependency “never interfered with his medical practice and he did not use alcohol during working hours.” Moreover, Ward failed to allege that he was unable to work in a broad class of jobs; thus he could not maintain a claim that KFH perceived him as disabled when it denied him staff privileges at the other facility. *Ward v. Kaiser Found. Hosp.*, No. 3:06-cv-02645 (N.D. Cal. Aug. 31, 2006).

**Seventh Circuit Finds Non-Board Certified Surgeon Failed To Prove Racial Discrimination After His Application For Active Status Was Not Approved**

The Seventh Circuit found a non-board certified neurosurgeon failed to prove a prima facie case of racial discrimination after his application for active status was denied by a hospital that required all surgeons be board certified. Dr. Kamaljit S. Paul, an Asian-Indian man, had active staff membership at Theda Clark Medical Center until 2003. At that time, the hospital denied Paul’s application to maintain active status because, as a non-board-certified neurosurgeon, he could not provide trauma call coverage at Theda Clark’s Level II trauma center. Paul sued Theda Clark alleging race discrimination. Theda Clark moved for summary judgment, which the district court granted. Paul appealed.

The Seventh Circuit affirmed. The appeals court found Paul failed to prove the second prong of the burden-shifting analysis set forth in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802-05 (1973), because he did not establish that he was qualified for active staff membership at Theda Clark as a non-board certified surgeon. The appeals court also found that Paul failed to prove that Theda Clark treated other non-board certified surgeons who were not Asian-Indian differently, as required by the fourth prong of the *McDonnell Douglas* analysis. The appeals court went on to explain that, even if Paul had
been able to establish a prima facie case of discrimination, “there is not enough evidence of pretext in the record to survive summary judgment.” Paul v. Theda Clark Med. Ctr., Inc., No. 06-1034 (7th Cir. Oct. 13, 2006).

**Tenth Circuit Affirms Finding That Nursing Home Violated ADA By Firing Cook With Hepatitis C**
The Tenth Circuit found October 26, 2006 that the issue of whether a nursing home violated the Americans with Disabilities Act (ADA) by firing a cook who had hepatitis C was properly allowed to go to a jury. According to the appeals court, the evidence that the nursing home regarded the cook as disabled was sufficient for a jury to find an ADA violation. The appeals court also held that the lower court erred in dismissing the issue of punitive damages since there was some evidence that the nursing home knew its actions could violate the ADA. Janet Edwards, who has hepatitis C, was fired from her job at York Manor Nursing Center in Muskogee, Oklahoma where she worked as a cook. She was terminated several days after the nursing home discovered she had hepatitis C, although the stated reason for Edwards’ termination was her failure to disclose the disease on her job application. Following a trial, the jury awarded Edwards $20,000 in compensatory damages and recommended a $1,240 award of back pay, which the court granted.

The Tenth Circuit found a “legally sufficient evidentiary basis” for a reasonable jury to conclude that the Equal Employment Opportunity Commission (EEOC) had shown by the preponderance of evidence that Heartway treated Edwards’ hepatitis as “significantly restrict[ing]” her “ability to perform either a class of jobs or a broad range of jobs” as compared to similarly trained individuals. The appeals court found the evidence also was sufficient to support a jury’s conclusion that the administrator treated Edwards as limited in performing other jobs where there was a chance she could transmit the disease. In addition, the appeals court noted Edwards was regarded as restricted from a class of jobs—namely “health care support” and “food preparation and food serving” that presented the risk of cuts and contamination. Remanding on the issue of punitive damages, the appeals court agreed with the EEOC that there was evidence the administrator knew of the ADA requirements and that the jury should be allowed to decide whether it showed he acted with knowledge that his actions violated federal law. Equal Employment Opportunity Comm’n v. Heartway Corp., Nos. 05-7011, 05-7016 (10th Cir. Oct. 26, 2006).

**Employment Contract Disputes**

**Missouri Supreme Court Finds Home Healthcare Provider’s Noncompete Agreements Are Valid And Enforceable**
A home healthcare provider located in Joplin, Missouri can enforce noncompete agreements signed by two nurse managers who resigned and, within weeks, started working for a competing provider in the same area, the highest court in that state ruled August 8. The Missouri Supreme Court also found that the home healthcare provider seeking to enforce its noncompete agreements was entitled to damages for patients lost to a competitor. Healthcare Services of the Ozarks, Inc., doing business as Oxford
Healthcare (Oxford) in Joplin, Missouri, hired Pearl Walker Copeland and LuAnn Helms, requiring each of them to sign a noncompete agreement that barred them from competing with Oxford within a 100-mile radius of Joplin for two years after leaving the company. In addition, the agreement barred them from diverting from Oxford any business or employees during the two-year period. Just after Copeland and Helms had given their notice at Oxford, ASA Healthcare Inc., doing business as Integrity Home Care (Integrity) in Joplin, successfully obtained a social services block grant from the Missouri Division of Aging to provide the same type of services as Oxford in the same counties in which Oxford did business. In order to satisfy one of the regulatory requirements for being awarded this block grant, Integrity specified that it had a certified manager, naming Copeland and including a copy of her certificate of provider certification training.

The Missouri Supreme Court held the agreements were enforceable, finding that Oxford had established a protectable interest in its patient base. The high court emphasized the fact that Copeland and Helms were both in the position to exert significant influence over the employees they supervised, had access to the salary information of Oxford’s employees, and could use this information to “recruit Oxford’s employees to raid Oxford’s patients.” The high court said the fact that Oxford is a not-for-profit organization did not mean it lacked protectable business interests and had no effect on its ability to protect itself from unfair competition by way of non-compete agreements.

The high court also found Oxford should be awarded damages for Copeland’s breach of her noncompete agreement, reasoning that “[a]lthough the use of Copeland’s certificate is not, in a strict sense, a customer contact, it was an essential element to Integrity’s ability to enter the market and to compete with Oxford for its patients.” The high court did not believe, however, that Oxford was entitled to damages for the loss of employees. “Integrity was free to hire any of Oxford’s employees as it was forming its business and taking steps towards entering the home health market irrespective of Copeland’s employment or her certificate,” the high court said. Healthcare Servs. of the Ozarks, Inc. v. Copeland, No. SC87083 (Mo. Aug. 8, 2006).

Alabama Supreme Court Allows Physician To Pursue Breach Of Employment Contract Claim In Dispute Over Insurance Premiums

The Alabama Supreme Court ruled October 20, 2006 that a trial court erred by entering summary judgment in favor of a health system that refused to pay the rising insurance premiums of an employed obstetrician-gynecologist. Dr. Dwight Hooper, the obstetrician-gynecologist, entered into a three-year employment contract with Columbus Regional Healthcare System (Columbus). The contract required Columbus to provide Hooper with privileges at two hospitals and to pay his professional liability insurance premiums at the “standard rate.” Following a medical malpractice case against Hooper and Columbus, Hooper’s professional liability premiums went up from $15,000 to over $110,000. An insurance broker informed Hooper that the best rate for physicians in similar practices in the area was $36,500 per year. Hooper asked Columbus to pay $36,500 toward his premium in accordance with his employment contract.
Hooper later moved to another city. He returned about one month later to open his own practice, but Columbus withdrew Hooper’s hospital privileges on the grounds that he lacked insurance coverage and had abandoned his patients. Ultimately, Hooper agreed to resign his privileges voluntarily. Hooper sued Columbus for breach of contract, wanton and/or willful conduct, and civil conspiracy. The trial court ruled in favor of Columbus and Hooper appealed.

The high court examined the contract, which provided that if Hooper’s premium exceeded the standard rate, Columbus would pay “that sum which is the insurer’s standard premium rate for physicians in similar practices in Columbus, Georgia.” Because this language supported Hooper’s position, the trial court erred when it entered summary judgment for Columbus on the breach of contract claim, the high court concluded. In his next claim, Hooper argued that Columbus committed the tort of willful and/or wanton conduct by trying to blemish his record and prevent him from opening a medical practice when it withdrew his hospital privileges. The high court disagreed and ruled that Hooper failed to establish Columbus had a duty to refrain from causing him the alleged injury or damage, or that Columbus violated any duty owed to him. *Hooper v. Columbus Reg’l Healthcare Sys.*, No. 1031128 (Ala. Oct. 20, 2006).

**Florida Appeals Court Upholds Temporary Enforcement Of Non-Compete Clause Where Physician Opened Practice Four Blocks From Previous Location**

A Florida appeals court refused October 18, 2006 to remove a temporary injunction enforcing a non-compete clause against a physician who left a practice and opened his own a few blocks away. Palm Beach Cardiovascular Clinic (clinic) recruited Zbigniew-Jacob Litwinczuk, M.D. and bought an existing practice to provide him with a patient base. In his employment contract with the clinic, Litwinczuk agreed that if he should terminate his employment, he would not enter into any competing enterprise for two years. Citing on-call requirements and disagreements concerning billing and treatment issues, Litwinczuk resigned from the clinic’s practice and opened a practice of his own a short distance away. Evidence indicated that within the first two months of his new practice, Litwinczuk saw at least forty-nine of the clinic’s patients, and that he practiced in the same hospitals as the clinic. The clinic filed for a temporary and permanent injunction enforcing the non-compete clause. The trial court issued the temporary injunction, but reduced the applicable geographic area in proportion to the clinic’s legitimate business interests.

Because the trial court found that Litwinczuk violated the covenant not to compete, the Florida District Court of Appeal cautioned, the clinic was entitled to a presumption of irreparable injury. Litwinczuk contended that the alleged harm was not irreparable because the clinic could calculate its monetary damages. Even if those losses could be calculated, the clinic’s investment and associated goodwill would remain unaddressed, the appeals court noted. Thus, the trial court did not abuse its discretion when it held that Litwinczuk did not rebut the presumption of irreparable injury. Likewise, the District Court of Appeal found that the trial court was within its discretion when it determined that the injunction was necessary to protect the clinic’s legitimate business interests,

Illinois Supreme Court Upholds Restrictive Covenants In Physicians’ Employment Contracts

The Illinois Supreme Court refused December 21, 2006 to find non-compete clauses in two physicians’ employment contracts unenforceable, either as a matter of public policy or as overly restrictive in scope. Affirming a preliminary injunction put in place by the appeals court, the high court also concluded that the defendant clinic and its owner had not materially breached the employment agreement so as to excuse the physicians’ compliance with its terms.

St. John Heart Clinic (Clinic) is an Illinois professional medical corporation founded by Dr. John Monteverde, who is board certified in internal medicine and cardiology. Doctors Ragu Ramadurai and Jyoti Mohanty (plaintiffs) entered into employment contracts with the clinics. Both contracts included “non-compete” clauses should plaintiffs’ employment at the Clinic end. The restrictive covenant in Ramadurai’s contract prohibited him from practicing medicine within a two-mile radius of any Clinic office or at any of the four hospitals where the Clinic operated for a three-year period. Mohanty’s contract prohibited him from practicing medicine within a five-mile radius of any Clinic office or any of the four restricted hospitals for five years. Plaintiffs subsequently terminated their employment with the Clinic, asserting that Monteverde had breached their employment contracts by refusing to give them partnership interests and by billing for patients they saw to avoid paying them as much compensation. Plaintiffs filed an action to have the restrictive covenants declared void as against public policy and unenforceable because of Monteverde’s alleged breach of their employment contracts. Monteverde and the Clinic then sought a preliminary and permanent injunction against plaintiffs.

The high court declined to find all restrictive covenants in physician employment contracts void as against public policy in Illinois, distinguishing its decision to do so with respect to attorney employment contracts. According to the high court, in the attorney context, restrictive covenants directly conflict with the Illinois Rules of Professional Conduct, but "no similar expressions of public policy” exist for physicians.

Plaintiffs also argued the agreement was unenforceable because defendants’ breached the employment agreement by billing Medicare for the technical component of certain diagnostic imaging tests they ordered for their patients. Their employment contracts specified that their annual salaries would be 50% of their gross receipts; thus, they argued the billing practice deprived them of compensation. Rejecting this argument, the high court found the evidence sufficient to conclude that no material breach had occurred in this respect.

Finally, the high court held the non-compete agreements were not overbroad in their temporal and activity restrictions. The high court found the restriction on the “practice of medicine” was not unreasonable because “[c]ardiology, like other specialties, is inextricably intertwined with the practice of medicine.” The high court also noted that the
restriction here was in a “narrowly circumscribed area of a large metropolitan area [Chicago].” Moreover, the three and five-year periods restricted under the contract were not unreasonable given that “it took more than 10 years for [the Clinic] to establish itself as a successful cardiology practice.” Mohanty v. St. John Heart Clinic, S.C., No. 101251 (Ill. Dec. 21, 2006).

Virginia High Court Finds Corporation Lacking License To Practice Medicine Cannot Enforce Noncompete Clause

A Virginia healthcare corporation that does not have a license to practice medicine may not enforce a noncompete clause contained in an employment agreement signed by a physician when it had a valid license, the state’s highest court ruled March 2, 2007. The Virginia Supreme Court reasoned that, because the corporation did not have a license to practice medicine, it was a non-professional entity that lacked a legitimate business interest in enforcing the noncompete clause.

In 1993, when Dr. Nipun O. Parikh signed an employment agreement with Family Care Center, Inc. (Family Care), it was a professional corporation directed and owned by Dr. Dennis E. Burns. The agreement contained a noncompete clause effective for three years following an employee’s termination. Ten years later, Dr. Burns died in an automobile accident. Family Care then passed to Burns’ wife, Karen Burns, who became the sole shareholder and president. Ms. Burns was not licensed to practice medicine. By operation of law, Family Care converted from a professional corporation to a non-professional corporation upon Dr. Burns’ death. At the end of 2003, Parikh terminated his employment with Family Care, and obtained employment with a family medical practice located within one mile of Family Care. Family Care sued Parikh in state court, alleging that Parikh had breached a covenant not to compete with Family Care.

After denying Parikh’s motion to dismiss, the state circuit court held at the conclusion of a bench trial that Family Care was entitled to enforce the noncompete covenant, and ordered a judgment against Parikh in the amount of $210,000. Parikh argued on appeal that the circuit court erred in enforcing the noncompete covenant because Family Care was no longer licensed to practice medicine in the state and therefore did not have a legitimate business interest in enforcing the covenant. The state supreme court agreed and therefore reversed the lower court’s judgment. Because Family Care could not engage in the practice of medicine, it also could not "engage in a competing practice of medicine with Dr. Parikh." Parikh v. Family Care Ctr., No. 060934 (Va. Mar. 2, 2007).

Indiana Appeals Court Says Medical Practice Breached Employment Agreement And Cannot Enforce Non-Compete Provisions

A cardiovascular medical practice breached a material term of its employment agreement with two physicians and therefore it could not enforce non-competition provisions against them, an Indiana appeals court held April 13, 2007. Physicians Ralph D. Millsaps and Julio A. Moreara (collectively, plaintiffs) were shareholders, directors, and employees of Ohio Valley Heartcare, Inc. (OVHC). Plaintiffs entered into employment agreements with OVHC that included non-compete provisions restricting them from practicing medicine for two years within an area of surrounding counties following termination.
Plaintiffs resigned from OVHC and sought a declaration in court that the non-compete agreements were void as against Indiana public policy. According to plaintiffs, OVHC had breached the agreement by failing to provide timely and competent billing and collection services, which resulted in nearly $2 million in account receivables that were over two years past due.

Reversing a trial court decision, the Indiana Court of Appeals held that OVHC breached a material term of the employment agreement to provide timely and competent billing and collection services. The appeals court noted that timely billing was an integral part of the agreement, which provided for the assessment of penalties against physicians who failed to submit their charge forms for processing in a timely fashion. According to the opinion, the billing problems stemmed from OVHC’s transition to a new software program in which the collection department failed to continue to process the outstanding accounts receivable that remained in the old system. As a result of these problems, OVHC asked its physician shareholders to reduce their monthly draws by $5,000 for twenty-two months, the practice became insolvent, and its overhead increased dramatically to pay for outside assistance. The appeals court was not persuaded by OVHC’s argument that the problem was only temporary, noting that a “‘temporary’ breach is no less a breach than a ‘permanent’ one.” Millsaps v. Ohio Valley Heartcare, Inc., No. 82A05-0603-CV-159 (Ind. Ct. App. Apr. 13, 2007).

Wrongful Discharge

New Jersey Supreme Court Says Radiology Practice’s Shareholder-Director Not An “Employee” Under State’s Whistleblower Protection Statute

A former shareholder-director of a radiology group was not an "employee" entitled to bring a claim under New Jersey's Conscientious Employee Protection Act (CEPA) alleging she was constructively discharged for her whistleblowing activities in violation of the statute, the New Jersey Supreme Court ruled July 5, 2006. Ruth Feldman had been one of five or six physician shareholder-directors at Hunterdon Radiological Associates (HRA) for nearly a decade when she filed a complaint in December 2001 against the group for unlawful retaliation under New Jersey’s CEPA, N.J. Stat. Ann. § 34:19-1 to –8, which prohibits retaliatory action against an employee whose whistleblowing actions benefit the health, safety, and welfare of the public. Feldman claimed she was constructively discharged because of quality concerns she raised about another HRA physician.

The New Jersey Supreme Court framed the issue as whether Feldman was sufficiently subject to HRA’s “control and direction” that she could reasonably be considered an employee rather than an employer. Relying heavily on Clackamas Gastroenterology Assocs. v. Wells, 538 U.S. 440 (2003), the high court concluded Feldman was not an “employee” within the meaning of the CEPA given her power and influence within the group. Feldman v. Hunterdon Radiological Assocs., No. A-71-05 (N.J. July 5, 2006).

Eighth Circuit Finds Terminated Physician Did Not Qualify As Whistleblower
A physician who brought a lawsuit against a physicians group that fired him was not a whistleblower under Missouri’s public policy exception to its employment-at-will doctrine, the Eighth Circuit held. C. Alan Scott was a physician and shareholder of MVP Missouri Valley Physicians, P.C. from 1988 until September 2002. Beginning in January 2002, Scott complained that MVP’s compensation formula violated the federal Stark law. At a meeting, two-thirds of the MVP Board of Directors voted to terminate Scott’s employment. Following his termination, Scott sued MVP and the other members of the MVP Board of Directors (defendants).

Affirming a lower court decision granting MVP summary judgment, the Eighth Circuit found Scott produced “no evidence other than his own deposition and affidavits to substantiate his claims” that MVP’s compensation policies violated the Stark law and that his action constituted whistleblowing activities. According to the appeals court, “[t]he district court correctly concluded that reporting of possible violations of Stark laws to the purported wrongdoers does not meet the whistleblowing exception because it does not further” the public policy goal of encouraging workers to report suspected wrongdoing to the proper authorities. Scott v. Missouri Valley Physicians, No. 05-4463 (8th Cir. Aug. 17, 2006).

U.S. Court In Tennessee Says Termination Of Tenured Faculty Members Violated Due Process

The termination of three tenured faculty members by a state medical school violated their constitutional right to procedural due process because they were not afforded any pre-deprivation process, a federal district court in Tennessee ruled August 3. Plaintiffs Frank W. Ling, M.D., Robert L. Summit, M.D., and Val Y. Vogt, M.D. were all tenured faculty members in the obstetrics and gynecology department at the College of Medicine at University of Tennessee Health Science Center (UTHSC). Plaintiffs had been terminated from the faculty after they resigned from the University of Tennessee Medical Group (UTMG), which had an affiliation agreement with UTHSC. The affiliation agreement required all geographical full-time faculty members of UTHSC to practice through UTMG “as a condition of their faculty employment.”

The U.S. District Court for the Western District of Tennessee found that treating resignations from UTMG as resignations from UTHSC was the established procedure, given the terms of the affiliation agreement and the understanding of the parties. Thus, the “alleged deprivation of property without due process was not the result of a random and unauthorized action such that it would have been impracticable for the state to provide any pre-deprivation process,” the court said in denying defendants’ motion for summary judgment. The court also refused to find the tenured factually members had constructively resigned when they resigned from UTMG, which under the affiliation agreement was a condition of faculty employment at UTHSC. According to the court, constructive resignation does not exist under Tennessee common law. Because defendants were acting under color of state law, plaintiffs were entitled to partial summary judgment on their § 1983 claims against defendants in their official capacities. Ling v. Herrod, No. 04-2484 Ma/P (W.D. Tenn. Aug. 3, 2006).
California Appeals Court Upholds Termination Of Physician For Refusing To Follow Superiors’ Orders To Stop Excessive Patient Tests

A California appeals court upheld December 28, 2006 a university hospital’s decision to discharge a primary care physician for allegedly refusing to follow his superiors’ orders to be less “wasteful” in using hospital resources. The California Court of Appeal found “substantial evidence” to support the lower court’s conclusion that the terminated physician was discharged for “insubordination” rather than “advocating for medically appropriate health care.”

The physician in the case, George Sarka, was employed for fourteen years as a primary care physician at the Arthur Ashe Student Health and Wellness Center (SHS) at the University of California at Los Angeles (University). When the University discharged Sarka, it sent him a letter indicating that his dismissal was based on his “wasteful use of resources and over-reliance on diagnostic testing in lieu of relying on medical judgment.” Prior to discharge, these same concerns had been stressed in several performance evaluations of Sarka over a period of years. Sarka claimed he was discharged for advocating for his patients in violation of Cal. Bus. & Prof. Code § 2056.

The California Court of Appeal noted that the case was not about negligence or malpractice. “Dr. Sarka’s claim he was practicing the best medicine he could does not transform his termination into a violation of Cal. Bus. & Prof. Code §2056,” the appeals court said. “What was relevant to § 2056 in this case was whether, in refusing to rely more on his own medical and clinical judgment and less on diagnostic testing, . . . Sarka was ‘advocating for medically appropriate health care,’” the appeals court explained. “Toward that end, . . . Sarka was obligated to demonstrate that his advocacy was ‘medically appropriate’ for primary care physicians in a large university’s student health service. This he did not do,” the appeals court said. Sarka v. The Regents of The Univ. of Cal., No. B181753 (Cal. Ct. App. Dec. 28, 2006).

Texas Appeals Court Affirms Retaliation Verdict For Former Nursing Home Employee Who Alleged She Was Fired For Reporting Possible Sexual Abuse

Sufficient evidence supported a jury’s finding that a nursing home violated statutory anti-retaliation provisions by firing an employee shortly after she reported a possible incident of sexual abuse against one of the residents, a Texas appeals court held February 7. Cathy Winters sued nursing home Town Hall Estates-Whitney, Inc. (Town Hall) where she formerly worked as a nurse, its owner, and its administrators alleging she was fired for reporting to her supervisor the possible sexual abuse of a nursing home resident by another employee. A jury found in Winters’ favor on her retaliatory discharge claim under Tex. Health & Safety Code Ann. § 242.133 and awarded her $3,100 for lost wages, $20,000 in compensatory damages, and $34,000 for attorney’s fees. The jury also found defendants acted with malice in terminating Winters’ employment and assessed $20,000 in exemplary damages against each administrator, $2,000 against Town Hall, and $350,000 against the owner of the nursing home—American Religious Town Hall Meeting, Inc. (ARTH). Pursuant to the statutory damages cap, the award against ARTH was reduced to $200,000. Section 242.133 provides a cause of action for nursing home employees who are retaliated against for reporting a violation of the law.
The Texas Court of Appeals affirmed as to Town Hall and the administrator defendants but held that ARTH could not be held vicariously liable for the nursing home’s retaliation under an alter ego theory. First, the appeals court held that Winters reported an incident of abuse as contemplated by § 242.133 even if she was uncertain whether the abuse actually occurred, noting that an employee’s subjective belief was irrelevant under the statute. While defendants argued they terminated Winters for insubordination and other prior violations, the appeals court found sufficient circumstantial evidence (timing, treatment of other similarly situated employees, etc.) from which a jury could reasonably conclude that the nursing home would not have terminated Winters when it did “but for” her report about the possible sexual abuse.

The appeals court refused, however, to disregard the corporate form, or “pierce the corporate veil,” and hold ARTH, as Town Hall’s parent company, vicariously liable. Finally, the appeals court found sufficient evidence to support the jury’s findings that Town Hall and defendant administrators acted with malice. Specifically, the appeals court cited circumstantial evidence that the administrators knew they were violating the law and Winters’ legal rights but they did not want to report the abuse because of potential financial repercussions. Town Hall Estates-Whitney, Inc. v. Winters, No. 10-04-00339-CV (Tex. Ct. App. Feb. 7, 2007).

Hostile Work Environment

Fifth Circuit Rejects Hostile Work Environment Claim Against Nursing Home

A former nursing home employee could not claim that he was subject to a hostile work environment because of alleged racial slurs made by a resident where his job specifically contemplated his interaction with mentally ill individuals, the Fifth Circuit ruled September 1, 2006. The Equal Employment Opportunity Commission sued Nexion Health at Broadway, Inc. (Nexion) alleging it forced a former employee, Terrence Johnson, to work in a racially hostile work environment in violation of Title VII of the Civil Rights Act of 1964. Johnson worked as a certified nurse’s assistant at a Nexion nursing home in Texas that primarily provides care for elderly persons with mental conditions. According to the Johnson, one of the home’s residents with schizophrenia made offensive racial comments against him and his superiors took no action to stop the verbal abuse. Nexion fired Johnson after he allegedly threatened to physically abuse the resident.

Affirming a lower court ruling, the Fifth Circuit held the harassment—i.e. the racial slurs directed against Johnson by the resident—did not affect a term, condition, or privilege of employment. The appeals court found the harassment at issue, while subjectively abusive to Johnson, did not create an objectively hostile or abusive workplace environment. “Although [the offensive comments] were more than isolated instances of harassment, they were not so frequent as to pervade the work experience of a reasonable nursing home employee, especially considering the source,” the appeals court said. Absent an objectively detrimental impact on Johnson’s work performance, the instant circumstances could not support a hostile work environment claim. Moreover, “[a]bsorbing occasional verbal abuse from such patients was not merely an inconvenience associated with his job;
it was an important part of the job itself;” the appeals court noted. *Equal Employment Opportunity Comm’n v. Johnson*, No. 05-51770 (5th Cir. Sept. 1, 2006).

**Labor Issues**

**Labor Union Ordered To Pay $17.3 Million For Defaming Hospital System**
A jury in Placer County, California has awarded not-for-profit Sutter Health $17.3 million in damages after finding the New York-based labor union United Here defamed the network in a mass mailing campaign that targeted communities served by its hospitals, according to a press release issued by Sutter Health July 21, 2006. Sutter Health and many of its affiliated hospitals sued United Here, whose members include industrial laundries, after the union mailed postcards to women of childbearing age in Northern California suggesting the hospitals used unsanitary linens that were cleaned by an outside laundry services, the release said. According to the release, at the time the postcards went out, United Here was in a labor dispute with the laundry service.

**The National Labor Relations Board Finally Provides Guidance On “Supervisors” Under The National Labor Relations Act**
The National Labor Relations Board (NLRB) issued long-awaited and anticipated decisions in three cases involving whether or not charge nurses, and their similarly-situated counterparts in other industries, will be considered supervisors under the National Labor Relations Act. In *Oakwood Healthcare*, 348 NLRB No. 37, the Board determined that charge nurses with the authority to assign other nursing personnel to specific patients for treatment were supervisors because this assigning required the exercise of independent judgment, even though the charge nurses did not exercise much else by way of supervisory authority. The determination on this issue substantially departs from prior Board precedent and will impact application of the National Labor Relations Act to an untold number of nurses. The Board did find, however, that *Oakwood’s* rotating charge nurses could not be considered supervisors because they did not exercise such supervisory authority in the regular course of their duties.

In two companion cases, the Board applied the rationale of *Oakwood Healthcare* and further clarified the application of its newly-announced criteria for supervisory status for those who do not satisfy one of the other Section 2(11) criteria. In *Croft Metals, Inc.*, 348 NLRB No. 38, the Board held that, although “lead persons” at the employer’s manufacturing plant had the authority to manage their assigned teams, to correct improper performance, and to decide the order in which work was to be performed, they were not supervisors because their exercise of judgment was so controlled by the employer’s directives and guidelines that it amounted to little more than routine or clerical direction.

Finally, in *Golden Crest Healthcare*, 348 NLRB No. 39, the Board, again applying the holding in *Oakwood Healthcare*, concluded that Golden Crest’s charge nurses were not supervisors because they did not have the authority to assign tasks to other nurses, to shift the assignments of other nurses, or to call in nurses from off-duty status. In addition, the Board held that, even though charge nurses were annually rated on their ability to direct
other nurses, there was little evidence that such a rating affected the charge nurses’ employment status.

SEIU Forms New Union For Healthcare Workers
Labor giant Service Employees International Union (SEIU) announced January 29, 2007 that it will form a new, national union of nearly 1 million healthcare workers. The goal of the new union “is to unite America’s 10 million health care workers in SEIU Healthcare to stand up for quality care, comprehensive health care reform, and good jobs that support families and encourage people to pursue careers as nurses and other health care workers,” according to SEIU’s press release. Dennis Rivera, the long-time leader of the nation’s largest local union of healthcare workers—New York-based 1199 SEIU United Healthcare Workers East—is slated to become chair of the new SEIU Healthcare, the release said.

D.C. Circuit Finds Nurse At Long Term Care Facility Lacked Supervisory Authority
The National Labor Relations Board’s (NLRB) decision that a registered nurse at a long term care facility was a “supervisor” as defined in the National Labor Relations Act (NLRA) must be set aside because it deviates from the NLRB’s own precedent and is not supported by substantial evidence, the D.C. Circuit ruled March 23, 2007. Lisa Jochims was a registered nurse (RN) at the long term facility, Wilshire at Lakewood (Wilshire) from 1999 until February 2002. During that time, she was the “weekend supervisor,” which meant that she was the highest-ranking employee at the facility over the weekend, but was provided the contact numbers of various managers to call in case of an emergency. Jochims was fired in 2002 for circulating a petition protesting Wilshire’s proposed “role reversal” plan, under which registered nurses (RNs) and licensed practical nurses (LPNs) would occasionally perform the duties of certified nursing assistants (CNAs).

Jochims filed an unfair labor practice charge with the NLRB, asserting that she was unlawfully discharged by Wilshire for engaging in protected activities in violation of the NLRA. An administrative law judge (ALJ) concluded that Jochims was a “supervisor” within the meaning of the NLRA, and therefore unprotected by the Act. The NLRB ultimately agreed, and ruled that Jochims’ dismissal was not an unfair labor practice under the NLRA. The NLRB based its decision on four factors related to Jochims’ role at Wilshire: (1) she completed written reports of employee misconduct; (2) she sent two employees home for misconduct as directed by management; (3) she let two employees leave work for family emergencies; and (4) she completed part of one evaluation on a probationary employer as directed by management.

In reversing the NLRB’s decision, the D.C. Circuit first explained that the NLRA defines “supervisor” as “any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline another employee, or responsibly to direct them, or to adjust their grievances, or effectively to recommend such action” (29 U.S.C. §152(11)). The appeals court said that none of the

In a related development, Senators Chris Dodd (D-CT), Richard Durbin (D-IL), and Edward Kennedy (D-MA) have introduced legislation—the Re-Empowerment of Skilled and Professional Employees and Construction Tradeworkers (RESPECT) Act—that would amend the NLRA to modify the definition of “supervisor” to ensure that no employee is unjustly denied his or her right to protections provided under the NLRA, according to a March 23, 2007 press release. “Senator Dodd’s bill would correct an unfair policy created by a series of [recent] decisions by the [NLRB], in which the [agency] ruled that charge nurses are supervisors, even though they have no authority to hire, fire, or discipline other employees,” the release said. The legislation would delete the terms “assign” and “responsibly to direct” from the definition of “supervisor” and would also require that a worker spend the majority of the workday in a supervisory capacity to be labeled a supervisor.

**EMTALA**

**U.S. Court In Texas Refuses To Dismiss EMTALA Claim That Uninsured Patient Received Fewer Tests**

The U.S. District Court for the Northern District of Texas in a July 17, 2006 ruling refused to dismiss a claim brought under the Emergency Medical Treatment and Labor Act (EMTALA) by the children of a man who died from a heart attack one day after he was discharged from a hospital emergency room. The court found allegations that the patient, who lacked health insurance, did not receive the full range of diagnostic tests provided to other patients with similar symptoms was sufficient to support the EMTALA claim. The children of Troy Lee Aylor sued United Regional Health Care System in Wichita Falls, Texas alleging it knew their father was uninsured, that he was having symptoms of a heart attack, and that he had a history of coronary artery disease. Plaintiffs also contended that United Regional had a policy of performing several specific medical tests and procedures on patients complaining of similar symptoms but did not administer those diagnostic tests to their father.

The U.S. District Court for the Northern District of Texas found the allegations in the complaint—that Aylor’s medical screening was not performed in an equitable manner and that United Regional failed to stabilize him before his release—could form the basis of an EMTALA claim making dismissal at this point improper. *Southard v. United Regional Health Care Sys.*, No. 7:06-CV-011-R (N.D. Tex. July 12, 2006).

**U.S. Court In Missouri Dismisses EMTALA Claim, Finding No Evidence That Uninsured Patient Was Treated Differently**

A federal court in Missouri granted a hospital’s summary judgment motion in an action alleging it had provided an inadequate screening in violation of the Emergency Medical Treatment and Labor Act (EMTALA). Delia White, who did not have any medical insurance, arrived at Pike County Memorial Hospital’s (PCMH’s) emergency room with a migraine headache and vomiting. Dr. Phillip Pitney examined and then discharged
White. White died the next day of acute hydrocephalus. White’s parents (plaintiffs) sued PCMH under EMTALA and sued Pitney under state law for medical malpractice. PCMH moved for summary judgment.

The U.S. District Court for the Eastern District of Missouri found plaintiffs could not maintain an inadequate screening claim under EMTALA because they failed to allege or present evidence that “decedent was treated differently from any other patient under similar circumstances.” Pitney testified that he performed an eye exam to check for signs of hydrocephalus and did not see any. Here, PCMH offered evidence in the form of Pitney’s deposition that he treated White the same way he would have treated any other patient, and plaintiffs failed to present any evidence to the contrary, the court said. *Irvin v. Pike County Mem’l Hosp.*, No. 2:05CV00014 AGF (E.D. Mo. Aug. 7, 2006).

**U.S. Court In Alabama Allows Pregnant Woman’s EMTALA Claim To Go Forward**

A federal court in Alabama allowed a pregnant woman’s Emergency Medical Treatment and Labor Act (EMTALA) claim to go forward, finding a jury could reasonably conclude that the defendant hospital failed to offer her an appropriate screening and unreasonably delayed treatment. Plaintiff Ginger Henderson was involved in a car accident when she was approximately thirty-eight weeks pregnant. Her doctor advised her to go to Medical Center Enterprise hospital (MCE) as it was the closest to where Henderson lived. She was told by a clerk that the on-call obstetrician was being contacted by the labor and delivery nurse and that the obstetrician would have to decide whether he would see her because she was not a regular OB patient at the hospital. Henderson opted to leave MCE and see her regular obstetrician.

The U.S. District Court for the Middle District of Alabama noted that MCE’s policy for obstetrical patients presenting to the ER stated that patients over twenty weeks gestation who were involved in a motor vehicle accident should be evaluated by an ER physician prior to being sent to labor and delivery. Henderson was not seen by an ER physician; therefore, a jury could conclude that MCE did not follow its policy in dealing with her, the court reasoned. In addition, “a jury could find that Mrs. Henderson was treated differently from other patients presenting with the same symptoms because her obstetrician did not practice at MCE. This difference in treatment not based upon a difference in symptoms would violate MCE’s obligation under EMTALA to provide appropriate medical screening,” the court found in denying the hospital summary judgment.

The court also denied summary judgment on Henderson’s claim that by failing to provide treatment to her until the on-call obstetrician decided whether to see her, MCE unduly discouraged her from remaining for further evaluation and could amount to “unreasonably delayed screening or treatment.” The court also found no merit to MCE’s claim that by leaving Henderson voluntarily withdrew her request for treatment. According to the court, questions remained as to whether MCE fulfilled its obligations under EMTALA to a patient refusing treatment. EMTALA requires a hospital to offer an individual refusing treatment further examination and/or treatment and to inform the
individual of the risks and benefits of such examination/treatment. If the individual then refuses to consent, the hospital is required to take “all reasonable steps” to secure the individual's written informed consent to refuse examination/treatment, the court said, noting that it was unclear whether MCE had followed this requirement. *Henderson v. Medical Ctr. Enter.*, No. 1:05-cv-823-MEF (M.D. Ala. Aug. 14, 2006).

In another decision related to this case issued on the same day, the Alabama federal court found a Centers for Medicare and Medicaid Services (CMS) investigation report was admissible against the hospital. In response to Henderson’s complaint, CMS had investigated MCE’s treatment of her and concluded the hospital had violated a number of federal regulations. In her EMTALA action, Henderson submitted exhibits relating to CMS’ investigation. MCE moved to strike the evidence.

The court held the evidence was admissible under Federal Rule of Evidence 803(8)(C), which allows [r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth . . . in civil actions and proceedings . . . factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.” The court found no merit to MCE’s arguments that the evidence must first be a public record and that the information in CMS’ report was not trustworthy. The court acknowledged that “Rule 803(8)(C) does not provide for the admissibility of the legal conclusions contained within an otherwise admissible public report,” and thus agreed not to consider those portions of the report that offered legal conclusions. In addressing MCE’s argument that the information constituted quality assurance information that was barred from evidence by Ala. Code § 22-21-8, the court noted that “the majority of federal courts in other states have declined to apply state peer review privileges in a wide variety of federal question actions.” *Henderson v. Medical Ctr. Enter.*, No. 1:05-cv-823-MEF (M.D. Ala. Aug. 14, 2006).

**Eleventh Circuit Affirms Holding That Patient Failed To Establish EMTALA “Inadequate Screening” Claim**

The Eleventh Circuit affirmed October 27, 2006 a lower court decision that a plaintiff did not allege a claim of inadequate screening under the Emergency Medical Treatment and Labor Act (EMTALA) after a hospital emergency room failed to detect her ruptured spleen when she sought treatment there following a car accident. Vickie Bryant sought treatment at John D. Archbold Memorial Hospital (Archbold) where she was examined by the attending physician Michael Crowley who determined that her head, neck, and heart were all functioning normally. Crowley subsequently informed Bryant that she had fractured two ribs, and discharged her from the ER with pain medication. A few days later, Bryant was diagnosed with a ruptured spleen and underwent emergency surgery. Bryant sued Archbold and Crowley, asserting an inadequate-screening claim under EMTALA and a state law claim of negligence.

The U.S. District Court for the Middle District of Georgia granted defendants' summary judgment motion, emphasizing that EMTALA is not a federal malpractice statute and requires only that the screening was consistent with established procedures. The Eleventh

**Eleventh Circuit Affirms Dismissal Of EMTALA Claims Finding No Evidence Of Violations**

The Eleventh Circuit, in an unpublished opinion, affirmed the dismissal of a patient’s Emergency Medical Treatment and Labor Act (EMTALA) claims, finding no evidence that the patient was treated any differently than other patients or was transferred or discharged within the meaning of the statute. According to Benjamin Johnson, he was diagnosed by emergency physicians at Health Central Hospital with an overdose of the psychiatric medication benzodiazepine and was admitted to the ICU under “suicide precautions.” Johnson was released the next day.

Johnson sued Health Central for violations of EMTALA alleging that Health Central failed to perform the “customary charcoal procedure to remove the pills” and stabilize him. In addition, Johnson alleged that he was still in a psychiatrically disturbed state when released and Health Central should have transferred or stabilized him before release. Health Central moved for summary judgment, arguing that Johnson was admitted with an alleged overdose and cocaine intoxication and became combative when transferred to the ICU. Health Central claimed Johnson left against medical advice. In addition, Health Central argued that EMTALA’s stabilization requirement did not apply because Johnson was not transferred but rather was admitted to the ICU and received treatment.

Affirming the district court’s grant of summary judgment to Health Center, the appeals court found no evidence that Johnson was treated differently than any other patient, rejecting his lay opinion that he should have been given a charcoal procedure. The appeals court agreed with the district court that “the failure to perform a particular non-EMTALA-mandated medical procedure was not a genuine issue of material fact because the omission did not rise to the level of a failure to appropriately screen and stabilize the patient, within the meaning of the EMTALA.” The appeals court also agreed that EMTALA’s stabilization requirement did not apply because “the record fails to establish that Johnson was either ‘transferred’ or ‘discharged’” within the meaning of EMTALA. *Johnson v. Health Central Hosp.*, No. 06-12426 (11th Cir. Nov. 30, 2006).

**U.S. Court In Kansas Dismisses “Failure To Screen” EMTALA Claim Alleged By Wife Of Man Who Died After Twenty-Minute Wait In Emergency Room**

A hospital that failed to conduct a screening examination of a man who collapsed and died in the hospital’s emergency department after a twenty-minute wait did not violate the Emergency Medical Treatment and Labor Act (EMTALA), a federal district court in Kansas ruled December 1. The U.S. District Court for the District of Kansas determined that, absent evidence the registration clerk violated hospital policy, the hospital’s failure to screen in this case did not constitute a violation of EMTALA even given allegations that, prior to triage, the clerk was allegedly informed of the man’s serious medical problems, including vomiting blood, difficulty breathing, and other symptoms that could indicate a heart attack.
Plaintiff Oneita Parker (Mrs. Parker) is the surviving widow of Paul H. Parker (Mr. Parker), who died at Salina Regional Health Center, Inc.’s (SRHC's) emergency department (ED). Mr. Parker weighed more than 300 pounds and had a medical history of diabetes and congestive heart failure. Mrs. Parker had driven her husband to SRHC’s ED, and the couple waited for approximately twenty minutes for a triage nurse before Mr. Parker collapsed while seated in front of the ED’s registration desk. During this twenty-minute wait, the Parkers approached the registration desk “of their own accord” and the clerk made some inquiry about insurance information. Mrs. Parker sued SRHC alleging violations of EMTALA and medical negligence. SRHC moved for summary judgment.

The district court first noted that, under EMTALA, hospitals must create standard emergency room screening procedures based on the hospital’s particular needs and circumstances. With respect to a court’s review of a failure to screen claim under EMTALA, the focus should only be on “whether the hospital adhered to its own procedures, not whether the procedures were adequate if followed,” the court explained. SHRC’s ED policy stated that the triage nurse would determine a level of need for care as per health center policy and prior to any inquiry regarding the individual’s method of payment or insurance status. “[W]hile plaintiff argues that the hospital violated its own policy since it appears there was at least some inquiry made prior to triage by virtue of Mr. Parker seating himself at the registration desk, in the court’s view, any such violation was minimal, or de minimis, under the circumstances of this case,” the opinion said. Moreover, “[t]his conclusion is supported by federal regulations pertaining to the EMTALA statute,” the court reasoned, noting that 42 C.F.R. § 489.24(d)(4)(iv) permits hospitals to “follow reasonable registration processes . . . including asking whether an individual is insured, and if so, what that insurance is, as long as that inquiry does not delay screening or treatment.” Parker v. Salina Reg’l Health Ctr. Inc., No. 05-04066-KGS (D. Kan. Dec. 1, 2006).

U.S. Court In Puerto Rico Declines To Dismiss EMTALA Claims Against Hospital That Transferred Newborn In Critical Condition

An infant delivered by cesarean section in a hospital operating room who developed medical problems requiring emergency treatment shortly after birth and was allegedly transferred to another hospital without being stabilized was covered by the Emergency Medical Treatment and Labor Act (EMTALA), a federal district court in Puerto Rico ruled February 22, 2007. The U.S. District Court for the District of Puerto Rico declined to dismiss EMTALA claims brought by the infant’s mother against the hospital that made the decision to transfer the infant, who died at the other hospital.

Iraida Lima-Rivera gave birth by cesarean section to a baby boy at Hospital San Pablo del Este (HSPE), and the newborn was initially taken to HSPE’s regular nursery. The newborn soon developed emergency conditions, including upper gastrointestinal bleeding and vomiting of blood. HSPE staff transferred the baby to its intensive care unit. At some point during the next day, a physician at HSPE decided to transfer the baby to Hospital Interamericano de Medicina Avanzada (HIMA), where records describe the baby on arrival as “crucially ill r/o sepsis.” According to the court, evidence showed that
upon leaving HSPE, the baby was “totally unstable, with . . . active upper gastrointestinal bleeding.” The baby died at HIMa two days later of cardiac arrest. Lima-Rivera sued HSPE’s, alleging its medical treatment of her now deceased baby violated EMTALA and constituted medical malpractice under Puerto Rico law. HSPE and its owner, UHS of Puerto Rico, Inc. (defendants), moved to dismiss, arguing lack of subject matter jurisdiction and failure to state a claim upon which relief could be granted.

The district court rejected defendants’ contention that they were not required to comply with EMTALA’s stabilization and transfer provisions because Lima-Rivera’s newborn was admitted as an inpatient in HSPE’s regular nursery. Citing Lopez-Soto v. Hawayek, 175 F.3d 170 (1st Cir. 1999), the court emphasized that EMTALA’s application is not limited to hospital emergency departments. In Lopez-Soto, the First Circuit held that “emergency room arrival is not a prerequisite to liability under EMTALA’s stabilization and transfer provisions,” joining other federal and state courts that have similarly held, the court explained. The court found that just as in Lopez-Soto, in the present case “the newborn’s arrival in the hospital’s operating room and the hospital’s prompt detection of an emergency medical condition, if proven, would be sufficient to trigger EMTALA’s stabilization and transfer requirements.”

The court also rejected defendants’ contention that Lopez-Soto should be disregarded because of a subsequent 2003 regulation (42 C.F.R. § 489.24(d)(2)(i)) in which the Centers for Medicare and Medicaid Services (CMS) clarified that EMTALA ceases to apply when an individual is admitted as an inpatient. CMS’ regulation is an interpretive rule, and therefore does not have “the force and effect of law” and is not “accorded that weight in the adjudicatory process,” the court said. Moreover, the regulation was not in effect when defendants allegedly violated EMTALA, as the claimed violations occurred four months before the rule was published in September 2003, the court continued. Finally, the court found Lima-Rivera’s allegations were sufficient to establish her claim of EMTALA violations. Lima-Rivera v. UHS of Puerto Rico Inc., No. 04-1798 (D.P.R. Feb. 22, 2007).

U.S. Court In Michigan Finds No EMTALA Violation In Transfer Of Patient To In-Network Hospital

The U.S. District Court for the Eastern District of Michigan granted a hospital summary judgment on claims that the hospital violated the Emergency Medical Treatment and Labor Act (EMTALA) when transferring a patient to an “in-network” hospital. The court found the plaintiff failed to prove the hospital had an improper motive in the transfer and also failed to show the patient’s treating physicians knew he had an unstable condition when the transfer took place.

Marcus Garrett was transported to Sinai-Grace Hospital after plaintiff Danielle Garrett (Marcus’ wife) called emergency medical services. At the hospital, Garrett was seen by defendant physicians Ronald Kim, a resident, and Robert Dunne, the attending. The doctors ordered several tests and then began a pre-authorization process with Garrett’s managed care provider—Health Alliance Plan—to transfer Garrett to an “in-network” provider, Henry Ford Hospital. Although not all of Garrett’s test results were back, Kim
diagnosed Garrett with diabetic ketoacidosis. He was given additional fluids, insulin, and potassium and then transferred to Henry Ford Hospital. Garrett died within an hour of his arrival of a pulmonary thromboembolism. Plaintiff filed a complaint alleging violations of EMTALA among other claims. Defendants moved for summary judgment, which the court granted.

In finding a genuine issue of material fact whether the hospital provided a substandard screening according to its own standards, the court pointed to testimony from Kim that pulmonary embolism was included in his differential diagnosis. The court noted Kim further testified that when a life threatening condition is included as part of a patient’s differential diagnosis reasonable measures must be undertaken to either confirm or rule out that condition, but in this case no tests for pulmonary embolism were ordered. But to sustain an EMTALA claim, a plaintiff also must establish an improper motive, which she failed to do. The court found “no evidence to suggest that if Garrett were not ‘out of network’ the tests to rule out pulmonary embolism would have been ordered.”

The court also found plaintiff did not present any evidence defendants knew Garrett had an emergency medical condition that was not stabilized at the time of his transfer. “What Plaintiff argues is that Defendants should have known that Garrett had an emergency medical condition, i.e., pulmonary embolism, if they had followed the proper standard of care. This is a classic claim of medical malpractice, not a violation of EMTALA,” the court found. Garrett v. Detroit Med. Ctr., No. 06-10753 (E.D. Mich. Mar. 14, 2007).

U.S. Court In Louisiana Finds Hospital Did Not Violate EMTALA Because Patient Was Treated Like Other Similar Patients
A federal court in Louisiana found April 4, 2007 that a hospital did not violate the Emergency Medical Treatment and Labor Act (EMTALA) by discharging a patient who later was found to have appendicitis because there was no evidence that the hospital treated any other patient with abdominal pain differently. Joyce Spillman (plaintiff) brought her minor son Brandon to the emergency room at Lake Charles Memorial Hospital (LCMH) complaining of severe abdominal pain. The physician who treated Brandon did not run any tests, but diagnosed him with acute gastritis and sent him home. Three hours later, Spillman brought her son to the emergency room at Christus St. Patrick Hospital (CSPH) where a CT scan was allegedly suspicious for appendicitis. Nevertheless, Brandon was discharged. Spillman finally brought her son to his family doctor who determined Brandon’s appendix had ruptured, requiring emergency surgery.

Spillman filed suit individually and on behalf of her son against Southwest Louisiana Hospital Association and Christus Health claiming violations of EMTALA. Christus Health (defendant) moved for summary judgment. The U.S. District Court for the Western District of Louisiana granted the motion. Spillman argued no adequate physical examination was performed on her son and that inaccurate CT scan results were relayed to a nurse practitioner, but the court agreed with defendant that no evidence was presented that it normally treats other patients with abdominal pain differently than it treated Brandon. Although the facts presented “may indeed form the basis of a medical malpractice claim, they do not support a claim under the EMTALA for failure to provide
an appropriate medical screening examination,” the court held. Because there was no diagnosis of an emergency medical condition, Spillman also could not support her claim for violation of EMTALA’s stabilization requirement, the court found. Although it found that appendicitis was a “presumptive diagnosis,” the court was unable to find any case law support for “the theory that a presumptive diagnosis triggers a hospital’s duty to stabilize or transport under the EMTALA.” *Spillman v. Southwest Louisiana Hosp. Ass’n*, No. 2:05 CV 450 (W.D. La. Apr. 4, 2007).

**ERISA**

Georgia Supreme Court Finds ERISA Preempts Unjust Enrichment Claims

The Georgia Supreme Court held that the Employee Retirement Income Security Act (ERISA) preempted claims that a pharmacy benefits manager was unjustly enriched by erroneously classifying a drug as a brand-name and thus collecting higher co-payments. Plaintiffs, a group of breast cancer survivors, were prescribed the drug tamoxifen and filled their prescriptions through their ERISA insurance plans, which required a higher co-payment for brand-name drugs as opposed to generic drugs. Plaintiffs sued Advance PCS, Inc. (PCS), a pharmaceutical benefits manager that contracted with plaintiffs’ ERISA plan providers, claiming it was unjustly enriched by improperly classifying tamoxifen as a brand-name drug, when it should have been classified as a generic drug.

The Georgia Supreme Court found plaintiffs’ claims depended on the terms of their respective ERISA plans and could have been raised in the context of ERISA’s civil enforcement provisions. Thus, the high court found ERISA both expressly and impliedly preempted the state law claims. *Advance PCS v. Bauer*, No. S05G2011 (Ga. June 26, 2006).

U.S. Court In Maryland Finds ERISA Preemption In Maryland Wal-Mart Legislation Challenge, Fourth Circuit Affirms

On July 19, 2006, Judge Frederick Motz of the U.S. District Court for the District of Maryland rendered a decision with potentially far-reaching implications for employers and health plans nationwide, as well as states that are attempting to address the problems of the growing number of uninsured and underinsured and escalating Medicaid costs. In the much-anticipated decision, Judge Motz held that the recently enacted Maryland "Fair Share" Legislation, commonly referred to as the "Wal-Mart legislation," is preempted by ERISA.

Under the Maryland Fair Share Health Care Fund Act, which was scheduled to become effective January 1, 2007, any non-governmental for-profit employer with 10,000 or more Maryland employees that failed to spend up to 8% of the total wages paid to Maryland employees on health insurance costs would be required to pay the difference to a state healthcare fund. The legislation, which was enacted only after Maryland’s General Assembly overrode a veto by then Governor Robert Ehrlich (R), was dubbed the “Wal-Mart Law” as the giant retailer was the only business in the state likely to be affected. Retail Industry Leaders Association (RILA), of which Wal-Mart is a member, challenged
the law in federal district court, arguing ERISA preempted the Act and the law violated the equal protection clause.

In an effort to avoid ERISA preemption, Maryland argued that the legislation did not amount to a "mandate," that the law regulated employers not employee benefit plans, and that the spending requirement was akin to a "tax" only tangentially related to employee benefit plans. The court flatly rejected these arguments, finding that the "choice" presented to employers was a "Hobson's choice" and that the purpose of the Maryland legislation was to require increased payments for the provision of health benefits.

Recognizing that conflicting, "fair share" spending requirements were enacted by local governments in New York (New York City and Suffolk County), and were pending or under consideration in several other states, the court also found that subjecting multi-state employers such as Wal-Mart to such differing requirements would violate ERISA's purpose of permitting nationally uniform administration of employee benefit plans. While detailing his concerns with various conflicting state and local "fair share" requirements, Judge Motz expressly left open the question of whether other "comprehensive" legislative approaches "to the problems of healthcare delivery and its attendant costs," specifically including Massachusetts' Universal Health Care Plan, could pass muster under ERISA. Retail Indus. Leaders Ass'n v. Fielder, Civil No. JFM-06-316 (D. Md. July 19, 2006).

On appeal, the Fourth Circuit in a 2-1 decision issued January 17, 2007 agreed that ERISA preempted the Maryland law. “Because [the law] effectively requires employers in Maryland covered by the Act to restructure their employee health insurance plans, it conflicts with ERISA’s goal of permitting uniform nationwide administration of these plans,” the appeals court concluded in affirming a lower court decision that was issued last July.

Finding the Act would ultimately force employers to restructure their employee benefit plans, the appeals court also rejected the state’s attempt to characterize the law as merely imposing a payroll tax on covered employers with the option of a credit against that tax for their healthcare spending. According to the state, revenue from the tax could help offset costs of its Medicaid program for covering uninsured workers. But the appeals court disagreed, noting that no reasonable employer would opt to pay the state a sum of money rather than increase the healthcare benefits it provides its employees. “In effect, the only rational choice employers have under the Fair Share Act is to structure their ERISA healthcare benefit plans so as to meet the minimum spending threshold,” the appeals court noted. Thus, the Act “has an obvious ‘connection with’ employee benefit plans and so is preempted by ERISA,” the appeals court held. The appeals court also found significant that other states and local governments had adopted or were considering healthcare spending mandates that would clash with Maryland’s Act, which would ultimately force a national company like Wal-Mart to tailor its healthcare benefit plans for specific areas of the country contrary to the uniformity envisioned by ERISA.

A dissenting opinion emphasized that the Act gave covered employers the option of paying an assessment into a state fund that would then be used to support Maryland’s
Medicaid program. “Thus, the Act offers a means of compliance that does not impact ERISA plans, and is not preempted,” the dissent contended. Retail Indus. Leaders Ass ’n v. Fielder, No. 06-1840 (4th Cir. Jan. 17, 2006).

On April 16, 2007, the Maryland Attorney General’s Office said it would not seek Supreme Court review of the Fair Share law. Given the broad preemptive scope courts accord to ERISA, “[w]e believe that seeking further review would not be successful,” said AG Douglas F. Gansler in a statement.

**U.S. Court In Ohio Finds ERISA Does Not Preempt Hospital’s State Law Claims Against Plan Administrator**

A hospital’s claims against a plan administrator alleging violations of Ohio’s direct pay and prompt pay statutes are not preempted by the Employee Retirement Income Security Act (ERISA), a federal district court in that state ruled August 7. Miami Valley Hospital (hospital) provided to Thomas Griffith, on an emergency basis, medically necessary hospital services. At the time of admission, Griffith signed a contract that assigned any insurance benefits he had to the hospital. Community Insurance Co., the plan administrator for the ERISA-governed plan that provided Griffith coverage, authorized the hospital to provide medically necessary care. The hospital notified Community Insurance of Griffith’s assignment and submitted its bill for $23,455.39. Community Insurance sent a check for $3,869.97 directly to Griffith, and provided no notice to the hospital that it was not going to pay the remaining balance to the hospital or that it was denying the hospital’s claim entirely. Griffith failed to remit to the hospital any amount of the check he received from Community Insurance.

The hospital claimed that Community Insurance had violated two specific state statutes, Ohio Rev. Code Ann. §§ 3901.385 and 3901.386, which require third-party payors to honor a validly executed assignment of benefits with a hospital for medically necessary hospital services provided on an emergency basis, and prohibit such payors from unfairly delaying the processing of a claim for healthcare services rendered. In addition, the hospital asserted that Community Insurance had violated Ohio’s prompt-pay statute, Ohio Rev. Code Ann. § 3901.381.

The U.S. District Court for the Southern District of Ohio held ERISA did not completely preempt the hospital’s claims, and granted the hospital’s request to remand the case to state court. The district court pointed out the hospital was not suing as Griffith’s assignee and that its claims were not derivative of his ERISA rights, which had already been determined by Community Insurance’s payment of benefits to him. The hospital’s claim against Community Insurance based on violations of Ohio’s prompt-pay statute was independent of the ERISA plan, and therefore was not preempted by the federal statute, the court concluded. Finally, the district court found that the hospital’s common law estoppel claim against Community Insurance also was not completely preempted by ERISA because the hospital did not seek to stand in the patient's shoes. The court acknowledged, however, that this claim could trigger a conflict preemption analysis under ERISA if it was determined that the claim substantially implicated plan

**Fifth Circuit Holds ERISA Does Not Preempt Louisiana Assignment Statute**

The Employee Retirement Income Security Act (ERISA) does not preempt a Louisiana statute requiring insurers to honor patient benefit assignments, the Fifth Circuit ruled August 16, 2006. Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana (Blue Cross) insures and administers various ERISA-governed employee welfare benefit plans. In the absence of a specific contract with a healthcare provider for direct payment, the plans' terms require that Blue Cross pay benefits directly to the subscriber and not recognize a patient's attempt to assign benefits to a provider. The Louisiana Assignment Statute, La. Rev. Stat. § 40:2010, requires insurers to honor patient benefit assignments even when the insurer has no agreement for direct payment with the provider receiving the assignment. Facing potential actions for violating state law, Blue Cross sought declaratory relief in federal district court against defendants Rapides Healthcare System and the state of Louisiana (defendants), contending that ERISA preempts § 40:2010.

The Fifth Circuit concluded that the state assignment statute was not preempted as being in conflict with ERISA’s exclusive enforcement mechanism. The appeals court distinguished the instant action from the U.S. Supreme Court’s decision in *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004), on which Blue Cross relied in arguing that the assignment statute created a “separate vehicle” for asserting benefits claims thus duplicating or supplanting ERISA’s exclusive enforcement scheme. According to the appeals court, the Texas law at issue in *Davila* was preempted largely because it involved a specific enforcement provision under ERISA regarding the denial of benefits. By contrast, ERISA is silent about the assignability of employee welfare benefits, the appeals court said.

Next, the appeals court held the assignment statute was not preempted under ERISA § 514 as a statute that “relates to” an employee welfare plan. After examining Supreme Court precedent on this issue, the appeals court determined that the state law did not “refer to” an ERISA plan because it applied to a spectrum of entities obligated to reimburse individuals for hospital charges. The appeals court also concluded that the assignment statute did not have an impermissible “connection with” ERISA plans. In so holding, the appeals court considered that the assignment statute operates to allow the plan participant to exercise their free will, which “is consistent with ERISA’s choice of beneficiary.”

The Fifth Circuit acknowledged that other federal appeals courts (the Eighth and Tenth Circuits) have concluded that ERISA preempts similar assignment statutes, but added that neither of those decisions “operated with the starting assumption that Congress did not intend to preempt state law in an area of traditional state regulation” as articulated by intervening Supreme Court precedent. *Louisiana Health Serv. & Indemnity Co. v. Rapides Healthcare Sys.*, No. 04-31114 (5th Cir. Aug. 16, 2006).
D.C. Circuit Says Insureds Not Entitled To “Make Whole” Relief From HMO’s Subrogation Claim

Participants in a health plan governed by the Employee Retirement Income Security Act (ERISA) could not avoid their insurer’s subrogation claim on a third-party tort recovery based on the “make whole” doctrine, the D.C. Circuit held August 29, 2006. Affirming the district court’s ruling, the appeals court held that the “make whole” doctrine did not apply here because of the unambiguous subrogation requirement in the ERISA plan at issue. Plaintiffs William and Judith Moore purchased a group health benefit plan from BlueCross/Blue Shield and its subsidiary, CapitalCare, Inc. (collectively CC/BCBS). Plaintiffs' daughter Alistaire sustained massive brain injury in a car crash and incurred substantial medical expenses. After several years disputing payment of her bills, plaintiffs sued CC/BCBS under § 502(a)(1)(B) of ERISA for unpaid benefits allegedly due under the plan. CC/BCBS subsequently learned that Alistaire had obtained a $1.3 million settlement from a personal injury action against a third party. CC/BCBS asserted a subrogation claim against plaintiffs and a third-party complaint against Alistaire and the irrevocable trust that held the settlement proceeds.

The D.C. Circuit affirmed the district court’s order granting CC/BCBS an equitable lien on Alistaire’s third-party recovery. Plaintiffs’ conceded on appeal before the D.C. Circuit that the Supreme Court’s recent decision in Sereboff v. Mid Atlantic Med. Servs., LLC, 126 S. Ct. 1869 (2006), made clear that “where the fund is identifiable, the remedy is equitable.” While Alistaire’s settlement did not fully compensate her for her injuries, the appeals court said it did not need to decide whether to adopt the make whole doctrine as the default rule because in this case “the ERISA plan unambiguously establishes a plan priority to any third party recovery the beneficiary obtains regardless whether the beneficiary has been made whole by the recovery.” Moore v. CapitalCare, Inc., No. 04-7121, 04-7122 (D.C. Aug. 29, 2006).

U.S. Court In Utah Finds Healthcare Provider’s State Law Claims Against Insurer Not Preempted By ERISA

The Employee Retirement Income Security Act (ERISA) does not preempt a healthcare provider’s breach-of-contract and other state common law claims alleged in an action seeking to recover promised payment from a third-party insurance carrier for medical treatment provided to a patient covered by an ERISA-governed employee benefits plan, a federal district court in Utah ruled September 6. As an employee of Wal-Mart, Jason McBride was covered under its benefits plan, which was administered by BC Life & Health Insurance Company. McBride sought treatment at St. Mark’s Hospital (St. Mark’s), owned and operated by Northern Utah Healthcare Corp. (Northern), for an elective surgery to treat an aortic valve disorder. Before the surgery, St. Mark’s called BC to confirm that the surgery and related expenses would be covered by McBride’s plan. According to St. Mark’s, these calls led them to believe that all qualifying expenses would be paid because McBride’s out-of-pocket and deductible obligations were believed to have been met.

Once the surgery was completed, St. Mark’s submitted three separate claims to BC for $3,789.97, $10,232.45, and $43,369.49. After paying the first two claims, BC refused to

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pay the third claim, indicating that McBride’s benefit cap had been exceeded. At this time, St. Mark’s discovered that, under McBride’s insurance coverage, he was entitled to qualifying expenses up to 100% “of the plan’s maximum benefit” of $25,000. Northern sued BC alleging state common law causes of action: breach of contract, promissory estoppel, and negligent misrepresentation.

BC attempted to remove the case to federal court based on ERISA preemption. The U.S. District court for the District of Utah concluded that ERISA’s preemptive provision did not reach the claims asserted in this case. “In order to warrant a finding that an employee benefit plan does not ‘relate to’ ERISA, courts have ruled that ERISA’s broad preemption scope does not reach independent claims based on state-common law,” the district court explained. In addition, courts in the Fifth, Ninth, and Eleventh Circuits have determined that a third-party healthcare provider, who relies to its detriment on the misrepresentation of an insurer, is an outside party to an ERISA plan, the court pointed out. The court further explained that an action brought by a healthcare provider to recover promised payment from an insurance carrier is distinct from an action brought by a plan participant against the insurer seeking recovery of benefits due under the terms of the insurance plan. *Northern Utah Healthcare Corp. v. BC Life & Health Ins. Co.*, No. 2:06CV077JTG (D. Utah Sept. 6, 2006).

**Fourth Circuit Rules ERISA Plan Must Pay For Cochlear Implant, But Not Attorneys’ Fees**

The Fourth Circuit ruled October 23, 2006 that an insurance plan administrator abused its discretion under the Employee Retirement Income Security Act (ERISA) when it denied coverage for an insured’s cochlear implant, but that the plan was not liable to the insured for attorneys’ fees. Carolyn L. McKenzie suffered a profound hearing loss in both ears. Her physician sought authorization for a cochlear implant from McKenzie’s employer’s ERISA plan, Carolina Care Plan (CCP). CCP denied the request in accordance with plan language excluding coverage for “items sought for “comfort or convenience,” specifically, “devices and computers to assist in communications and speech.” McKenzie sued in federal district court. The district court ruled that CCP abused its discretion and ordered CCP to cover the implant and pay attorneys’ fees.

The Fourth Circuit first said the ERISA administrator’s decision was entitled to less deference here, noting “[o]ver time, a predilection to deny coverage pays well, even for inexpensive and infrequent treatments.” The plan excluded coverage for “devices” designed to “assist with communication and speech.” The appeals court reasoned that this language could “easily be read” to exclude devices that assist both communication and speech, not devices like cochlear implants that do not directly aid speech. Because the plan language is ambiguous, it should be construed against CCP as the drafting party, according to the appeals court. This construction is appropriate because it shifts the cost of ambiguity to the party best-positioned to both avoid it (by writing a clear plan) and bear it (by spreading it across all policy-holders.)

The appeals court went on to find that awarding McKenzie attorneys’ fees was not warranted. Although CCP could easily pay the fees, there was no evidence of bad faith
associated with the denial. If attorneys’ fees were awarded in this case, then “every time a claimant prevailed in overturning an administrator’s decision denying ERISA benefits, the claimant would be entitled to attorneys’ fees,” the appeals court reasoned. CarolinaCare Plan v. McKenzie, No. 05-2060 (4th Cir. Oct. 23, 2006).

**Tenth Circuit Rules ERISA Preempts Insured’s Claims Of Injury From Step Drug And Does Not Provide Equitable Relief**

Not only does the Employee Retirement Income Security Act (ERISA) preempt an insured’s claims that his insurer injured him by requiring his physician to prescribe a “step drug,” but the federal statute does not provide any alternate equitable relief, the Tenth Circuit ruled October 31, 2006. James D. Lind was diagnosed with multiple sclerosis. Lind’s physician prescribed a three-drug regime that successfully reversed Lind’s symptoms, but several months later his pharmacist told him that Aetna would only authorize continued payment for the prescribed medication after he tried a step drug. Lind’s symptoms returned and were irreversible, making him disabled and unable to work.

On appeal, the Tenth Circuit characterized Lind as part of a “long—and growing—line of plaintiffs who find themselves squeezed between the broad preemptive sweep of ERISA and narrow construction of remedies under the Act itself.” As the Supreme Court found in *Aetna Health, Inc., v. Davila*, 542 U.S. 200 (2004), preemption occurs even where the elements of the state law claim do not duplicate the elements of an ERISA claim. In *Davila*, the Court found ERISA preemption based on “similar claims and nearly identical facts,” according to the Tenth Circuit. The plaintiff in that case suffered a severe reaction after he tried a step drug upon Aetna’s refusal to authorize a prescribed medication. Lind attempted to distinguish his case by arguing that Aetna acted outside of the plan because it did not follow appropriate notification procedures when it declined to renew his medication. “That, however, is a distinction without a difference,” the appeals court ruled. ERISA preempts claims based on denial of coverage whether the denial is proper or improper under the plan’s rules.

Nor did the doctrine of respondeat superior save Lind’s claims from preemption, the appeals court determined. Although an Aetna employee determined that Lind should be prescribed the step drug, this was not a case in which a health maintenance organization directly provided medical services, rather than simply arranging treatment, and negligent care was imputed to the plan. Lind’s claim involved administration of benefits and is therefore preempted by ERISA, the appeals court concluded. Turning to whether the trial court should have permitted Lind to amend his complaint to include ERISA claims, the Tenth Circuit analyzed whether Lind was eligible for equitable relief under ERISA. Here, Lind did not seek the restoration of particular funds, such as reimbursement of funds or premiums. Because Lind’s claims were legal, rather than equitable, they were not actionable under ERISA, the appeals court concluded. *Lind v. Aetna Health, Inc.*, No. 05-5055 (10th Cir. Oct. 31, 2006).
U.S. Court In Washington Rules “Make Whole” Doctrine Precludes ERISA Plan From Recovering Accident Settlement Funds

The U.S. District Court for the Western District of Washington ruled November 8, 2006 that the “make whole” doctrine prevented an Employee Retirement Income Security Act (ERISA) plan from recovering expenditures for an automobile accident victim’s healthcare from an underinsured motorist settlement award. Sarah Block was seriously injured in an automobile accident. She was insured by Providence Health System (Providence), an ERISA plan, which paid $801,664 for her care, with projections of additional costs reaching $1 million. Another insurer agreed to settle Block’s underinsured motorist claims for more than $2 million. Block’s guardian placed the settlement funds in a Special Needs Trust, despite Providence’s intervention to protect its interest in the funds. Providence sued the guardian and trustee (defendants) to establish a constructive trust or equitable lien over the funds, in accordance with ERISA.

The district court first concluded that it had jurisdiction because the suit targeted “readily traceable” funds and did not seek to impose personal liability on the trustee. Turning to defendants’ argument that Providence was not entitled to reimbursement because the settlement funds were not adequate to make Block whole, the court examined whether ERISA preempts the make whole doctrine. In the Ninth Circuit, federal common law dictates that an insured be made whole before an insurer can enforce its right to subrogation, the court established. Federal common law only applies where the ERISA plan itself is silent, however. In this case, plan language described duplication of benefits from other sources, third-party liability, and recovery of excess payments, but “[n]owhere in the plan language is there a suggestion, let alone a clear statement, that a plan beneficiary is signing away his or her make whole right,” the court determined. Contrasting other cases in which plan language expressly or clearly addressed the make whole doctrine, the court ruled that, in this case, plan silence invoked federal common law gap filler provisions, including the make whole doctrine. *Providence Health Sys. v. Bush*, No. C06-5268 RBL (W.D. Wash. Nov. 8, 2006).

U.S. Court In New York Rules ERISA Plan Cannot Seek Recovery Of Overpayment From Hospital

The U.S. District Court for the Eastern District of New York ruled November 16, 2006 that the representatives of a benefits plan governed by the Employee Retirement Income Security Act (ERISA) cannot recover overpayments from a hospital because ERISA provides for only equitable, not compensatory relief. Health Fund 917 (the Fund) is a self-insured multi-employer benefit plan. In 2001, a Fund plan participant was admitted to Trinitas Hospital through the emergency room. Trinitas contacted the Fund for pre-certification of inpatient treatment costs. The Fund pre-certified a total charge of $16,500. Trinitas later billed the Fund $68,553.51, which the Fund reduced to the in-network price of $55,290.13, then paid. Upon discovering the $38,790.13 difference between the pre-approved amount and the paid amount, the Fund attempted to recover the funds from Trinitas. Trinitas refused to pay. The Fund’s representatives filed an ERISA claim against Trinitas in federal court. Trinitas sought summary judgment on the ground that ERISA provides only equitable remedies, not recovery of overpayments.
The court found the remedy sought by the Fund was not “appropriate equitable relief” under § 502(a)(3) of ERISA. The Fund argued that it was entitled to restitution because it could identify specific checks paid to Trinitas, as well as the bank accounts into which Trinitas deposited the checks, making the funds traceable with enough particularity to establish an equitable lien on the funds. But the federal district court disagreed, finding that the Fund’s interpretation “would encompass nearly every payment between two parties in which the source and destination of the funds paid could be identified.” *Vacca v. Trinitas Hosp.*, Nov. 05-CV-0368 (JFB)(AKT) (E.D.N.Y. Nov. 14, 2006).

**U.S. Court In Texas Finds ERISA Preempts Infusion Therapy Provider’s Claim Alleging Aetna Violated State Any Willing Provider Law**

The Employee Retirement Income Security Act (ERISA) completely preempts a home-infusion chemotherapy provider’s claim that Aetna Health Inc. violated Texas’ Any Willing Provider statute by refusing to pay for services that it rendered as an out-of-network provider to an Aetna plan participant, the U.S. District Court for the Southern District of Texas ruled December 26, 2006. Quality Infusion Care Inc. (Quality Infusion) first filed its lawsuit in Texas state court, alleging damages from Aetna’s refusal to pay for $71,850 in at-home chemotherapy infusion services provided to an Aetna health maintenance organization (HMO) participant with breast cancer. Aetna had denied Quality Infusion’s reimbursement claim because of its policy of not covering out-of-network medical expenses when the same services were available from participating providers. Quality Infusion alleged in its lawsuit that Aetna’s refusal to pay for the services violated the Texas Any Willing Provider statute, Tex. Ins. Code Ann. art. 21.52B, which prohibits a health insurance policy or managed care plan from denying a medical or pharmacy provider’s right to participate in the plan if the provider meets all the terms and requirements that apply to participating providers.

Aetna removed the case to federal district court, asserting that ERISA § 502 completely preempted Quality Infusion’s state law claim. Quality Infusion moved for remand. The court refused to remand the case, holding ERISA preempted Quality Infusion’s claim under the Supreme Court’s 2004 decision in *Aetna Health Inc. v. Davila*, 542 U.S. 2000 (2004). “Under *Davila*, complete preemption applies to Quality Infusion’s claim,” the court said, adding that “[t]his suit, brought under the Texas Any Willing Provider statute and the ERISA plan, is a suit for benefits due under an ERISA Plan and could have been brought under ERISA.”

Turning to Aetna’s motion for summary judgment, the district court concluded that, “as a matter of law, Quality Infusion could not show a violation of the Texas Any Willing Provider statute that would provide a basis for recovery, either under the plan and that statute or under ERISA.” Quality Infusion’s claim under ERISA “depends on its claim that under the Texas Any Willing Provider statute, Aetna was required to pay for non-network services despite the Plan provision excluding coverage for out-of-network services,” the court said. The court agreed with Aetna’s argument that Quality Infusion could not as a matter of law show a violation of the law because it “does not cover a participant in a managed care plan, such as the participant in the Plan at issue who

**U.S. Court In Florida Finds Medical Provider Lacks Standing Under ERISA To Bring State Law Claims Against Health Insurer**

Because a plaintiff-medical provider suing a health insurer for state law claims did not have standing under the Employee Retirement Income Security Act (ERISA) as a participant or beneficiary, ERISA preemption did not apply and the case must be remanded to state court, a federal district court in Florida ruled December 28, 2006. In reaching this conclusion, the U.S. District Court for the Southern District of Florida relied on *Hobbs v. Blue Cross Blue Shield of Alabama*, 276 F.3d 1236 (11th Cir. 2001), in which the Eleventh Circuit held that, in some cases, a healthcare provider’s derivative standing to sue under ERISA may be allowed, but only “when the healthcare provider had obtained a written assignment of claims from a patient who had standing to sue under ERISA as a ‘beneficiary’ or ‘participant.’” The district court found defendants here had “not met their burden of showing the written assignments of claims from the ERISA beneficiaries to Plaintiff provider,” the district court said.

In 2003, plaintiff Riverside Medical Associates (Riverside), doing business as Ruggiero Sports Medicine and Injury Institute, entered into contracts with various health insurance companies, including several owned and operated by defendant, Humana, Inc. Under these contracts, Riverside agreed to provide specialist physician services to the Humana entities’ members, in exchange for which Humana would pay Riverside 70% of the Medicare fee schedule or physician’s usual and customary charges, whichever was less. Subsequently, in June 2004, Riverside entered into a participating provider agreement with defendant American WholeHealth Networks, Inc. (AWHN), and, under the terms of that agreement, gave a 15% discount off its regular rates to AWHN’s members. At the beginning of 2006, both Humana and AWHN began paying current claims, including any remaining from 2005, at a capitation rate of less than $10 per visit.

Riverside sued Humana and AWHN in state court for breach of contract, fraud, and state RICO claims. Humana and AWHN alleged that the insurance contracts at issue had expired in July 2005, and that from that point forward, it had treated and reimbursed Riverside as a nonparticipating provider. Humana and AWHN removed the case to federal court, arguing that because the contracts at issue were employer provided health benefits they were subject to ERISA. Riverside moved to remand to state court, arguing that its lawsuit was based on its independent contract with defendants, and that it lacked standing under ERISA as a participant or beneficiary.

**Tenth Circuit Remands ERISA Suit Against CEO To Determine Whether Failure To Act Breached Fiduciary Duty**

A company CEO who also was a fiduciary of its self-funded medical benefit plan did not breach his fiduciary duties under the Employee Retirement Income Security Act (ERISA) in making funding allocations that adversely affected the plan, the Tenth Circuit ruled January 17, 2007. According to the appeals court, these decisions were the result of business judgment in his capacity as company CEO and therefore fell outside of ERISA fiduciary obligations. At the same time, the appeals court held that the district court, which granted summary judgment in the CEO’s favor, failed to address other allegations asserted by the employee-plan participants that the CEO breached his fiduciary duty in failing to take any action on the plan’s behalf. The appeals court therefore remanded the action to the district court to consider those claims.

Terrence D. Holdeman brought a class action on behalf of himself and other employees of the State Line Hotel and Silver Smith Casino, which is owned and operated by State Line Hotel, Inc. (State Line), against various officers and directors of State Line, including President and CEO Michael Devine, for alleged violations of ERISA. Plaintiffs participated in an ERISA-governed self-funded employee benefit plan sponsored and funded by State Line. According to plaintiffs, State Line failed to adequately fund the plan and they were left with outstanding medical bills totaling nearly $1 million when the company filed for bankruptcy. In particular, plaintiffs noted that Devine, when State Line was struggling financially, made a number of distributions to its owners totaling over $1.2 million.

The Tenth Circuit concluded that Devine was “wearing his CEO hat” when making the allocation-of-funding decisions at issue and therefore did not breach his fiduciary duties to the plan. But the appeals court found the district court failed to address all of plaintiffs’ allegations against Devine—namely, that in his role as fiduciary he failed to take any steps to address how best to manage the plan and its assets. Specifically, the district court on remand should consider plaintiffs’ claims that Devine should have resigned as fiduciary so that someone without a conflict of interest could be appointed; hired outside counsel for the plan; informed the beneficiaries that the plan was not a reliable source of healthcare benefits and they might need to seek alternative medical coverage; and considered or threatened suing State Line on behalf of the Plan for unpaid contributions. *Holdeman v. Devine*, No. 05-4302 (10th Cir. Jan. 17, 2007).

**Seventh Circuit Rejects Breach Of Fiduciary Duty Claims Against PBM**

A pharmacy benefit manager (PBM) was not acting as a fiduciary under the Employee Retirement Income Security Act (ERISA) with respect to drug price negotiation and formulary management services it provided to a fund that offered healthcare benefits to members of a labor union, the Seventh Circuit ruled January 19, 2007. The appeals court found the PBM under its contracts with the fund was not required to pass along all the savings it realized in negotiating prices and rebates with drug manufacturers nor was it given ultimate discretion to administer formulary and drug-switching programs.
The Chicago District Council of Carpenters Welfare Fund (Carpenters) sued Caremark Inc. and its parent company Caremark Rx, Inc. for breach of fiduciary duties under ERISA. Carpenters had entered into contracts with Caremark in 1996, 1999, and 2003 to manage the prescription drug benefit provided to union members. The contracts expressly stated that Caremark was not an ERISA fiduciary and that Carpenters had the sole authority to control and administer the plan. According to Carpenters, despite the contract language to the contrary, Caremark had discretion to negotiate with drug retailers over drug prices; to negotiate with drug manufacturers over rebates and other discounts; to manage the formulary program; and to manage the drug-switching program (i.e. trying to persuade prescribers to switch a prescription to a therapeutically similar, but lower cost, drug). Thus, giving rise to ERISA fiduciary duties. Carpenters contended Caremark breached its fiduciary duties by charging Carpenters a higher price than the PBM negotiated with retail pharmacies and by choosing more expensive drugs for the formulary so it could obtain additional rebates.

The Seventh Circuit rejected Carpenters’ contention that Caremark had discretionary authority to negotiate the prices Carpenters paid for drugs obtained by plan members. Reviewing the three contracts, the appeals court found instead that Carpenters agreed to pay set prices for the drugs, and any prices negotiated with Caremark were at arm’s length. Moreover, nothing in the contracts required Caremark to pass along all of the savings it negotiated with drug retailers, the appeals court said. Carpenters got the benefit of Caremark’s market power when the PBM negotiated with retailers, and Caremark made money by passing on some of those savings to clients while keeping the difference, the appeals court observed.

In addition, the contracts did not require or authorize Caremark to enter into agreements on behalf of Carpenters with drug manufacturers. Rather, Caremark had a non-discretionary duty to pay a fixed rebate to Carpenters, not to pass on 100% of the rebates it received from manufacturers. Finally, the appeals court said while Caremark acted like a claims administrator with respect to the formulary and drug switching programs, Carpenters retained final authority over the content of the formulary and the administration of the drug-switching programs. Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., No. 05-3476 (7th Cir. Jan. 19, 2006).

U.S. Court In Michigan Finds Plan Member Has Standing To Sue Under ERISA Even Without Proof Of Personal Injury

A federal trial court in Michigan found January 25, 2007 that a plaintiff who is a member of an Employee Retirement Income Security Act (ERISA) plan has standing to sue under the statute for injuries sustained by the plan regardless of whether the plaintiff can prove he personally suffered an injury. Plaintiff Anthony Deluca is covered as a dependant by a self-funded ERISA health benefit plan sponsored and maintained by his wife’s employer Flagstar Bank. Blue Cross Blue Shield Michigan (BCBSM) administers the plan. BCBSM also is the parent company of a health maintenance organization called Blue Care Network (BCN). According to the court, BCBSM negotiated agreements with various hospitals throughout Michigan regarding the rates BCBSM would pay for medical services rendered to both ERISA plan and BCN participants and beneficiaries.
Plaintiff filed a putative class action alleging that in its agreements with Michigan hospitals, BCBSM had negotiated rates more favorable to its BCN than to the ERISA plans it administers. According to plaintiff, this conduct constituted a breach of §§ 404(a)(1) and 406(b) of ERISA. As a result, plaintiff claimed that the plans paid excessive reimbursement rates to Michigan hospitals and that participants and beneficiaries paid excessive contributions, deductibles, and/or co-payments. BCBSM moved to dismiss.

After first finding that plaintiff had standing under both ERISA and the U.S. Constitution to pursue the claim, the U.S. District Court for the Eastern District of Michigan denied BCBSM’s motion to dismiss. The court reviewed several cases addressing standing to sue under ERISA and noted that, ERISA grants four plaintiffs “the right to sue a fiduciary of an ERISA plan, on behalf of the plan, for injuries incurred by the plan due to a breach of the fiduciary's ERISA duties, regardless of whether the plaintiff individually suffered any injury as a result of the breach.” Thus, the court found that plaintiff had standing regardless of whether he could show that he personally suffered or would suffer a concrete injury as a result of BCBSM’s conduct. Deluca v. Blue Cross Blue Shield of Mich., No. 06-12552 (E.D. Mich. Jan. 25, 2007).

Third Circuit Finds ERISA Preempts Lawsuit Against Insurer For Failing To Timely Approve Medical Treatment
The Employee Retirement Income Security Act (ERISA) preempts a lawsuit brought in state court by a woman who claimed that she sustained lupus-related multi-organ system failure because her health plan failed to approve her medical treatment in a timely manner, the Third Circuit ruled March 1, 2007 in an unpublished decision. Plaintiff Maureen Kurtek was diagnosed with lupus in 1989 and began receiving intravenous immunoglobulin (IV IG) therapy in 1998. Kurtek underwent IV IG therapy in 1998, 1999, and 2002, and all three of these treatments were paid for by her insurance plan at the time, Pennsylvania Blue Cross Blue Shield. In January 2003, defendant Capital Blue Cross (Capital) became Kurtek’s insurance provider. Kurtek sought reauthorization for another recommended IV IG treatment, but a Capital representative told her the procedure appeared to be experimental and that he would contact her when a preauthorization decision had been made. Kurtek made several follow-up calls in the next few weeks, but was told each time that the matter was being researched. A month later, Kurtek suffered multi-organ system failure.

Kurtek and her husband sued Capital in Pennsylvania state court asserting that her medical complications would not have occurred had Capital granted authorization for the IV IG therapy in a timely manner. Capital removed the case to federal court, arguing ERISA preemption, and then moved to dismiss. Kurtek moved to remand back to state court. The U.S. District Court for the Middle District of Pennsylvania agreed with Capital and dismissed the lawsuit.

Affirming, a three-judge panel of the Third Circuit noted its previous holding that “claims that merely attack the quality of benefits do not fall within the scope of [ERISA] §
502(a)’s enforcement provisions and are not preempted, whereas claims challenging the quantum of benefits due under an ERISA-regulated plan are completely preempted under § 502(a)’s civil enforcement scheme.” The appeals court rejected Kurtek’s argument that Capital’s delay in approving her IV IG therapy was a medical decision affecting the quality of the benefits she received. The appeals court reasoned that Kurtek could have challenged Capital’s decision by filing a claim under ERISA § 502(a)(1)(b) to recover benefits due to her under the terms of her plan, and therefore such claim was completely preempted by ERISA.

Kurtek argued that she could not have brought a claim under § 502(a) because she challenge the delayed approval of a medical procedure, and not a denial of benefits. Rejecting this argument, the appeals court noted that Kurtek “could have sought an injunction under § 502(a) to accelerate the approval of the procedure or could have paid for the IV IG therapy and then sought reimbursement.” The appeals court also noted that it had rejected a similar argument in Pryzbowski v. U.S. Healthcare, Inc., 245 F.3d 266 (3d Cir. 2001), in which it noted that although certain delays, such as a physician waiting to perform “urgent surgery on a patient whose appendix was about to rupture,” pertain to quality of care, “a claim alleging that an HMO declined to approve certain requested medical services or treatment on the ground that they were not covered under the plan would manifestly be one regarding the proper administration of benefits,” and therefore would be preempted by ERISA. Kurtek v. Capital Blue Cross, No. 05-4325 (3d Cir. Mar. 1, 2007) (unpublished).

Third Circuit Holds Fiduciary Exception To Attorney-Client Privilege Did Not Apply To Health Insurer Sued Under ERISA

The fiduciary exception to the attorney-client privilege did not apply to defendant-health insurers in a beneficiary’s lawsuit brought under the Employee Retirement Income Security Act (ERISA), the Third Circuit ruled April 2, 2007 in vacating a lower court’s decision ordering disclosure of certain otherwise privileged documents. On an issue of first impression in the Third Circuit, the appeals court declined to reject or adopt the fiduciary exception generally, finding instead that it was inapplicable to the ERISA fiduciaries (i.e. the health insurers) in this case.

Plaintiffs Zev and Linda Wachtel were participants in a point-of-service (POS) plan insured by Health Net of New Jersey Inc., a subsidiary of Health Net, Inc. They sued Health Net and its subsidiaries in the U.S. District Court for the District of New Jersey alleging the insurers breached their fiduciary duties under ERISA by using outdated data to calculate participants’ copayments for out-of-network services. During discovery, Health Net claimed attorney-client privilege and work product protections for numerous documents sought by plaintiffs. A Special Master appointed by the court concluded that, while the Third Circuit had not yet spoken on the issue, the fiduciary exception applied and that the documents at issue must be disclosed. The district court agreed.

Under this exception, certain fiduciaries who obtain legal advice in the course of their fiduciary duties may not assert the attorney-client privilege against their beneficiaries. Vacating the district court’s order, the Third Circuit acknowledged that the fiduciary
exception has been adopted by a number of other federal appeals courts, but noted that “no court has considered whether the fiduciary exception to the federal attorney-client privilege applies with equal force to all fiduciaries under ERISA.” The appeals court concluded that the fiduciary exception did not apply to an insurer like Health Net because the plaintiff-beneficiaries here “are not the ‘real’ clients obtaining legal representation” and because its disclosure obligations are more limited than those imposed on trustees under the common law. The appeals court found a number of differences between insurance company fiduciaries and other ERISA fiduciaries to whom the fiduciary exception has been applied.

Unlike other ERISA fiduciaries, insurance companies providing insurance policies are not required to hold plan assets in trust, which demonstrates that Health Net had “a substantial and legitimate interest in the management of its assets—even while it engages in fiduciary acts.” In addition to this factor, the Third Circuit also observed that Health Net had conflicting interests regarding profits, had the additional conflict of handling multiple ERISA benefit plans at once, and paid for legal advice using its own assets, not those of its beneficiaries. Taken together, these factors “indicate that an insurer which sells insurance contracts to ERISA-regulated benefit plans is itself the sole and direct client of counsel retained by the insurer, not the mere representative of client-beneficiaries,” the appeals court said.

The appeals court also held the other rationale for the fiduciary exception—the duty to disclose—was not applicable here. While noting that insurers servicing an ERISA plan have some disclosure obligations, the appeals court emphasized that the fiduciary obligations of insurers that contract with ERISA plans are not well-settled at law and that uncertainty in the application of the attorney-client privilege could cause insurer-fiduciaries to reevaluate their relationships with ERISA plans. Wachtel v. Health Net, Inc., No 06-3031/3032 (3d Cir. Apr. 2, 2007).

**FOOD AND DRUG LAW/LIFE SCIENCES**

*Legislative and Other Developments*

**Bush Uses First Veto On Stem Cell Bill**

President George Bush used the first veto of his presidency July 19, 2006 to reject the Stem Cell Research Enhancement Act (H.R. 810), a bill that would have expanded research opportunities on embryonic stem cells. In vetoing the legislation, Bush reiterated his policy of allowing research only on embryonic stem cell lines derived from embryos that have already been destroyed. Under this policy, twenty-one human embryonic stem cell lines are currently in use in research that is eligible for federal funding. The House and Senate were unable to come up with the two-thirds majorities needed to override the veto.

The 110th Congress took up the same measure, with the House passing the stem cell bill (H.R. 3) on January 11, 2007 by a 253-174 margin and the Senate April 11, 2007 clearing it (S. 5) in a 63-34 vote, but still short of the two-thirds majority needed to override a
presidential veto. Following the House passage, the White House Domestic Policy Council released a paper January 9, 2007 arguing that the President’s current policy “has allowed stem cell research to advance in rapid and promising ways . . . without sacrificing the inherent dignity and matchless value of every human life.” The paper also contends that several new discoveries offer promise for developing viable stem cell lines in other ways, including a recent approach discussed in the journal *Nature* in which researchers reported using amniotic fluid as a source of stem cells.

The Senate also on April 11, 2007 passed a more limited stem cell bill, the Hope Offered Through Principled and Ethical Stem Cell Research Act (HOPE Act), by a vote of 70-28. The measure (S.30) does not extend stem cell research as far as S. 5, instead requiring the Department of Health and Human Services Secretary to develop techniques for the isolation, derivation, production, or testing of stem cells, provided that such techniques do not involve: (1) the creation of a human embryo or embryos for research purposes; or (2) the destruction or discarding of, or risk of injury to, a human embryo of embryos other than those that are naturally dead. President Bush has expressed his support for the more conservative HOPE Act, stating that the bill builds on “ethically appropriate research” by encouraging further development of “alternative techniques for producing stem cells without embryo creation or destruction.”

**IOM Issues Recommendations For Improving FDA Post-Market Drug Surveillance**

The Food and Drug Administration’s (FDA's) ability to oversee the safety of prescription drugs after they hit the market is undermined by a number of systemic deficiencies—including chronic under funding, organizational problems, and inadequate data—that require far-reaching changes to address, according to a new report by the Institute of Medicine (IOM) of the National Academies. The IOM report, *The Future of Drug Safety: Action Steps for Congress*, included twenty-five broad recommendations for strengthening the FDA’s post-market drug surveillance capabilities ranging from expanding the agency's regulatory authority and arsenal of enforcement tools to additional labeling requirements for new drugs. For example, the report called for new drugs to carry a special symbol on their labels and promotional materials for two years after they are on the market to alert consumers that there may be uncertainties about a drug’s risks. In addition, direct-to-consumer advertising should be restricted during this time, the report added. The IOM also urged Congress to beef-up both funding and personnel available to the FDA for monitoring new drugs.

In response to the IOM report, the FDA unveiled additional plans for shoring up the agency’s monitoring of prescription drugs over their life cycle. Among the steps the FDA detailed in a report issued January 30, 2007 responding to the IOM's recommendations are plans for a pilot program to profile the safety of newly approved drugs on a regular basis. Based on the pilot, the agency said it would determine whether to extend post-marketing evaluations to all new drugs as suggested by the IOM. The FDA also has agreed to exchange information with the Veterans Health Administration about drugs, vaccines, other biological products, and medical devices as a way to gain insight into safety, effectiveness, and patterns of use.
Under the broad heading of improving communication and information flow, FDA said it is establishing a new advisory committee to evaluate and offer recommendations on the agency’s current communication policies and practices. Other efforts in this area include issuing (in the first quarter of 2007), final guidance on communicating important drug safety information to the public. The FDA did reject, however, the IOM’s recommendation that it post all New Drug Application supplements and assessments of post-market safety studies, saying doing so did not make sense from a resource standpoint.

In terms of operations and management, another overarching area of weakness flagged by the IOM, the FDA said it plans to seek the advice of external management consultants to help devise a strategy for improving its organizational culture.

**President Signs Homeland Security Spending Bill With Drug Importation Provision**

President Bush signed October 4, 2006 the Fiscal Year 2007 Department of Homeland Security appropriations bill (Pub. L. No. 109-295), which contains a provision that would allow individuals to bring Food and Drug Administration-approved drugs over the border from Canada for personal use. The $34.8 billion spending bill (H.R. 5441) passed the House by a 412-6 margin and cleared the Senate by voice vote on September 29, 2006. The drug importation language included in the bill, which reflected a compromise reached by House and Senate negotiators in conference, would allow individuals to “physically transport” non-narcotic prescription drugs from Canada for their personal use, according to a summary of the bill.

**URAC Releases First Draft Standards For Accreditation Of Pharmacy Benefit Managers**

URAC issued October 17, 2006 its “first-ever” draft accreditation standards for pharmacy benefit management companies (PBMs). “The pharmacy benefits management industry recognizes that this is the right time for industry-wide standards,” commented John D. Jones, RPh, JD, vice president of government affairs and pharmacy policy for Prescription Solutions and chairman of URAC’s Pharmacy Benefits Management Advisory Committee. Jones added that “URAC’s PBM accreditation standards will provide a uniform approach that PBM organizations can use to demonstrate best practices across the board.” The draft PBM standards, which are presented in seven modules, address a wide range of PBM industry practices. These modules are: organizational integrity, customer service/communications/disclosure, pharmacy distribution channels, drug use management, formulary development, medication therapy management, and benefit design/administration. The deadline for public comments on the draft standards was December 1.

**FDA Proposes Expanded Access To Experimental Drugs**

The Food and Drug Administration (FDA) would significantly expand access to experimental drugs to patients with no other treatment options under two new proposed rules issued in the December 14, 2006 Federal Register (71 Fed. Reg. 75147, 75168). The proposal would modernize the current rule to include all circumstances under which access to experimental drugs are permitted, including: single patients in non-emergency
and emergency settings; small groups of patients; and larger groups of patients under the Investigational New Drug regulations.

The rules also clarify the circumstances and the costs for which a manufacturer can charge for an experimental drug. Under the rule, such charges are “permissible in a clinical trial only to facilitate development of drugs that promise significant advantages over existing therapies, and might not otherwise be developed because of their high cost,” according to the FDA. In addition, the proposal clarifies that allowing manufacturers to charge for treatment use of an experimental drug is intended to encourage access to drugs that might not be made available unless a manufacturer is able to recover its costs.

**FDA Proposes Boosting User Fees To Fund Post-Market Drug Surveillance, Reviews Of DTC Ads**

The Food and Drug Administration (FDA) proposed January 11, 2007 increasing annual user fees collected from the pharmaceutical industry by $87.4 million to help boost resources available for post-market drug surveillance activities and reviews of direct-to-consumer (DTC) advertisements. The proposal outlines FDA’s recommendations, made in conjunction with industry stakeholders, to Congress for the fourth reauthorization of the Prescription Drug Use Fee Act (PDUFA), which established the user fee program in November 1992. PDUFA programs must be reauthorized by Congress every five years. The user fees collected from the drug industry are used by the agency to supplement its annual appropriations.

FDA said its proposed increase in user fees to $392.8 million annually will “place[] the drug review process on a sound financial footing.” Of the recommended increase, $29.3 million would go to bolstering FDA’s drug safety activities while a drug is on the market, an area that increasingly has come under scrutiny from lawmakers and consumer groups. The proposal also calls for $4.6 million in new user fees and twenty employees to help FDA expand its implementation of guidance for its reviewers and develop other industry guidelines. Another $4 million would be devoted to moving the agency and industry towards an all-electronic environment, FDA said.

The FDA is proposing creating a separate user fee program to collect new fees from companies seeking FDA advisory reviews of their DTC television advertisements. FDA said the remainder of the user fee increase will be used to stabilize PDUFA IV’s financial base line to keep pace with expanding program costs.

**Senate Passes User Fee Reauthorization Bill**

The Senate passed May 9, 2007 by a vote of 93-1 the Food and Drug Administration Revitalization Act (S. 1082), reauthorizing expiring industry user fee programs and adding new measures to reform the Food and Drug Administration’s (FDA’s) post-market drug surveillance function. Senator Bernie Sanders (I-VT) was the sole vote in opposition to the bill.

In addition to the user fee provisions, the behemoth bill requires the Secretary to assess and collect fees for advisory review of direct-to-consumer television advertisements for
prescription drug products. Under the bill, the Secretary must (1) annually set the fee for advisory review based on the number of direct-to-consumer advertisements that the Secretary will review in the next fiscal year; and (2) establish a Direct-to-Consumer Advisory Review Operating Reserve to continue the program in the event the fees collected in any subsequent fiscal year do not generate the fee revenue amount established for that fiscal year. The program would be terminated if the Secretary fails to receive a certain amount of advisory review fees and operating reserve fees.

After a week of lengthy floor debate, the final bill included a number of amendments, including one offered by Senate Finance Committee Chairman Charles Grassley (R-IA) to increase civil monetary penalties for companies that fail to comply with FDA directives. Grassley's amendment, which passed by a vote of 64-30, increases the minimum civil monetary penalty from $10,000 to $250,000 for a drug maker that is knowingly out of compliance. The penalty doubles for every 30-day period of non-compliance up to $2 million.

Another amendment offered by Grassley was narrowly defeated. That amendment would have made the FDA office that studies drugs once they are on the market an equal partner with the FDA office that initially approves drugs for all post-approval decisions related to drug safety, according to Grassley. Although Grassley argued the amendment "was fundamental to reforming and improving the FDA’s performance and ability to monitor the safety of FDA-approved drugs and devices." Senate Health, Education, Labor and Pensions Ranking Member Mike Enzi (R-WY) countered during floor debate that the measure "would add an unnecessary layer of bureaucracy to what we have designed to be a nimble and responsive process to deal with emerging drug safety issues." Ultimately, the amendment was rejected 46-47.

The legislation also includes an amendment offered by Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME) to combat counterfeit prescription drugs. The Senators' other amendment that would have allowed drug importation from Canada was effectively blocked by a competing amendment that would require FDA to certify the safety of all imported drugs. The adopted amendment requires all prescription drugs have a unique serial number within 18 months and requires manufacturers to add counterfeit resistant technologies to all prescription products within 30 months. “The drug companies objected to our bipartisan drug importation amendment because of what they said were concerns about counterfeit drugs. The drug companies will now be required to develop the enhanced safety measures,” said Dorgan.

Senators Debbie Stabenow (D-MI), Trent Lott (R-MS), John Thune (R-SD), Sherrod Brown (D-OH), Herb Kohl (D-WI), Orrin Hatch (R-UT), and Tom Coburn (R-OK) won approval of their amendment that would stop brand name drug companies from filing frivolous petitions that delay market entry of generic drugs. "The delayed access to lower priced generics costs employers, health insurance providers, government health programs and consumers hundreds of millions of dollars," Stabenow said. Stabenow noted that between 2003 and 2006, 23 of 25 petitions filed by brand drug companies requesting delay or denial of approval of a competing generic drug were found to be frivolous.
These petitions, however, “still served to restrict competition from lower cost drugs, for
days, weeks, months and in some cases years,” Stabenow said.

**FDA Commissioner Says Agency Did Not Rush To Approve Antibiotic Ketek**

Food and Drug Administration (FDA) Commissioner Andrew C. von Eschenbach, M.D.
defended March 22, 2007 the agency’s approval of the antibiotic Ketek, saying despite
having to disregard one safety study “the product was otherwise shown to be safe and
effective.” Von Eschenbach testified at a hearing before the House Energy and
Commerce Subcommittee on Oversight and Investigations that focused on the adequacy
of the nation’s drug supply. Von Eschenbach said he welcomed the opportunity to discuss
Ketek’s approval following label changes announced in February 2007 that narrowed the
usage of the drug from three to one approved indication.

Ketek (telithromycin), which is manufactured by Sanofi-Aventis, will remain on the
market for treatment of community acquired pneumonia of mild to moderate severity, but
its label must carry a “black box” warning that it is contraindicated in certain instances.
“Notwithstanding the great need for new antibiotics, and contrary to some of the
misimpressions that have circulated publicly, FDA did not rush to approve Ketek. The
agency approved Ketek after three cycles of rigorous scientific review,” von Eschenbach
asserted. At an earlier hearing, Senator Charles Grassley (R-IA) said his investigation of
the drug revealed that "FDA gave its advisory committee questionable data on Ketek and
did not tell them about problems with the data." Grassley also said FDA approved Ketek
without much safety data from the U.S., but instead relied almost exclusively on foreign,
post-marketing safety data.

**Survey Finds Most Physicians Have Some Ties To Drug Industry**

Most physicians (94%) in a recent survey reported some type of relationship with the
drug industry, according to an article appearing in the *New England Journal of Medicine*.
The national survey involved 3,167 physicians, with a little over a half of them
responding, in six specialties (anesthesiology, cardiology, family practice, general
surgery, internal medicine, and pediatrics). The survey was conducted in late 2003 and
early 2004. Overall, researchers conducting the survey concluded that relationships
between physicians and pharmaceutical companies are still common place, although the
extent and nature of these relationships vary depending on specialty, practice type, and
professional activity. According to the article, most of these relationships involved
receiving food in the workplace (83%) or receiving drug samples (78%). Thirty-five
percent of survey respondents reported receiving reimbursement for professional
meetings or continuing medical education, while 28% said they were paid for consulting,
giving lectures, or enrolling patients in clinical trials. The article reported that certain
specialties were significantly less likely than others to receive drug samples,
reimbursements, and payments for professional services, suggesting that "the industry
may focus marketing efforts on physicians who are perceived as influencing the
prescribing behaviors of other physicians." For example, cardiologists, who are perceived
to influence the prescribing patterns of non-specialists, “are significantly more likely to
receive direct payments from companies than are physicians in other specialties.” The
survey also found that physicians in solo or group practices were more likely than physicians who practice in hospitals to have relationships with the drug industry.

**House Approves Genetic Non-Discrimination Bill**

By an overwhelming 420-3 vote, the House passed April 25, 2007 a bill that prohibits health insurers and employers from discriminating against individuals on the basis of genetic information. The Genetic Information Non-Discrimination Act of 2007 (H.R. 493), which was introduced in the House by Representatives Louise Slaughter (D-NY) and Judy Biggert (R-IL), would bar employers from using individuals’ genetic information when making hiring, firing, job placement, or promotion decisions. The bill also would make it illegal for group health plans and health insurers to deny coverage to healthy individuals or charge them higher premiums based solely on a genetic predisposition to a specific disease. The companion measure in the Senate (S. 358) was introduced by Senator Olympia Snowe (R-ME) and co-sponsored by Health, Education Labor and Pensions (HELP) Committee Chairman Edward Kennedy (D-MA) and Ranking Member Mike Enzi (R-WY). S. 358 cleared the Senate HELP panel on January 31, 2007.

**Case Law**

**U.S. Court In Pennsylvania Says Federal Law Preempts State Failure-To-Warn Claims Involving Prescription Drugs**

A federal district court in Pennsylvania dismissed a products liability action against name-brand and generic manufacturers of the anti-depressant Paxil alleging that inadequate labeling led to the suicide of plaintiff’s wife. The court found that Food and Drug Administration (FDA) regulations promulgated pursuant to the Federal Food, Drug and Cosmetic Act (FDCA) preempted the action. Plaintiff Joseph Colacicco sued drug manufacturers GlaxoSmithKline (GSK) and Apotex, Inc. alleging the suicide death of his wife, Lois, resulted from their failure to warn of the increased risk of suicidal behavior linked to Paxil and its generic equivalent. Lois initially started taking Paxil and then before she died switched to the generic version, which is manufactured by Apotex.

The U.S. District Court for the Eastern District of Pennsylvania held the FDCA impliedly preempted plaintiff’s state law failure-to-warn claims, according “significant deference” to the FDA’s preemption position as expressed in several amicus briefs and the preamble of the new drug labeling regulations, which the agency issued in January 2006 (71 Fed. Reg. 3922). On an issue of first impression, the court said the preemption preamble, which was issued in 2006, likely is an “interpretive rule” clarifying existing law and therefore could be applied retroactively to the date of plaintiff’s wife’s death in 2003. The court said it need not decide this issue, however, given the other evidence of the FDA’s preemption position. *Colacicco v. Apotex, Inc.*, No. 05-5500 (E.D. Pa. May 25, 2006).

**U.S. Supreme Court Lets Stand Decision Upholding Maine Pharmacy Benefits Law**

The U.S. Supreme Court declined to review June 5, 2006 a First Circuit decision rejecting the Pharmaceutical Care Management Association's (PCMA's) challenge to a Maine law that would require pharmacy benefit managers (PBMs) to disclose
information about drug pricing negotiations and conflicts of interest to health plans. The UPDPA requires PBMs to act as fiduciaries for their clients and imposes certain disclosure requirements for any financial benefits that a PBM obtains from a pharmaceutical manufacturer or other related company. PCMA, a national trade association representing PBMs, filed suit in September 2003 against the state of Maine to block the UPDPA from taking effect. According to PCMA, the Act is expressly preempted by the Employee Retirement Income Security Act (ERISA) and violates several constitutional clauses.

The First Circuit found that PBMs are not ERISA fiduciaries and that the UPDPA did not have an impermissible “connection with” ERISA plans that would impede the goal of national uniformity. The appeals court also concluded that the UPDPA did not represent an impermissible “reference to” an ERISA plan because the state law applied to a broad spectrum of healthcare institutions and health benefit providers, including but not limited to ERISA plans. Pharmaceutical Care Management Ass’n v. Rowe, No. 05-1606 (1st Cir. Nov. 8, 2005), review denied, No. 05-1297 (U.S. June 5, 2006).

U.S. Supreme Court Denies Review Of Ruling That Certain Agreements On Generic Drug Market Entry Were Not Anticompetitive
The U.S. Supreme Court denied review June 26, 2006 of an Eleventh Circuit ruling that certain agreements to delay the entry of generic drugs on the market were not anticompetitive. Schering-Plough Corporation entered into settlement agreements with two generic drug manufacturers, which effectively delayed entry of generic competitors to one of Schering-Plough's drugs. The Federal Trade Commission (FTC) filed an administrative complaint against the companies and an administrative law judge (ALJ) found both agreements were lawful settlements of legitimate patent lawsuits. The FTC then issued an opinion reversing the ALJ and finding both agreements to be anticompetitive.

On March 8, 2005, the Eleventh Circuit vacated the FTC's decision with respect to both agreements, finding the agreements were not anticompetitive. See Schering-Plough Corp. v. Federal Trade Commn., 402 F.3d 1056 (11th Cir. 2005). In reaction to the Supreme Court's refusal to hear the case, four Senators—Herb Kohl (D-WI), Patrick Leahy (D-VT), Charles Grassley (R-IA), and Charles Schumer (D-NY)—announced new legislation that would prohibit brand-name drug manufacturers from using “pay-off” agreements to keep cheaper generic equivalents off the market.

Fourth Circuit Upholds FDA’s Ruling That Brand-Name Drug Manufacturer Can Market “Authorized Generic” During Hatch-Waxman Exclusivity Period
The Fourth Circuit found July 5, 2006 that a pioneer drug manufacturer was allowed to market a generic version of its own brand-name drug through a third-party license at the same time that another company was marketing its generic version of that drug, even though the generic drug company was the first applicant to obtain approval to market the generic version of the drug and therefore was entitled to a 180-exclusivity period under the federal Food, Drug & Cosmetics Act (FDCA). Proctor and Gamble, Inc. (P&G) is the holder of an approved New Drug Application (NDA) for it brand-name drug, Macrobid,
which is used to treat urinary tract infections. Mylan Pharmaceuticals, Inc. (Mylan), as the first filer of an approved Abbreviated New Drug Application (ANDA) to market a generic version of the drug, was therefore entitled to the 180-day exclusivity period under the Hatch-Waxman amendments to the FDCA. On the same day Mylan began commercial marketing of its generic, Watson Pharmaceuticals began selling the “authorized” generic version of Macrobid under a license from P&G. In subsequent litigation, Mylan claimed that it lost sales worth “tens of millions” of dollars as a result of this competition.

Mylan’s dispute with the FDA commenced approximately one month before the agency had approved Mylan’s ANDA. In anticipation of P&G’s strategy to market a generic version of its brand-name drug via a license agreement with a third-party, Mylan filed a citizen petition with the FDA requesting that the agency prohibit the marketing and distribution of “authorized generic” versions of the brand-name drug until the expiration of the first ANDA applicant’s 180-day exclusivity period.

The Fourth Circuit agreed with the FDA that 21 U.S.C. § 355(j)(5)(B)(iv)—the FDCA provision at issue in the case—did not prohibit either an ANDA or NDA holder’s use of alternative marketing practices, such as a license agreement with a third-party to develop and market a generic version for its own brand-name drug. “Although the introduction of an authorized generic may reduce the economic benefit of the 180 days of exclusivity awarded to the first paragraph IV ANDA applicant, § 355(j)(5)(B)(iv) gives no legal basis for the FDA to prohibit the encroachment of authorized generics on that exclusivity,” the appeals court said. Mylan Pharmaceuticals, Inc. v. Food and Drug Admin., No. 05-2160 (4th Cir. July 5, 2006).

U.S. Court In California Says Federal Law Preempts Pharmaceutical Failure-To-Warn Claims
A federal district court in California dismissed class action claims against Pfizer alleging it failed to warn that its popular drug Celebrex carried increased cardiovascular risks. The court concluded that the claims were preempted because they conflicted with the Food and Drug Administration’s (FDA’s) regulation of prescription drug labels. The case arose from several putative class actions brought by plaintiffs on behalf of consumers and third-party payors who purchased or paid for Celebrex, a drug manufactured by Pfizer, from December 1, 1998 to the present. According to plaintiffs, the Pfizer defendants engaged in a deceptive marketing scheme by suppressing data about Celebrex’s cardiovascular risks and falsely claiming that Celebrex had fewer side-effects than other non-steroidal anti-inflammatory drugs (NSAIDs).

The U.S. District Court for the Northern District of California concluded plaintiffs’ failure-to-warn claims conflicted with the FDA’s determination of what warnings are substantiated by the scientific evidence and therefore were preempted. The court pointed to the preamble of the recent final rule on prescription drug labeling requirements (71 Fed. Reg. 3935 (2006)), in which the FDA said it believes state laws conflict with the “full objectives and purposes of Federal law when they purport to compel a firm to
include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.”

The court refused to dismiss, however, plaintiffs’ claims that Pfizer falsely claimed Celebrex had fewer gastrointestinal complications than other NSAIDs and was more effective than these drugs. The fact that Pfizer submitted its Celebrex advertisements to FDA and the agency made no major objections to their content did not equate to a determination that they were not deceptive, the court said. Unlike with prescription drug labeling, the FDA has been silent as to the preemption of lawsuits challenging false claims in prescription drug advertisements. “This silence suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims,” the court held. In re Bextra and Celebrex Marketing Sales Practices and Prod. Liability Litig., No. M: 05-1699 CRB (N.D. Cal. Aug. 16, 2006).

U.S. Court In Maryland Rejects County’s Bid To Implement Drug Importation Program
A federal district court in Maryland dismissed an action brought by Montgomery County challenging the decision of Department of Health and Human Services’ (DHHS’) officials to deny its waiver request for a drug importation program. According to the court, the decision was in accordance with applicable law, which provided for such waivers only after the DHHS Secretary certifies the safety and cost-effectiveness of drug importation. Montgomery County, Maryland brought an action against DHHS Secretary Michael Leavitt and Food and Drug Administration (FDA) Commissioner Andrew C. von Eschenbach after they denied the County a limited certification waiver under the Medicare Modernization Act (MMA) to implement a Canadian drug importation program. The FDA maintains that drug importation poses significant safety risks and that such programs would violate the Federal Food, Drug, and Cosmetic Act (FDCA). Section 384 of the MMA provides that the FDA may allow drug importation if the DHHS Secretary first certifies that implementing such a program would pose no additional risk to the public and would result in significant consumer savings.

The U.S. District Court for the District of Maryland dismissed the action and denied the County mandamus relief, holding the FDA’s denial of the County’s waiver request was in compliance with the FDCA, which establishes the FDA’s comprehensive regulatory authority over drugs manufactured, marketed, and sold in the U.S. While the MMA authorizes waivers for importation by individuals, as well as pharmacists and wholesalers, it does so only if the Secretary has made the necessary safety and cost-effectiveness certifications. The court also concluded that judicial review of the Secretary’s failure to issue the safety and cost-effectiveness certification under MMA § 384 was not available because the statute did not require him to act. The MMA does not state that the Secretary must issue the certifications, nor does it include any specific time frames for doing so. Montgomery County, Maryland v. Leavitt, No. AW-06-477 (D. Md. Aug. 22, 2006).

U.S. Court In Texas Finds Compounded Drugs Not Subject To FDA’s New Drug Approval Process
Compounded drugs that are created based on a prescription written for an individual patient are not “new drugs” as defined in the Federal Food, Drug, and Cosmetics Act (FDCA), and therefore are not subject to the new drug approval process and related requirements, a federal district court in Texas ruled August 30, 2006. In September 2004, a group of ten state-licensed pharmacies that specialize in compounding prescription drugs filed a lawsuit challenging the Food and Drug Administration's (FDA's) authority to prohibit and enforce against pharmacy compounding pursuant to the FDCA, 21 U.S.C. § 301 et seq.

In its written order, the U.S. District Court for the Western District of Texas concluded that “compounded drugs, when created for an individual patient pursuant to a prescription for a licensed practitioner, are implicitly exempt from the new drug definitions” contained in § 321 of the FDCA. The court noted that the Food and Drug Administration Act of 1997 (FDAMA), 21 U.S.C. § 353a, originally exempted compounded drugs from the FDA’s new drug approval process, as long as the compounding pharmacies complied with specified restrictions. Although some provisions of that statutory section were later struck down, the remaining language remains fully effective and “demonstrates that Congress intended to declare . . . compounding . . . an approved and legal practice,” the court said.

The district court recognized, the FDA’s valid concerns that pharmacies claiming to be compounding are actually manufacturing drugs. The court therefore limited the exemption for compounded drugs from the FDCA’s new drug definition to those “made . . . upon receipt of a valid prescription for an individual patient from a licensed physician,” and specifically excluded “[d]rugs . . . compounded in large quantities before a prescription is received from a doctor.” *Medical Ctr. Pharmacy v. Gonzales*, No. MO-04-CV-130 (W.D. Tex. Aug. 30, 2006).

**U.S. Court In Kentucky Finds No Federal Preemption Of State Law Failure-To-Warn Claims**

A federal district court in Kentucky held November 28, 2006 that state law failure-to-warn claims against a drug manufacturer in a products liability action did not conflict with federal drug labeling regulations where the Food and Drug Administration (FDA) had yet to make a conclusive finding about the drug's risks. In so holding, the court noted that FDA regulations provide other avenues for drug makers to alert consumers and healthcare providers about a drug’s potential risks beyond the original FDA-approved label.

The case arose when plaintiff Philip C. Weiss sued Novartis Pharmaceutical Corporation (NPC) alleging it failed to warn her or her physicians about the adverse health risks associated with two of its drugs. In 2003, Weiss began taking NPC’s drugs, Elidel and Protopic, to treat her eczema. She later developed cancer and other health problems. According to Weiss, NPC knew as early as 1999 that use of the drugs carried these potential risks. FDA approved a revision to the Elidel label in 2006 to include a boxed warning of “rare cases of malignancy . . . .”
The U.S. District Court for the Eastern District of Kentucky refused to dismiss the action, concluding the state law failure-to-warn claims did not conflict with federal regulations. FDA issued in January 2006 new drug labeling regulations, which stated in the preamble that the agency believes its approval of a drug label preempts contrary state law. The court was persuaded by the FDA’s position insofar as it rejects failure-to-warn claims based on conduct that allegedly occurred before and during the labeling approval process or based on proposed warnings that the agency found scientifically unsubstantiated. In the instant case, the court concluded that additional warnings required under state law would not conflict with federal regulations because those regulations provide several avenues for drug manufacturers to warn the public about newly discovered risks other than the original FDA-approved label. "NPC could conceivably have possessed information not available to the FDA that they could have communicated . . . consistent with FDA's regulations," the court noted. *Weiss v. Fujisawa Pharmaceutical Co.*, No. 5:05-527-JMH (E.D. Pa. Nov. 28, 2006).

U.S. Court In District Of Columbia Dismisses Challenge To Pharmacy Benefits Law

The U.S. District Court for the District of Columbia dismissed March 6, 2007 the Pharmaceutical Care Management Association’s (PCMA’s) challenge to a D.C. law that imposes fiduciary duties and financial disclosure requirements on pharmaceutical benefit managers (PBMs) and vacated a preliminary injunction preventing the statute’s enforcement. Citing the First Circuit’s decision in *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005), which upheld a similar statute in Maine, the court found collateral estoppel barred PCMA’s action here.

PCMA, a national trade association representing PBMs, sought to block enforcement of Title II of the AccessRx Act, which the D.C. Council passed in 2004 in an effort to lower prescription drug costs. The court granted PCMA a preliminary injunction, concluding it had demonstrated a substantial likelihood of success on the merits of its takings claim. Defendants appealed to the D.C. Circuit, arguing the First Circuit’s decision in *Rowe* precluded PCMA from litigating the validity of Title II under principles of collateral estoppel. The D.C. Circuit remanded to the district court to consider the effect of *Rowe*, which upheld Maine’s Unfair Prescription Drug Practices Act (UPDPA), a law requiring PBMs to disclose information about drug pricing negotiations and conflicts of interest to health plans. The Supreme Court declined to review the *Rowe* decision. After the First Circuit’s decision in *Rowe*, the D.C. Council amended Title II to essentially mirror Maine’s UPDPA.

On remand, the district court granted defendants’ motions to vacate the injunction and for summary judgment, agreeing that collateral estoppel barred PCMA from continuing its challenge to Title II. The court first noted that the issues in the instant action were the same as those presented in *Rowe*, including that the Employee Retirement Income Security Act (ERISA) preempted Title II and various constitutional challenges. “Because the Maine and D.C. statutes are substantially similar, the issues raised by the plaintiff here are identical to the issues raised and contested by the parties in *Rowe*.” The court also found that the issues raised by PCMA in the instant case were actually and necessarily determined by the First Circuit in *Rowe*, which held the UPDPA, a "statute
with the same or broader wording as Title II,” was not preempted by ERISA or constitutionally invalid. PCMA said in a statement that it would immediately appeal the ruling to the D.C. Circuit “for an independent review of this case on the merits.” *Pharmaceutical Care Management Ass’n v. District of Columbia*, No. 04-1082 (D.D.C. Mar. 6, 2007).

**Settlements**

**GlaxoSmithKline Agrees To Pay $70 Million To Settle AWP Dispute**

GlaxoSmithKline (GSK) announced August 10 that it will pay $70 million to settle class action claims brought on behalf of certain consumers, health plans, and insurance companies alleging it artificially inflated the average wholesale price (AWP) of its medication including cancer drugs Kytril and Zofran. According to the company’s press release, the settlement includes all claims filed against GSK in the multidistrict litigation pending in a federal trial court in Boston (*In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456 (D. Mass)). The company said it also has reached civil settlements in AWP litigation filed by the Attorneys General of New York, California, Connecticut, Nevada, Montana, and Arizona, as well as potential AWP claims by thirty-four states and the District of Columbia. GSK agreed to settle the litigation without admitting any wrongdoing “to put this historical matter behind it.”

**Schering-Plough To Pay $435 Million To Settle Allegations Of Illegal Marketing, Fraud**

Schering-Plough Corp. and one of its subsidiaries have agreed to a $435 million global settlement to resolve criminal charges and civil claims that they engaged in illegal sales and marketing schemes and defrauded Medicaid, U.S. Attorney for the District of Massachusetts Michael Sullivan announced August 29, 2007. The settlement stems from allegations that the company marketed its drug Temodar and Intron A for so-called “off label” uses that had not been approved by the Food and Drug Administration (FDA). The settlement also resolves charges of Medicaid fraud involving Schering’s drugs Claritin Redi-Tabs, a non-sedating antihistamine, and K-Dur, used to treat stomach conditions. Under the settlement, which is subject to court approval, Schering Sales Corp., a subsidiary of the New Jersey-based drug manufacturer, will plead guilty to one count of conspiracy to make false statements to the government and pay a $180 million criminal fine, and Schering-Plough Corp. will pay another $255 million to settle civil liabilities, the government's release said. As a result of its criminal conviction, Schering Sales Corp. will be excluded permanently from participating in all federal healthcare programs. According to the government, Schering Sales reported a false best price to the Centers for Medicare and Medicaid Services for Claritin Redi-Tabs from April 1998 through 1999 to avoid paying millions of dollars in Medicaid rebates and attempted to mislead the FDA regarding the pervasiveness of certain illegal promotional activities. In a statement, Schering-Plough said the agreement closes an investigation that began before a new management team took the reins of the company.
Settlement Calls For Ceasing Publication Of AWP Drug Pricing Data
A proposed settlement reached in a class action brought by two members of the consumer health advocacy coalition—The Prescription Access Litigation Project (PAL)—against a leading publisher of U.S. prescription drug prices, First DataBank Inc., will ultimately result in a substantial reduction in what health plans pay pharmacies for drugs that represent 95% of the retail branded drug market, according to a press release issued by PAL on October 6, 2006. In dollar value, the terms of the proposed settlement are “projected to result in savings of approximately $4 billion,” PAL’s press release said. A very significant outcome of the proposed settlement is First DataBank’s agreement to cease publishing Average Wholesale Price (AWP) data within two years of the court’s approval of the settlement, which signals the demise of the AWP system. The PAL complaint alleged that from 2002 to 2005, First DataBank conspired with a leading prescription drug wholesaler, McKesson Corp., to arbitrarily increase by 5% the markups between what pharmacies pay wholesalers for prescriptions drugs and what health plans and insurers reimburse pharmacies for those drugs. McKesson was not part of the settlement agreement reached with First DataBank, and therefore remains a defendant in the pending litigation. A federal district court in Massachusetts issued a preliminary ruling in November 2006 finding the settlement was fair but finding further information was needed before certifying a class of third-party payors and consumer purchases for purposes of the settlement. New England Carpenters Health Benefits Fund v. First DataBank Inc., No. 1:05-CV-11148-PBS (D. Mass.) (settlement agreement filed Oct. 6, 2006).

Bristol-Myers Squibb Announces Agreement With Government To Settle Drug Pricing Claims
Bristol-Myers Squibb announced December 21, 2006 an agreement in principle with the Department of Justice (DOJ) to settle several investigations related to the company’s drug pricing and sales and marketing activities. According to the company’s statement, it expects to pay about $499 million to resolve civil liabilities and to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General. The statement also noted that under the agreement there would be no criminal charges brought against the company. The company emphasized that the settlement is contingent on the parties agreeing to final terms and requires DOJ’s approval.

Bayer Agrees To $8 Million Multi-State Settlement
Bayer Corporation has agreed to pay a total of $8 million to thirty states to resolve a consumer protection enforcement action initiated over concerns that the company failed to adequately disclose safety risks associated with Baycol—a cholesterol lowering drug. According to Florida Attorney General Bill McCollum, Bayer knew that Baycol had a higher risk associated with its use than other statin drugs, yet the company failed to adequately warn consumers. Baycol was withdrawn from the prescription drug market in August 2001 and an investigation was launched in 2004. “Manufacturers shouldn’t be allowed to hide medical information that doctors rely on to prescribe the correct medicine for their patients,” McCollum said. As part of the settlement, Bayer will register most of its clinical studies and then post the results at the end of each study. In addition, the
company is required to comply fully with state laws regulating the marketing, sale, and promotion of its pharmaceutical and biological products and is prohibited from making false and misleading claims relating to any such product sold in the United States.

**Drug Maker Agrees To Pay $24 Million To Settle Allegations Of Improper Marketing**

EMD Serono, Inc. and Merck Serono International S.A. (Serono) have agreed to pay $24 million to settle a class action lawsuit alleging the company wrongfully encouraged doctors to prescribe its AIDS drug Serostim to patients for whom it was unnecessary, according to a press release issued by plaintiffs, the Prescription Access Litigation Project (PAL) and PAL member AFSCME District Council 37 Health and Security Plan. The suit alleged that Serono promoted the use of an unapproved medical device that improperly diagnosed people as having AIDS wasting (the condition that Serostim is used to treat), provided doctors with travel stipends in exchange for their agreement to prescribe Serostim, and marketed the drug for uses that were not approved by the Food and Drug Administration. Serono reached a $704 million settlement with the Department of Justice in 2005 and agreed to plead guilty to criminal charges for the unlawful promotion of Serostim. According to PAL, the “DOJ settlement reimbursed government programs for their Serostim payments but did not include reimbursement for patients and private health plans that paid out-of-pocket for Serostim treatment.” The class action sought to recover payments for those groups. To that end, the settlement calls for a fund to be established to reimburse both individual patients who paid the entire cost of Serostim prescriptions or who had private health coverage and were responsible for a co-payment for their prescriptions, and third-party payors that paid for the drug.

**Pfizer Subsidiaries To Pay $34.7 Million In Criminal Fine For Offering Kickbacks, Penalties For Off-Label Promotion**

Two Pfizer subsidiaries reached settlements with the Department of Justice (DOJ) totaling $34.7 million involving one charge of paying kickbacks on a distribution contract for the human growth hormone product, Genotropin, and separate allegations that Genotropin was illegally promoted for “off label” uses, according to an April 2, 2007 press release issued by the U.S. Attorney for the District of Massachusetts Michael J. Sullivan.

The first subsidiary—Pharmacia & Upjohn Company, Inc.—agreed to plead guilty to the charge that it violated the Anti-Kickback Statute by offering to make $12.3 million in excess payments on a distribution contract with a pharmacy benefit manager (PBM) subsidiary in exchange for better formulary placement of its drug products, the release said. To resolve the criminal charge, Pharmacia will pay a criminal fine of $19.68 million and, as a result of the conviction, will be excluded permanently from participating in all federal healthcare programs.

The other subsidiary—Pharmacia & Upjohn Company, LLC—entered into a thirty-six-month deferred prosecution agreement for promoting Genotropin for uses not approved by the Food and Drug Administration (FDA), including for anti-aging, cosmetic use, and improved athletic performance. Genotropin is FDA-approved for the treatment of
children with hormone-related growth failure and other growth-related diseases. According to Sullivan’s release, Pharmacia has agreed to institute specific training mechanisms to prevent illegal promotion activities in the future and will pay a monetary penalty of $15 million. In a statement, Pfizer noted the subject of both settlements related to activities that occurred before it acquired Pharmacia in 2003.

**OxyContin Manufacturer Agrees To Settlements On Illegal Marketing, Promotion**

Purdue Pharma, manufacturer of the drug OxyContin, reached a multi-state settlement with 26 states and the District of Columbia to resolve allegations that the company failed to adequately inform the public that the drug posed an unusually high risk of abuse, and that it marketed OxyContin for “off-label” uses, DC Attorney General Linda Singer announced May 8, 2007. The consent judgment, to be filed in D.C. Superior Court, contains an injunctive provision that restricts how OxyContin is marketed and requires Purdue Pharma to maintain an abuse and diversion-detection program to detect and report problem prescribing, Singer said. In addition, Purdue Pharma will pay the participating states a total of $19.5 million under the settlement agreement.

Meanwhile, the Food and Drug Administration (FDA) May 10, 2007 announced that Purdue Frederick Company reached a settlement with FDA’s Office of Criminal Investigations to resolve charges that the company pursued several illegal schemes to promote, market, and sell OxyContin. According to FDA, the company trained its sales representatives to make false representations to healthcare providers about the side-effects and addictiveness of OxyContin. The Purdue Frederick Company will pay more than $700 million to resolve the charges. To resolve the criminal charges, Purdue pled guilty to a felony count of misbranding a drug with intent to defraud and mislead, FDA said, and will pay a $600 million settlement. In a separate civil settlement, Purdue agreed pay $100.6 million to the United States.

**Cell Therapeutics Agrees To Pay $10.5 Million To Resolve Claims Alleging Illegal Marketing Of Anti-Cancer Drug**

Cell Therapeutics Inc. (CTI), a Seattle biotechnology company, agreed to pay the United States $10.5 million to resolve allegations that it illegally marketed the anti-cancer prescription drug Trisenox, the U.S. Department of Justice (DOJ) announced April 17, 2007. According to the government's complaint, CTI promoted Trisenox for various uses that were not approved by the Food and Drug Administration (FDA) as safe or effective. The government’s complaint further alleged that CTI’s illegal marketing of Trisenox caused physicians who prescribed the drug "off-label" to unwittingly submit false claims for reimbursement to Medicare. The government contended “CTI knew that Trisenox was FDA-approved for only one type of cancer and was not listed as a medically accepted treatment in the compendia for any other condition,” but nevertheless suggested otherwise to physicians. The government's complaint also alleged that CTI paid illegal kickbacks to induce physicians to prescribe Trisenox. The underlying case, *United States ex rel. Marchese v. Cell Therapeutics Inc.*, began on February 1, 2006, when James Marchese, a former CTI employee, filed a qui tam action under the False Claims Act in the U.S. District Court for the Western District of Washington. CTI denied any wrongdoing in settling the matter.
FRAUD AND ABUSE

DOJ Announces Record $3.1 Billion In Fraud Recoveries For FY 2006
A $920 million False Claims Act settlement with Tenet Healthcare Corp. in July, 2006 helped propel the federal government’s fraud recoveries to a record $3.1 billion in fiscal year (FY) 2006, the Department of Justice (DOJ) announced November 21, 2006. According to a DOJ press release, the vast majority of the recoveries (72%) were healthcare related. The FY 2006 recoveries surpassed the previous high of $2.2 billion set in FY 2003. DOJ said whistleblower actions brought under the FCA’s qui tam provisions continue to play a key role in overall fraud recoveries—accounting for $1.3 billion of the total recovery in FY 2006. These whistleblowers were awarded $190 million for their efforts in bringing fraudulent schemes to the government’s attention, DOJ added.

CMS Issues Long Awaited Guidance On False Claims Act And Whistleblower Education Requirement
On December 13, 2006, the Centers for Medicare and Medicaid Services (CMS) released guidance to State Medicaid agencies on the implementation of § 6032 of the Deficit Reduction Act of 2005 (DRA). The DRA imposes new compliance program requirements on healthcare entities that receive $5 million dollars or more in Medicaid funds in a fiscal year. Effective January 1, 2007, the DRA will require these entities to educate their employees, contractors, and agents about federal and state false claims acts and about the whistleblower protections under the acts.

The new CMS State Medicaid Director letter now clarifies a number of unanswered issues about DRA's education program requirements, including that a healthcare company or provider that receives or makes $5 million dollars of aggregate Medicaid payments in a calendar year, must comply with the training requirement of Section 6032. CMS' letter specifically confirms that that threshold will be calculated in the aggregate, regardless of whether a company or provider "furnishes items or services at more than a single location" or "using one or more provider numbers." Many institutional healthcare providers are likely to meet that threshold if they participate in Medicaid.

Under the DRA provisions, a covered entity must also "establish and disseminate written policies that must be adopted by its contractors and agents." The CMS Guidance defines a "contractor or agent" to include any person, company or organization that is involved in providing or otherwise furnishing Medicaid healthcare items or services of the entity, performs billing or coding functions for the entity, or is involved in monitoring of healthcare provided by the entity. At a minimum, CMS' interpretation of the law will require an entity to send out its policies to its contractors and agents, apprise them of the fraud and abuse provisions of federal and state laws, and ensure that the contractors and agents are knowledgeable about how to report possible fraud or abuse to the entity and governmental entities.

CMS confirmed in its guidance that all state Medicaid agencies must implement the DRA False Claims Act education requirements by January 1, 2007. Therefore, states are expected to require all providers to be in compliance by that date as well. CMS expects
each state Medicaid program to amend its Medicaid provider contracts to accomplish this. CMS expects each state to submit a state plan amendment effective January 1, 2007. Under CMS rules, a state could submit a state plan amendment as late as March 31, 2007, to be effective retroactively to the first day of the year. CMS will only allow a state to extend the implementation date if the state can certify to CMS, and CMS agrees, that state legislation is required to implement the provisions.

CMS also expects state Medicaid agencies to monitor compliance with the new law's requirements. In its state plan amendment, a state must include "a description of the methodology of compliance oversight and the frequency with which the State will reassess compliance on an ongoing basis."

Medicare Fraud Strike Force Yields 38 Arrests Of Individuals Charged With Fraudulently Billing Medicare For Over $142 Million

Department of Health and Human Services (DHHS) Secretary Michael O. Leavitt and Attorney General Alberto R. Gonzales announced May 9, 2007 that 38 individuals in the durable medical equipment (DME) and infusion therapy supply business have been arrested on charges of bilking the Medicare program of more than $142 million in the first phase of the Medicare Fraud Strike Force’s operations. The Medicare Fraud Strike Force is a “multi-agency team of federal, state and local investigators” that was established “specifically to combat Medicare fraud through the use of real-time analysis of Medicare billing data.” The first phase of the strike force’s operations began March 1, 2007 in southern Florida, focusing on Miami-based DME and infusion therapy suppliers. Charges brought against the defendants in these cases include conspiracy to defraud the Medicare program, criminal false claims, and violations of the Anti-Kickback Statute.

The strike force has established multiple teams that are each led by a federal prosecutor who is supervised by both the Department of Justice (DOJ) Criminal Division’s Fraud Section in Washington, D.C. and the office of the U.S. Attorney for the Southern District of Florida. Each team has four to six agents, at least one agent from the Federal Bureau of Investigation as well as from the DHHS Office of Inspector General, and representatives of local law enforcement.

Anti-Kickback Issues

DHHS OIG Approves City’s “Insurance-Only” Billing Proposal For Emergency Services Provided To Residents

A municipality’s proposal to use local tax revenues as payment of otherwise applicable cost-sharing amounts due from residents for emergency medical services provided through a municipally owned and operated ambulance service would not generate prohibited remuneration under the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) concluded in Advisory Opinion No. 06-07, which was posted June 29, 2006.

While noting its "longstanding" concerns about “insurance-only” billing provisions, the OIG said it would not impose administrative sanctions in connection with the proposal, citing the special rule for providers and suppliers owned and operated by a state or a
political subdivision of a state. See Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual Chapter 16, § 50.3.1 ("a [state or local government] facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment"). *Advisory Opinion No. 06-07* (Dep’t of Health and Human Servs. Office of Inspector Gen. June 26, 2006).

**DHHS OIG Says Free Clinic May Dispense Drugs On Behalf Of PAPs To Financially Needy Part D Enrollees**

The Department of Health and Human Services Office of Inspector General (OIG) found in *Advisory Opinion No. 06-08* that a clinic’s practice of dispensing drugs on behalf of patient assistance programs (PAPs) sponsored by pharmaceutical manufacturers that provide free drugs to financially needy patients, including Medicare Part D enrollees, would not run afoul of federal fraud and abuse laws.

The opinion, posted June 30, 2006, was requested by a non-profit, tax-exempt community-based free clinic that serves West Virginia residents under strict financial need criteria and provides no treatment to insured patients, including those with Medicare or Medicaid. The opinion found that the arrangement did not implicate the Anti-Kickback Statute because there was “no apparent remuneration” provided by the PAPs to the clinic and that any benefit to the clinic “inures to the public good in the form of increased availability of health care items and services for an underserved population.” In addition, the OIG noted that the clinic was not in a position to generate business for any PAP sponsor that would be payable by a federal healthcare program given the physicians who work at the clinic did so on a volunteer basis. *Advisory Opinion No. 06-08* (Dep’t of Health and Human Servs. Office of Inspector Gen. June 27, 2006).

**OIG Approves Charitable Organization’s Proposed Subsidization Of Medicare Part D Premiums For Certain Patients With Kidney Disease**

In an advisory opinion posted August 25, 2006, the Department of Health and Human Services Office of Inspector General (OIG) gave the green light to a nonprofit charitable organization’s proposal to use funds donated from dialysis providers and suppliers and pharmaceutical manufacturers to subsidize Medicare Part D drug benefit premium and cost-sharing obligations owed by financially needy patients with end-stage renal disease and chronic kidney disease.

The requesting organization operates a publicly supported charity providing direct financial assistance, comprehensive education, clinical research, and community service programs to individuals at risk for, and suffering from, kidney disease. Under the proposed arrangement, the requestor would add two programs to assist financially needy Medicare beneficiaries with kidney disease. The first program would subsidize premiums for Medicare Part D plans offering expanded formulary coverage for prescription drugs used to treat kidney diseases and beneficiary cost-sharing obligations under Part D. The second program would subsidize Medicare Part D cost-sharing obligations for products that prevent and manage abnormalities and other health risks associated with kidney disease.
The OIG approved the proposed arrangement, noting that “[l]ong-standing [agency] guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy Medicare beneficiaries by contributing to independent, bona fide charitable assistance programs.” If the program is properly structured, such donations should give rise to “few, if any, concerns about improper beneficiary inducements,” the OIG said. Advisory Opinion No. 06-09 (Dep’t of Health and Human Servs. Office of Inspector Gen. Aug. 25, 2006).

OIG Approves Charitable Organization’s Financial Assistance To Needy Medicare Patients For Treatment Of Certain Diseases

In an advisory opinion posted September 21, 2006, the Department of Health and Human Services Office of Inspector General (OIG) approved a nonprofit, tax-exempt, charitable organization’s practice of providing certain therapy management services and financial assistance to financially needy Medicare beneficiaries undergoing treatment for certain diseases. Although the OIG concluded that this arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute if the requisite intent to induce or reward referrals were present, the agency ultimately found that based on the facts it would not impose administrative sanctions.

The requesting organization wants to expand the assistance it has traditionally offered to financially needy Medicare beneficiaries, including beneficiaries enrolled in a Part D plan. The requestor operates its program to assist financially needy patients with any of several diseases that require therapy with certain types of costly medications, or “specialty therapeutics.” Under the arrangement, the requestor has established financial need criteria based on certain national standards of indigence. Medicare beneficiaries qualify for assistance from the requestor if they meet the financial need criteria, are diagnosed with a disease covered by the program, and are undergoing treatment with a specialty therapeutic. Under the arrangement, the requestor provides financial assistance to help with eligible patient’s cost-sharing obligations for these specialty therapeutics under both Medicare Parts B and D.

In approving the arrangement, the OIG concluded that, because the arrangement’s particular design and administration “interposes an independent . . . charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor,” it was unlikely that donor contributions would influence any Medicare beneficiary’s selection of a particular provider, practitioner, supplier, or product. Similarly, “there appears to be minimal risk that donor contributions would improperly influence referrals by the Requestor,” the OIG said. Among the favorable factors highlighted by the OIG was the independence of the requestor from donors, that no link existed between donors and patients, and that the requestor employs verifiable and uniform measures of determining financial need. Advisory Opinion No. 06-10 (Dep’t of Health and Human Servs. Office of Inspector Gen. Sept. 21, 2006).
OIG Approves Two Cities’ Exclusive Contracts For Non-Emergency Inter-Facility Ambulance Transport Services

In Advisory Opinions Nos. 06-11 and 06-12, posted September 25, 2006, the Department of Health and Human Services Office of Inspector General (OIG) said it would not impose administrative sanctions on two cities’ proposals for exclusive contract arrangements for non-emergency inter-facility ambulance transport services. In each case, the city requesting the opinion provides emergency medical transport services. As an adjunct to these services, the cities also would like to provide non-emergency inter-facility transport services. The cities proposed to adopt ordinances that would authorize them to execute an exclusive contract with a medical transport service provider (franchisee). The agreement in each case would require the franchisee to pay a flat fee of $50,000 to the city per year for each of the three years of the contemplated contract.

In the opinions, the OIG first noted that “pay to play” arrangements such as these fit “squarely within the language of the anti-kickback statute.” In approving the arrangements, the OIG pointed to several factors that would mitigate the risks of fraud or abuse, including that the fee paid to the cities would only partially offset their operation costs, the fee would not be tied directly or indirectly to the volume or value of referrals between the parties, and that the fees paid to the cities would inure to the public benefit. Advisory Opinion 06-11 (Dep't of Health and Human Serv. Office of Inspector Gen. Sept. 18, 2006) and Advisory Opinion 06-12 (Dep't of Health and Human Serv. Office of Inspector Gen. Sept. 18, 2006).

OIG Approves Charity's Proposed Grants To Financially Needy With Certain Diseases To Defray Costs Of Medicare Premiums

A nonprofit, tax-exempt charitable organization’s proposal to provide financially needy persons who have particular diseases with grants to defray the costs of Medicare premiums and cost-sharing obligations would not constitute grounds for imposing sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted September 25, 2006. The OIG also said while the arrangement could implicate the Anti-Kickback Statute, it would not impose administrative sanctions based on the particular facts.

The requesting organization provides funding for research, education, and patient services related to particular diseases. It offers a comprehensive array of services to patients and their families, including educational programs, support groups, and financial aid. Under the proposed arrangement, the requestor intends to institute a cost-sharing and insurance premium payment assistance program for financially needy individuals suffering from any of the particular diseases, including Medicare beneficiaries.

The OIG approved the proposed arrangement, noting that “[l]ong-standing [agency] guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy Medicare beneficiaries by contributing to independent, bona fide charitable assistance programs.” In support of decision, the OIG enumerated factors similar to those cited in Advisory Opinion No. 06-10, which involved
DHHS OKs Drug Maker’s Pharmaceutical Assistance Program For Financially Needy Part D Enrollees
The Department of Health and Human Services Office of Inspector General (OIG) gave its blessing to another pharmaceutical assistance program (PAP) operated by a drug manufacturer that provides outpatient prescription drugs to financially needy Medicare Part D enrollees in an advisory opinion posted September 26, 2006. In an advisory opinion posted September 26, 2006, the OIG said it would not impose administrative sanctions under the Anti-Kickback Statute (AKS) because the PAP as described by the drug manufacturer would operate entirely outside the Part D benefit. The opinion did not identify the requestor, but Eli Lilly and Company posted an announcement on its website the same day that the OIG had given the green light to its PAP—LillyMedicareAnswers.

To qualify for the PAP, Medicare Part D enrollees would have to demonstrate they use one or more of the PAP’s covered drugs, are enrolled in Part D, and meet certain financial need criteria. Those beneficiaries qualifying for the PAP would pay a fixed fee of $25 for each month’s supply of the drugs, which would be dispensed by a mail order pharmacy under agreement with the drug manufacturer. The OIG said that while the proposal could potentially generate prohibited remuneration under the AKS, if the requisite intent were present, the PAP included sufficient safeguards to ensure that it would operate outside the Part D benefit and therefore posed little risk of fraud and abuse such as steering beneficiaries to particular drugs or increasing Medicare costs.

One key feature of the proposed PAP that the OIG highlighted was the fact that Part D plans would be notified about enrollees' participation in the PAP via data sharing agreements with the Centers for Medicare and Medicaid Services. This notification would help ensure that Medicare did not make payments for drugs provided under the PAP and that no part of the PAP’s payment would be counted toward any Part D enrollee’s TrOOP, or true out of pocket expenses, the OIG said. Advisory Opinion No. 06-14 (Dep’t of Health and Human Servs. Office of Inspector Gen. Sept. 21, 2006).

OIG Approves Company’s Agreement To Act As Pay-For-Performance Payment Administrator For State Medicaid Agency
A company’s agreement with a state Medicaid agency to disburse pay-for-performance financial incentives to physicians on behalf of a specific Medicaid disease management program does not implicate the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted October 6, 2006.

The requestor is a company that sells products and services relating to managed care. In March 2005, it agreed to develop on behalf of a state Medicaid agency a disease management program that included a pay-for-performance component. Following a competitive bidding process, which the requestor ultimately won, the pay-for-performance program was implemented pursuant to a Medicaid waiver. A key feature of
the pay-for-performance component is for the agency to pay physicians financial incentives for recommending certain services. Under the agreement, the requestor is required to disburse agency-approved financial incentives to Medicaid providers participating in the pay-for-performance program in the form of checks drawn on one of the requestor’s bank accounts. In exchange, the requestor “earns a fair market value fee for the administrative services it provides.”

The OIG noted that the question of whether the company’s arrangement with the state Medicaid agency violates the Anti-Kickback Statute “arises because of the appearance that Requestor is making payments to physicians by issuing Pay-for-Performance Program checks drawn on Requestor’s bank account.” Under these circumstances, the OIG concluded that “[i]t is the substance—not the form—of [the] arrangement that governs under the anti-kickback statute,” and that “[s]uperficial appearances are not controlling.” Therefore, requestor’s duties as a payment administrator in this case do not implicate the Anti-Kickback Statute, the OIG found. The OIG cautioned, however, that “there is nothing talismanic about Requestor’s status as a payment administrator that leads to this conclusion,” adding that it might reach a different conclusion in considering a similar arrangement but involving an administrator that had power to control payments that related to its products. Advisory Opinion No. 06-15 (Dep’t of Health and Human Servs. Office of Inspector Gen. Oct. 6, 2006).

OIG Finds DME Manufacturer’s Proposal To Offer Suppliers Free Advertising Problematic
A proposed arrangement in which a durable medical equipment (DME) manufacturer would provide free advertising and reimbursement consulting services to some of its DME supplier customers could generate prohibited remuneration under the Anti-Kickback Statute and may trigger administrative sanctions, according an advisory opinion posted October 10, 2006 by the Department of Health and Human Services Office of Inspector General (OIG). Specifically, the OIG found a "substantial likelihood" the proposal "would be a vehicle to pay unlawful kickbacks" that could result in overutilization, increased federal healthcare program costs, and unfair competition.

The requesting company makes wheelchairs and other items of DME, which it mostly sells to DME suppliers that in turn provide DME to patients, including those enrolled in federal healthcare programs. Under the proposal, the DME manufacturer would provide free advertising to certain of its DME supplier customers selected based on their current and potential markets. The DME manufacturer also is proposing to provide free reimbursement consulting services such as coding advice and general claims submission information.

According to the OIG, the proposal clearly implicates the Anti-Kickback Statute because the advertising assistance and reimbursement consulting services would constitute remuneration to the DME suppliers, who are in a position to generate business for the manufacturer. The OIG found the manufacturer's proposal to subsidize its customers' advertising costs problematic because it would essentially be covering costs they would otherwise incur to promote and operate their businesses. The OIG acknowledged that the
provision of certain reimbursement support services by manufacturers in connection with the sale of their products is permissible where those services standing alone "have no substantial independent value to the purchaser." But in this case, the reimbursement consulting services under the proposal "would be neither limited in nature, nor free-standing" and could confer "substantial independent value upon the DME supplier." Advisory Opinion No. 06-16 (Dep't of Health and Human Servs. Office of Inspector Gen. Oct. 3, 2006).

OIG OKs Network Organizer's Variable Compensation Arrangement With Marketing Firm That Generates Minimal Federal Healthcare Program Business
The Department of Health and Human Services Office of Inspector General (OIG) in an advisory opinion posted October 13, 2006 approved a variable compensation arrangement between an organizer of a dental preferred provider network and a marketing firm that “tangentially” generates federal healthcare program business for the network. The network organizer charges employers and other clients a per employee per month fee for access to the network. Under an agreement with the marketing company, the network organizer pays a designated percentage of any access fees resulting from the firm’s marketing efforts. One of the business relationships generated by the marketing company for the network was a federal employee health benefits plan. According to the parties, the amount of federal healthcare program dollars at stake is minimal (estimated at less than 1% of billings).

The OIG noted that variable compensation structures are problematic under the Anti-Kickback Statute because they relate to the volume or value of business generated between the parties. Despite these general concerns, the OIG said administrative sanctions would not be warranted under the circumstances because “the compensation owed to the Marketing Company under the arrangement appears only tangentially related to the generation of any Federal health care program business.” The OIG based its conclusion on the facts that federal healthcare program dollars paid to the network dentists as a result of the arrangement would be minimal and that the compensation paid to the marketing company created “no discernable incentive” for it to generate federal healthcare program business for the network. Advisory Opinion No. 06-17 (Dep’t of Health and Human Services Office of Inspector Gen. Oct. 6, 2006).

OIG Approves Healthcare Provider’s Medical Outreach Program That Pays For Volunteer Travel Costs To Rural Areas
A healthcare provider’s volunteer services program for the provision of specialty medical care and professional development in rural areas that involves paying travel costs does not constitute grounds for imposing administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted November 2, 2006. The requestor is the largest healthcare provider in its area, operating six acute care hospitals, one specialty rehabilitation hospital, and numerous outpatient clinics. Through its volunteer program, the requestor “facilitates the delivery of volunteer specialty medical and community services and professional development in rural communities by covering travel costs for volunteers,” the opinion said. The program is administered by the requestor’s employees, but the requestor conducts an initial needs
assessment to determine if a community requesting assistance qualifies for the program, according to the opinion. The requestor then matches volunteers with the recipient community. Volunteers, who are not paid by the program, are required to spend at least 20% of their time during a volunteer trip, not including travel time, on program activities.

The OIG said the payment of volunteer travel costs under the program could constitute remuneration implicating the Anti-Kickback Statute. But the OIG found fraud an abuse unlikely because “the program’s structure ensures that the volunteer will not unduly profit” from the trips. Under the conditions imposed on volunteers by the program, “a volunteer is almost certain to generate less income on . . . a trip than when practicing at his or her own medical office,” the opinion said. Moreover, the program was not likely to generate appreciable referrals, and provides significant community benefits, with a commendable objective of benefiting residents of rural areas. Advisory Opinion No. 06-18 (Dep’t of Health and Human Serv. Office of Inspector Gen. Oct. 26, 2006).

OIG Approves Two PAPs That Offer Free Drugs To Financially Needy Part D Enrollees

The Department of Health and Human Services Office of Inspector General (OIG) approved two more pharmaceutical assistance programs (PAPs) that provide free prescription drugs to financially needy Medicare Part D enrollees in an advisory opinion posted November 2, 2006. In the opinion, the OIG said it would not impose administrative sanctions under the Anti-Kickback Statute in connection with the PAPs because they would operate entirely outside the Part D benefit. Under the proposed arrangement, the requesting drug manufacturer would operate two PAPs—one that provides free outpatient prescription drugs that treat cancer (PAP A) and a second that provides other outpatient medications for a broad spectrum of indications (PAP B), the opinion said. Both PAPs would assess qualifying financial need using two tests: (1) an income below 350% of the federal poverty level (PAP A) or below 250% of the federal poverty level (PAP B) and (2) expenditures of at least $600 on outpatient prescription drugs already that coverage year. The PAPs also would coordinate assistance they provide with Medicare Part D coverage so as to ensure that free drugs would not count towards a Part D enrollee’s true out-of-pocket spending (TrOOP).

The OIG noted drug manufacturer PAPs that subsidize the cost-sharing amounts for drugs payable by the Part D program raise fraud and abuse concerns, including steering enrollees to particular drugs and increasing Medicare costs. But because the two PAPs at issue contained sufficient safeguards to ensure they operate entirely outside the Part D benefit, they posed minimal risk of fraud and abuse, the OIG concluded. Advisory Opinion No. 06-19 (Dep’t of Health and Human Serv. Office of Inspector Gen. Oct. 26, 2006).

OIG Says DME Supplier’s Provision Of Free Home Oxygen, Testing Services Is Problematic

A durable medical equipment (DME) supplier’s practice of providing free home oxygen to patients until they qualify for Medicare coverage could constitute grounds for civil monetary penalties (CMPs) for violating the prohibition against offering inducements to
beneficiaries, the Department of Health and Human Services Office of Inspector General (OIG) concluded in Advisory Opinion No. 06-20. The OIG also found problematic the DME supplier’s proposal to provide patients with a free overnight oximetry test, which is used to measure blood-oxygen levels. Both the existing and proposed arrangements also could generate prohibited remuneration under the Anti-Kickback Statute and possibly lead to administrative sanctions, the OIG said.

The requestor operates DME suppliers that provide home oxygen products and services to patients including Medicare and Medicaid beneficiaries. The OIG explained in the opinion, which was posted November 8, 2006 that Medicare covers physician-prescribed home oxygen only after the coverage is justified by an oximetry test. The test cannot be conducted by a DME supplier to qualify a beneficiary for Medicare. And Medicare does not cover the so-called “interim oxygen” ordered before the qualifying test is completed. Under its existing arrangement, the DME suppliers provide “interim oxygen” free of charge. The requestor contends that such arrangements are common in the home oxygen industry.

Although the interim oxygen and oximetry tests are not covered by Medicare, many of the requestor’s DME and home care goods and services are reimbursable by federal healthcare programs, the OIG noted. With respect to the CMP, the free interim oxygen and the testing would constitute remuneration paid to the beneficiaries who receive them that would likely influence their selection of the requestor as their DME supplier over other competitors, the OIG reasoned. The OIG also noted the structure of the existing and proposed arrangements “appear calculated to generate subsequent business for the Requestor,” particularly given that the free oxygen and testing are offered to a group likely to require oxygen and other federally payable goods and services in the near future. The OIG cited the same reasoning for why the existing and proposed arrangements could violate the Anti-Kickback Statute. Advisory Opinion No. 06-20 (Dep’t of Health and Human Servs. Office of Inspector Gen. Nov. 8, 2006).

DHHS OIG Approves Patient Assistance Program That Helps Financially Needy In Medicare Part D
The Department of Health and Human Services Office of Inspector General (OIG) gave the green light to another patient assistance program (PAP) operated by a drug maker that provides free outpatient drugs to financially needy Medicare Part D enrollees. The advisory opinion, posted November 9, 2006, is the latest in a series of similar opinions ruling out administrative sanctions under the Anti-Kickback Statute for PAPs that operate entirely outside the Part D benefit. As with the other approved arrangements, the proposal here would involve a PAP that provides assistance to Medicare beneficiaries enrolled in Part D who demonstrate their financial need and use one or more of the PAP’s covered drugs. The determination of financial need would be based on household income below a set multiple of the federal poverty level and the patient having spent a substantial portion of that income on outpatient prescription drugs already that coverage year. The PAP would not provide drugs free of charge, but rather would charge enrollees a cost-sharing amount based on the patient’s income and the number of months’ supply of the drug obtained.
Although the proposed PAP poses concerns under the Anti-Kickback Statute, the OIG said the risks of fraud and abuse were minimal because the PAP would operate entirely outside the Part D benefit. Specifically, the PAP would notify enrollees’ Part D plans via data sharing agreements with the Centers for Medicare and Medicaid Services that the PAP drugs are being provided outside the Part D benefit. In addition, PAP assistance would be based solely on financial need using criteria “entirely divorced from considerations related to a Part D enrollee’s choice of Part D plan, the benefit design of the enrollee’s Part D plan, or where a Part D enrollee is on his or her Part D plan’s spectrum.” As a result, the OIG saw little chance the PAP drugs would be used to tie Medicare beneficiaries to particular outpatient drugs payable by Part D or that the PAP drugs would increase costs to Medicare. *Advisory Opinion No. 06-21* (Dep’t of Health and Human Servs. Office of Inspector Gen. Nov. 9, 2006).

**OIG Approves Hospital’s Proposed “Gainsharing” Arrangement With Cardiac Surgical Group**

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted November 16, 2006 that a hospital’s proposal to share a percentage of its cost savings with cardiac surgeons who implement certain cost-reduction measures in the operating room would not trigger administrative sanctions because of features designed to mitigate concerns raised by “gainsharing” agreements. The OIG said that gainsharing arrangements have the potential to implicate the Anti-Kickback Statute and the civil monetary penalty (CMP) for reductions or limitations of direct patient care services provided to federal healthcare program beneficiaries. The OIG noted that such arrangements also raise concerns under the physician self-referral (Stark) law, but added that this was not an area under its purview. The proposed arrangement here “is markedly different from many ‘gainsharing’ plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities,” the OIG observed in the advisory opinion.

Under the proposal, the hospital would pay the group of cardiac surgeons 50% of first-year cost savings achieved by implementing twenty-four cost-saving measures in their operating room practices. At the end of the first year, cost savings would be calculated separately for each of the twenty-four recommendations. The twenty-four cost saving recommendations are grouped into three categories—limiting the use of certain surgical supplies (the “use as needed” recommendations); substituting less costly items for those currently being used by surgeons; and product standardization of certain cardiac devices where medically appropriate.

Regarding the product substitution recommendations, the OIG said the CMP was not triggered as the hospital certified the substitutions would involve items and services with no appreciable clinical significance such as reusable hyperthermia blankets instead of the disposal ones currently used. In so far as the use as needed and product standardization recommendations, the OIG said these implicated the CMP as they constituted an inducement to reduce or limit the current medical practice at the hospital, but found a number of safeguards mitigated its concerns about fraud and abuse. Specifically, the OIG
noted that the proposed arrangement promoted transparency by clearly linking specific cost-saving actions and resulting savings, which would allow public scrutiny and individual physician accountability for any adverse effects of the proposal. With respect to the product standardization recommendations, the OIG noted that individual physicians would still have the same selection of cardiac devices available to them after the proposal was implemented. Moreover, the OIG said the financial incentives under the proposal are reasonably limited in duration and amount and that, because the surgeon group’s profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Likewise, the OIG found the proposed arrangement implicated the Anti-Kickback Statute, but that administrative sanctions would not be warranted. In reaching this conclusion, the OIG highlighted that participation in the proposed arrangement would be limited to surgeons already on the hospital’s medical staff; that potential savings derived from procedures payable by federal healthcare programs would be capped based on the prior year’s admissions of federal healthcare program beneficiaries; and that the contract term would be limited to one year. *Advisory Opinion No. 06-22* (Dep’t of Health and Human Servs. Office of Inspector Gen. Nov. 9, 2006).

**DHHS OIG Rules Out Sanctions On Hospital Proposal To Provide Free Dialysis**

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted January 25, 2007 that it would not impose administrative sanctions in connection with a hospital’s proposal to provide free acute dialysis treatment services to chronic dialysis patients, including Medicare and Medicaid beneficiaries, who would otherwise be unable to obtain that care.

The requesting hospital is part of a large public health system with a high proportion of indigent patients under a statutory duty to provide healthcare to area residents. The hospital's dialysis unit does not provide outpatient care but rather is available only to inpatients and those in need of emergency services. According to the hospital, many chronic dialysis patients are unable to obtain dialysis care, either because of payment issues or inadequate capacity, and end up in the hospital's emergency room or its outpatient renal clinic, which does not provide dialysis. These patients are then admitted for dialysis, occupying inpatient beds that would otherwise be available to acute care patients. The hospital is proposing to admit these patients for dialysis and then immediately discharge them. The hospital would not bill any third-party payor, including Medicare or Medicaid, for the admissions.

The OIG said the proposal could potentially implicate both the civil monetary penalty provision prohibiting beneficiary inducements and the Anti-Kickback Statute because the hospital would be conferring a substantial benefit on federal healthcare program beneficiaries. But the OIG concluded that it would not impose administrative sanctions because the proposal presented little risk of federal healthcare program abuse “while providing significant benefits to an underserved patient population.” The OIG acknowledged that the free dialysis could generate a general feeling of “goodwill” toward the hospital that may sway patients’ selection of non-dialysis services in the future, but

**OIG Cautions Healthcare System About Hospital's Proposal To Subsidize Non-Local Ambulance Transportation For Out-Of-Area Patients**

In an advisory opinion posted March 14, 2007, the Department of Health and Human Services Office of Inspector General (OIG) said that a hospital’s proposal to subsidize the costs of ambulance services for patients transported to the hospital from outside the hospital’s local area could generate prohibited remuneration under the Anti-Kickback Statute. Thus, the OIG could not rule out sanctions in connection with the arrangement under the Anti-Kickback Statute and the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries.

The Hospital, a subsidiary of the requesting healthcare system (Requestor), is an acute care facility with over 1,000 physicians on its medical staff and is a recognized leader in cardiovascular services. The Requestor indicated that, at various times, patients have been transferred by ambulance to the Hospital from hospitals outside its local area. The local Medicare carrier historically paid the claims for such transportation services, but recently began refusing to do so citing Medicare rules providing only local ambulance transportation “except where non-local transportation is necessary to take the patient to the ‘nearest institution with appropriate facilities.’”

As a result, patients complained to the Hospital about the bills they had received from their ambulance suppliers for the uncovered portions of the non-local ambulance trips to the Hospital (i.e., the excess mileage), according to the opinion. In turn, the opinion said, these complaints led to “a disinclination on the part of physicians to order or recommend the transfer of patients to the Hospital” in cases involving an out-of-area patient (i.e., a patient that would likely incur excess mileage charges). For these reasons, the Hospital proposed an arrangement under which it would contract with various ambulance suppliers to transport patients to the Hospital from hospitals located outside its locality.

The OIG concluded that the Hospital’s proposal could generate prohibited remuneration and trigger sanctions under the CMP provision because “the payment or subsidy of an expense that would ordinarily be borne by a patient constitutes remuneration to the patient.” Moreover, the opinion said, the proposed arrangement would likely influence patients’ “initial and subsequent choice of the Hospital for hospital services” based on the patients’ anticipated receipt of items or services reimbursable by Medicare or Medicaid. The OIG noted that many of the patients who would benefit from the proposed arrangement would be cardiac patients, who likely would develop ongoing relationships with a hospital provider. In addition, the proposed arrangement could influence patients “to choose the Hospital’s ambulance suppliers over other suppliers, whether for initial or future ambulance transports,” the opinion pointed out. Even if the Hospital ensured no direct advertising of its ambulance services to its patients, this was “not a meaningful safeguard” because the “availability of the reduced cost services will be known to patients’ physicians who may serve as indirect channels of information dissemination in

OIG OKs Use Of Credit Card Rewards For Purchase Of Nursing Home Goods And Services And Employee Remuneration
The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted April 3, 2007 that it would not impose administrative sanctions in connection with the use of rewards from credit card issuers for the benefit of a residential healthcare facility and its employees. The opinion was issued in response to a request from a nursing home that proposed to use credit cards issued in its name to purchase goods and services for the home and then use rewards provided by the credit card issuer (such as airline miles, cash rebates, etc.) to purchase additional goods and services or to give to nursing home employees as performance-based compensation.

In finding that the proposed arrangement would not violate the Anti-Kickback Statute, the opinion noted it “is axiomatic that there can be no violation of the anti-kickback statute absent potential referrals of Federal health care program business. On the facts presented, there will be no such referrals between the credit card issuers (or any affiliates) and the Requestor or its Nursing Home.” Therefore, OIG said, neither the transfer of rewards by the credit card issuers to the nursing home, nor the subsequent use of some rewards to purchase items or services would give rise to sanctions under §§ 1128(b)(7) or 1128A(a)(7) of the Anti-Kickback Statute.

OIG next found that the proposed compensation to employees of credit card rewards would fall within the statutory exception and regulatory safe harbor for employee compensation. Because only bona fide employees would be eligible to receive the rewards, OIG explained that “the risk of fraud and abuse is typically reduced with bona fide employer-employee relationships, in part because the employer is generally fully liable for the actions of its employees and is thus more motivated to supervise and control them.” Advisory Opinion No. 07-03 (Dep’t of Health and Human Servs. Office of Inspector Gen. Mar. 27, 2007).

OIG Says It Would Not Impose Sanctions On Pharmaceutical Company’s Proposal To Assist Needy Medicare Part D Enrollees
The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted April 6, 2007 that, although a pharmaceutical company’s proposal to provide free outpatient prescription drugs to financially needy Medicare Part D enrollees could violate the Anti-Kickback Statute, the agency would not impose sanctions. The OIG concluded that the pharmaceutical company’s proposal to expand its patient assistance programs (PAPs) to include needy Medicare Part D beneficiaries contained sufficient safeguards to ensure that the PAPs would operate entirely outside the Part D benefit, and therefore the risk of fraud and abuse under the Part D program was minimal.

As with other PAPs approved by the OIG, the instant drug maker’s proposal would applicants to meet a number of eligibility criteria, including using one or more of the
PAPs’ covered drugs and demonstrating financial need (income test and spending threshold); would coordinate assistance with Medicare Part D coverage; would ensure that free drugs are not counted as a beneficiary’s true out-of-pocket spending (TrOOP) under the Part D program; would notify enrollees’ Part D plans via data sharing agreements with the Centers for Medicare and Medicaid Services that the free drugs are being provided outside the Part D benefit. “Taken as a whole, these safeguards substantially mitigate the risk . . . that the PAPs’ drugs will be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable by the Medicare Part D program,” the OIG concluded. Advisory Opinion No. 07-04 (Dep’t of Health and Human Servs. Office of Inspector Gen. Mar. 30, 2007).

OIG Confirms Physician Investment Guidance Applies to Device Companies and Distributors

With unusual speed and emphasis, on October 6, 2006 the Office of Inspector General (OIG) issued clarifying guidance to AdvaMed's September 6, 2006 request for further guidance regarding physician investment in joint ventures arrangements involving medical device products. Noting the apparent proliferation of physician investments in medical device and distribution entities, including group purchasing organizations, the OIG cautioned such arrangements raised the strong potential for improper inducements and that physician joint ventures should be closely scrutinized under fraud and abuse laws. In providing guidance in response to AdvaMed's questions, the OIG confirmed that the 1989 Special Fraud Alert on Joint Ventures, as well as other relevant guidance, applies to the medical device industry. Its guidance letter expressly addressed whether the amount of the revenues generated by the physician investor directly or indirectly is a relevant factor in evaluating anti-kickback compliance. In confirming indirect revenue generated is a relevant factor, the OIG referenced its Supplemental Guidance for Hospitals (issued January 2005), and the point that where "a substantial portion of a venture's gross revenues is derived from participant-driven referrals is [a] potential indicator of a problematic joint venture." October 6, 2006 guidance letter at p.2.

The OIG further opined that its guidance is not sector specific and applies to all health industry sectors. This point is compelling for the hospital community, which is often the purchaser of products involved in the physician joint ventures that may be potentially suspect, warranting hospital scrutiny of its procurement decisions and purchases for compliance with the anti-kickback requirements, as well as conflict of interest provisions. The AdvaMed request and OIG response is also noteworthy in that an important industry trend affecting daily compliance advice provided by healthcare attorneys to physicians, hospitals, GPOs, and the device industry has generated timely confirmation of OIG guidance and discussion of clarifying guidance.

Washington High Court Finds State Antikickback Law Does Not Prohibit Physicians From Dispensing Prescription Drugs To Patients For A Profit

Washington’s antikickback statute, Wash. Rev. Code § 19.68.010, does not prohibit physicians from making a profit by dispensing prescription drugs to their patients, that state’s high court held in a unanimous decision rendered October 12, 2006. The Washington Supreme Court therefore vacated a state trial court’s decision holding that a
physician violated the antikickback statute at issue by dispensing, at a profit, a
prescription drug combination commonly known as “fen-phen” to patients seeking to lose
weight. In 1998, three women brought a lawsuit against Dr. Milan Jeckle, alleging
injuries related to their taking fen-phen that they received from him. Plaintiffs also
alleged that Jeckle violated Washington’s Consumer Protection Act (CPA), Wash. Rev.
Code § 19.86.020, by engaging in deceptive acts in trade or commerce, and that he
breached his fiduciary duty to them. The “deceptive act,” according to plaintiffs, was
Jeckle’s alleged violation of the antikickback statute by making a profit from dispensing
fen-phen to them.

The high court found no violation of the antikickback statute in the instant case. “While
not a model of clarity by any means,” the high court determined the statute prohibits
paying or receiving anything of value in return for a referral. At the same time, “the
statute does not prevent a patient from paying a health care provider for services rendered
or prescriptions received . . . [n]or does it prevent a health care provider from making a
profit on furnishing goods or care to patients,” the high court reasoned. “Clearly, the
chapter is aimed at preventing kickbacks, not at preventing medical professionals from
profiting off the goods and services that they themselves provide,” the high court

**False Claims**

**Tenet To Pay Government Over $900 Million To Settle FCA Allegations Involving Billing Practices**
Tenet Healthcare Corp. (Tenet) has agreed to pay the United States more than $900
million to resolve False Claims Act allegations involving its billing practices, announced
the head of the Department of Justice’s (DOJ's) Civil Division, Assistant Attorney
General Peter D. Keisler and U.S. Attorney for the Central District of California Debra
Wong Yang in a June 29, 2006 press release. More than $788 million of the settlement
amount resolves claims that Tenet received excessive outlier payments, while the
remainder stems from claims that it paid kickbacks to physicians in exchange for
Medicare referrals and engaged in “upcoding.” Tenet also agreed to enter into a multi-
year corporate integrity agreement with the Department of Health and Human Services
Office of Inspector General.

**Highmark Medicare Secondary Payer Settlement And Model Agreement**
Highmark and the U.S. Attorney's Office in Philadelphia entered into a False Claims Act
Agreement and developed a Model Agreement relating to insurer obligations under
Medicare Secondary Payer (MSP) regulations that govern Medicare and private insurance
coordination of benefit (COB) determinations. The settlement agreement contains
provisions for a Independent Review Organization (IRO) to review MSP compliance.
The agreement does not contain an Office of Inspector General corporate integrity
agreement (CIA). The Model Agreement addresses the application of specific MSP
regulations involving the working aged (over 65) and has audit and refund provisions.
The Highmark False Claims Act action was initiated under the qui tam provisions of the
False Claims Act and there is a separate settlement with the relator. MSP is a compliance
issue for insurers and providers and has the potential for False Claims Act liability. The MSP provisions have also been specially addressed in the fraud and abuse provisions of the Medicare Modernization Act (MMA).

Tenet Executes Five-Year CIA With OIG
Tenet Healthcare Corp. agreed September 28, 2006 to a far-reaching corporate integrity agreement (CIA) that includes “unprecedented provisions” requiring a committee of its board of directors to review the effectiveness of the company’s compliance program and adopt needed resolutions based on its findings, according to a Department of Health and Human Services Office of Inspector General (OIG) announcement. The CIA follows a settlement deal Tenet reached in June 2006 to pay the federal government more than $900 million to resolve allegations related to upcoding, improper outlier payments, kickbacks to physicians, and other fraudulent conduct. The CIA requires Tenet to implement a comprehensive compliance program including corporate, regional, and hospital compliance officers; compliance policies and training; an employee hotline and reporting mechanism; and mandatory reporting and repayment of overpayments. Under the agreement, independent review organizations will examine Tenet’s diagnosis related group claims, outlier payments, physician relationships, and clinical quality management. Tenet must submit annual reports to the OIG and include certifications by Tenet officers that the company is in compliance with federal healthcare program requirements.

Omnicare To Pay $52.5 Million To Settle Medicaid Fraud Allegations In Michigan
Michigan Attorney General Mike Cox announced October 5, 2006 a record $52.5 million civil settlement of Medicaid fraud allegations with Specialized Pharmacy Services, a wholly owned subsidiary of Omnicare, Inc. State and federal fraud investigators found Specialized Pharmacy, the largest long term care pharmacy in the state, defrauded the Michigan Medicaid program by as much as $17 million from 1999 through 2005, according to Cox's press release. The release said the investigation focused on improper billing for medication that the company dispensed in unit doses; failure to credit Medicaid for drugs that were not consumed by Medicaid beneficiaries; improper billing of Medicaid drugs for Medicaid patients in hospice care; and billing Medicaid for medications dispensed to beneficiaries who were deceased. Specialized Pharmacy will execute a two-year corporate integrity agreement aimed at improving its billing practices and demonstrating its regulatory compliance.

Medco To Pay $155 Million To Settle Fraud, Kickback Allegations
The nation’s second largest pharmacy benefits manager (PBM) Medco Health Solutions agreed to pay $155 million to settle allegations that it defrauded federal healthcare programs and paid and received kickbacks, according to a Department of Justice (DOJ) release posted October 23, 2006. The case stemmed from whistleblower actions brought in 1999 by former Medco pharmacists Walter W. Gauger and George Bradford Hunt, who worked at the PBMs largest automated mail order facility in Las Vegas, Nevada, and in 2000 by Joseph Piacentile, M.D. Both cases were later consolidated. The federal government intervened in the qui tam lawsuit and the U.S. Attorney's Office in the Eastern District of Pennsylvania filed a complaint against Medco in December 2003.
The complaint alleged the New Jersey-based PBM submitted false claims for mail order prescription drug services it was required by contract to provide to federal employees and their families, the DOJ release said. In addition, the company allegedly destroyed and canceled valid patient prescriptions to cover-up its failure to provide them in a timely manner so as to avoid contractual penalties, solicited and accepted kickbacks from drug makers to favor their drugs, and paid kickbacks to health plans for their business. As part of the settlement, the government agreed to release further claims against Medco’s former Vice President Diane Collins, who managed the firm’s Tampa, Florida mail order pharmacy. Medco also agreed to enter into a corporate compliance agreement with the Department of Health and Human Services Office of Inspector General and the Office of Personnel Management Office of Inspector General.

**InterMune To Pay $36.9 Million To Settle Allegations Involving Off-Label Drug Marketing**

Biopharmaceutical firm InterMune, Inc. agreed to pay the U.S. over $36.9 million and has entered into a deferred prosecution agreement to resolve civil and criminal allegations that it illegally promoted one of its drugs for off-label uses and caused the submission of false claims, according to an October 26, 2006 Department of Justice (DOJ) press release. According to the allegations, InterMune promoted its drug Actimmune, which the Food and Drug Administration has approved to treat certain immune system disorders, for lung scarring, an unapproved use.

Because the government alleged InterMune acted with the intent to defraud or mislead, the company was charged with a felony violation of the Food, Drug, and Cosmetic Act. Under a deferred prosecution agreement, DOJ has agreed to recommend deferring prosecution provided the company cooperate with its investigation and continue to overhaul its compliance policies, the release said.

**Omnicare To Pay $49.5 Million To Settle Charges Of Medicaid Prescription Drug Fraud**

Omnicare Inc. has agreed to pay $49.5 million to the federal government and forty-three states to resolve allegations that it defrauded Medicaid by improperly switching patients from cheaper to more expensive versions of certain drugs solely to increase its reimbursement rate, U.S. Attorney for the District of Northern Illinois Patrick J. Fitzgerald announced November 14, 2006. The settlement stems from whistleblower actions brought under the False Claims Act claiming that Omnicare, the nation’s largest provider of pharmacy services to the elderly, substituted three drugs—Ranitidine capsules, Fluoxetine tablets, and Buspirone tablets—when less expensive versions had been prescribed. The settlement agreement, which covers reimbursement claims submitted from April 2000 through 2005, does not include any finding of wrongdoing or any admission of liability by Omnicare. The case represents the first time a U.S. Attorney’s Office has joined forces with the National Association of Medicaid Fraud Control Units to conduct a joint healthcare fraud investigation, the release said. As part of the settlement, Omnicare also agreed to enter into a five-year corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.
Florida Hospital Pays $15.4 Million To Resolve FCA Claims Involving Alleged Kickbacks

The Department of Justice (DOJ) announced November 30, 2006 that Larkin Community Hospital and its current and former owners have paid $15.4 million to resolve fraud claims involving alleged kickbacks paid to physicians for patient admissions and medically unnecessary treatments. The government filed the False Claims Act case in 2004 against the Miami, Florida hospital and Dr. Jack Michel, Dr. James Desnick, Morris Esformes, and Philip Esformes. DOJ alleged that in 1997 Jack Michel was paid for patient admissions that he and his brother George Michel made to the hospital, which Desnick owned at the time. Jack Michel purchased the hospital in 1998, according to the release. The government also alleged that from 1998 to 1999 Jack Michel, George Michel, the Esformes, Frank Palacios, and Claudia Pace conspired to admit patients, some of whom came from assisted living facilities owned by Jack Michel and the Esformes, to Larkin for medically unnecessary treatments. Thirty-four related companies owned by the Esformes that were used to operate nine assisted living facilities also are a part of the settlement, along with an employee of one of the companies and an employee of the hospital, the release said.

Nursing Home Operator Pays Government $7.5 Million To Settle FCA, Kickback Allegations

Long term care facility operator SCCI Health Services Corporation (SCCI) and its subsidiary, SCCI Hospital Ventures Inc., agreed to pay the United States $7.5 million to settle allegations that the companies violated the Stark self-referral statute and the False Claims Act, the Justice Department (DOJ) announced January 5, 2007. The government’s complaint alleged SCCI entered into prohibited financial relationships with three physicians and paid the physicians illegal payments in violation of the Stark statute. In addition, the complaint alleged that SCCI either submitted or caused false claims to be submitted to the Medicare program in violation of the False Claims Act. The settlement resolves a civil case filed by whistleblowers on behalf of the government. The five whistleblowers who originally filed the claim will share $1.7 million, DOJ said.

Judge Imposes Civil Penalties Of $190 Million Against Amerigroup Companies, Raising Their Total Liability To $334 Million

In a judgment issued March 13, 2007, U.S. District Judge for the Northern District of Illinois Harry D. Leinenweber imposed civil penalties of more than $190 million against Amerigroup Illinois Inc. and its parent company, Amerigroup Corp., raising the insurance companies’ total liability to more than $334 million. In October 2006, a federal jury found the Medicaid health maintenance organization violated the False Claims Act (FCA) by avoiding enrolling pregnant women and other individuals with expensive health conditions. The verdict followed a three-week trial of an action originally filed by whistleblower Cleveland Tyson, a former Amerigroup vice president of government relations. The U.S. Department of Justice and Illinois Attorney General Lisa Madigan intervened in the FCA qui tam action in 2005.
According to the government, Amerigroup was paid $243 million to set up a Medicaid managed care health plan in Illinois to help the state’s low-income residents. As part of its contract and under federal law, Amerigroup was required to market the plan to all eligible Medicaid beneficiaries without discriminating based on their health status. By systematically discriminating against pregnant women, particularly those in their third trimester, and other individuals with costly medical conditions, Amerigroup and its Illinois subsidiary defrauded the Medicaid program, the government argued.

Fitzgerald and Madigan subsequently asked U.S. District Judge Leinenweber to impose additional civil penalties on each of over 18,000 false claims the jury found Amerigroup submitted. In granting that request, Judge Leinenweber based the penalties he imposed on a finding of 18,130 false claims and assessed a penalty of $10,500 on each false claim for a total of over $190 million. In a statement, Amerigroup said it intended to appeal the judgment to the Seventh Circuit.

**NJ Hospital Agrees To Pay U.S. $7.5 Million To Resolve Medicare Fraud Charges**

Raritan Bay Medical Center, headquartered in Perth Amboy, N.J., agreed to pay the United States $7.5 million to settle allegations that it improperly increased charges to Medicare patients to obtain enhanced reimbursements from the federal healthcare program, the Department of Justice (DOJ) announced March 15, 2007. The government alleged that Raritan Bay purposefully inflated charges for inpatient and outpatient care in order to receive Medicare outlier payments. The allegations were filed in three separate federal lawsuits brought by whistleblowers under the federal False Claims Act. As part of the settlement agreement, the hospital entered into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

**OIG Approves State False Claims Acts Submitted For Review By Hawaii And Virginia**

The Department of Health and Human Services Office of Inspector General (OIG) has approved state False Claims Acts (FCAs) submitted for review by Hawaii and Virginia, finding that these states’ statutes meet all the requirements set forth in the Deficit Reduction Act of 2005 (DRA) to be eligible for the financial incentive bonus. Under § 6031(b) of the DRA, a state is eligible to receive a 10% incentive bonus (i.e., the state will receive a 10% increase in its share of Medicaid fraud recoveries from a state action brought under the state FCA) if it enacts a state FCA that: establishes liability to the state for false or fraudulent Medicaid claims; contains provisions that are at least as effective as the federal FCA in rewarding and facilitating qui tam actions; contains a requirement that qui tam actions be filed under seal for sixty days with review by the state attorney general; and contains a civil penalty that is not less than the amount of the civil penalty authorized under the federal FCA.

In two separate letters dated March 13—one addressed to Hawaii Attorney General Mark J. Bennett (R) and the other to Virginia Attorney General Robert McDonnell (R), the OIG said that each state’s laws meet all of the § 6031(b) requirements. Hawaii’s statutory scheme in this area consists of two different statutes—its false claims statutes (Haw. Rev. Stat. §§ 661-21 to -29) and its Whistleblowers’ Protection Act (Haw. Rev. Stat. §§ 378-
Virginia's FCA is otherwise known as the Virginia Fraud Against Taxpayers Act (Va. Code. Ann. §§ 8.01-216.1 to -216.19). The OIG approved three other states’ FCAs in December 2006: Illinois (740 Ill. Comp. Stat. §§ 175/1-175/8), Massachusetts (Mass. Gen. Laws ch. 12, § 5A), and Tennessee (Tenn. Code Ann. §§ 71-5-181 to -185). However, seven other states—California, Florida, Indiana, Louisiana, Michigan, Nevada, and Texas—received December 2006 letters from the OIG specifying the reason(s) their state FCAs did not meet all of the requirements enumerated in § 6031(b), and that amendments would be necessary in order to be eligible for the incentive bonus.

U.S. Court In Nevada Finds Government Failed To Establish FCA Claims That Physician Improperly Billed Medicare
The federal government failed to establish that a physician knowingly submitted false claims to Medicare by billing for simple pulmonary stress tests when performed as part of a pulmonary rehabilitation program, or that the physician was unjustly enriched as a result of his billing practices, a federal district court in Nevada has ruled. The physician, R.D. Prabhu, is a board certified physician in both pulmonary and internal medicine who operates a medical practice in Las Vegas, Nevada. The government alleged Prabhu violated the False Claims Act (FCA) by unlawfully billing non-covered pulmonary rehabilitation services as simple pulmonary stress tests. In addition, the government contended that Prabhu failed to properly document the medical necessity of services to some of his patients.

The U.S. District Court for the District of Nevada concluded that the record did not support a finding of falsity as a matter of law with respect to the two basic services underlying the government’s lawsuit, i.e., pulmonary rehabilitation services and simple pulmonary stress tests. “The Government’s own expert agree[d] that pulmonary rehabilitation was covered by Medicare in various settings and in different jurisdictions,” the district court found. In addition, both the government’s expert and the carrier’s medical director concurred that “Medicare has always covered pulmonary stress tests when furnished as a component part of a pulmonary rehabilitation program,” the court noted. “In light of this, the Government has failed to prove that . . . Prabhu violated a controlling rule, regulation, or standard for purposes of FCA liability,” the court said. Moreover, the government did not dispute the overwhelming evidence that Prabhu was following the instructions he received from his carrier in billing for the stress tests as part of the rehabilitation program, the court observed.

Thus, the undisputed evidence demonstrated that Prabhu did not knowingly submit any false claims because “his billing practice conformed to a reasonable interpretation of ambiguous regulations that he, and his staff, believed in good faith were proper,” the court found. The government’s case also “makes no economic sense” because Prabhu lost money in providing pulmonary rehabilitation services to his patients and therefore had no monetary incentive to furnish more services than were medically indicated and necessary, the court reasoned. United States v. Prabhu, No. 2:04-CV-0589-RCJ (D. Nev. July 19, 2006).
U.S. Court In Illinois Dismisses Qui Tam Complaint Against Pharmacy Benefit Services Company
A second amended qui tam complaint filed under the False Claims Act (FCA) by four former employees of a pharmacy benefit services company failed to allege claims with sufficient particularity and therefore must be dismissed, a federal district court in Illinois held August 21, 2006. The pharmacy benefits company, Caremark Inc., and its parent, Caremark Rx Inc. (collectively, Caremark), allegedly used fraudulent practices in distributing prescription drugs to members of various federal health insurance plans. Under its contracts with these federal health plans, Caremark is required to ship prescription drugs to plan members within a specified number of days after receiving their orders and must pay a penalty for failing to meet turn-around time guarantees. In addition, under the government contracts, Caremark provides “intervention” services aimed at lowering federal health plans' costs such as obtaining approval from plan members’ physicians to convert a prescription drug to an over the counter drug.

The four whistleblowers initially filed a four-count amended complaint under the FCA as well as under several state false claims acts, which was dismissed for failing to plead fraud with the required particularity under Federal Rule of Civil Procedure 9(b). In their 178-page second amended complaint accompanied by over a thousand pages of attached exhibits, plaintiffs set forth in detail their personal knowledge of Caremark’s alleged schemes. But the court found plaintiffs’ second amendment complaint was still deficient because they failed to “identify a single order with falsified turn-around time” or “identify an instance of improper authorization,” the court said. Despite the opportunity provided to plaintiffs to cure the pleading defects, they have failed to do so by continuing to allege only generalized schemes and neglecting to specify a single false claim, the court concluded. United States ex rel. Fowler v. Caremark Rx Inc., No. 03C8714 (N.D. Ill. Aug. 21, 2006).

U.S. Court In Arkansas Dismisses Qui Tam Lawsuit Against Hospital And Oncologist At Affiliated Radiation Therapy Facility
An Arkansas federal court found an amended qui tam complaint filed under the False Claims Act (FCA) by the former director of a hospital’s radiation therapy facility failed to allege claims with sufficient particularity and therefore must be dismissed. The hospital, North Arkansas Regional Medical Center (NARMC), and an oncologist, Dr. Helen H. Kim, who worked for NARMC’s radiation therapy institute, had allegedly developed a working relationship under an arrangement that involved kickbacks and referrals in violation of the Anti-Kickback Statue (42 U.S.C. §§ 1320a-7b) and the Stark Law (42 U.S.C. § 1395nn). The whistleblower in the case was Nadra Lee Woods, the former director of the radiation therapy facility. NARMC had allegedly provided Kim with office space, services of NARMC staff, and furniture and equipment for “less than fair market value” in exchange for Kim’s referral of patients to NARMC for medical treatment, including inpatient and outpatient hospital services and surgery. Woods alleged that NARMC and Kim violated the FCA by submitting claims for payment to federal healthcare programs that falsely certified compliance with the anti-kickback and Stark laws. Woods also alleged that Kim submitted false claims for a number of specific services.
In dismissing the case, the U.S. District Court for the Western District of Arkansas concluded that Woods failed to plead her FCA claims with the particularity required by Federal Rule of Civil Procedure 9(b). Woods’ amended complaint failed to provide “some representative examples” of the alleged fraudulent activity or to specify who was involved in submitting fraudulent claims, the district court found. There are multiple pleading deficiencies, according to the court, including the failure to identify the particular individuals alleged to have made the decision to provide Kim with office space and staff for less than fair market value; what the actual market value for these goods and services was, and what Kim was charged; the names of any patients Kim allegedly referred to NARMC; the individuals who were involved in submitting fraudulent claims and cost reports; what money was fraudulently obtained as a result of the arrangement; and how Woods learned of the alleged fraudulent claims and their submission for payment.

Because Woods had already had an opportunity to cure the deficiencies before, the court decided to dismiss the action with prejudice. The court also summarily rejected a “statement of interest” filed by the U.S. government that indicated its investigation was ongoing and that therefore any dismissal of claims should be without prejudice. The district court emphasized that the action had been pending for three years and that during this time period, the government had been granted three extensions in which to evaluate whether or not to intervene in the case. Therefore, the government had “ample opportunity” to determine whether it should pursue the claims at issue, the court concluded. *United States ex rel. Woods v. North Arkansas Reg’l Med. Ctr.*, No. 3:03-cv-03086-JLH (W.D. Ark. Sept. 7, 2006).

**U.S. Court In Tennessee Declines To Dismiss Qui Tam Lawsuit Against Manufacturer Of Implant Medical Devices**

A second amended qui tam complaint brought under the False Claims Act (FCA) in which the whistleblower presented five specific examples of how a manufacturer of implant medical devices (IMDs) allegedly engaged in concealing warranty credits from hospitals met the particularity pleading requirement in Federal Rule of Civil Procedure 9(b), a federal district court in Tennessee ruled September 13, 2006. Based on this conclusion, the U.S. District Court for the Middle District of Tennessee denied a motion to dismiss the amended complaint.

The whistleblower, Robert A. Fry, was employed as a salesman for Guidant Corporation, a company that manufactures and sells IMDs (e.g., defibrillators and pacemakers) to physicians and hospitals throughout the United States. According to Fry’s amended complaint, from April 1981 through March 1997, Guidant engaged in a fraudulent scheme to defraud hospitals by concealing the existence of warranty rebates and “upgrade” credits for replacement IMDs. This, in turn, caused hospitals to submit Medicare claims that overstated the actual replacement costs for those devices. Fry presented in his amended complaint five specific examples identifying patients who received upgraded IMDs under warranty. In each of these examples, because hospital personnel were deprived of access to these warranties, the hospitals paid full price for the
upgrades, and the costs were ultimately passed on to the federal government through Medicare and Medicaid reimbursement.

Based on this record, the district court found that “Mr. Fry has well met the Rule 9(b) pleading requirements for his FCA cause of action.” In addition to alleging with particularity the overall scheme by which Guidant allegedly precluded hospitals from using warranty credits, Fry provided specific examples, including dates of procedures and serial numbers of devices implanted and replaced, demonstrating how hospitals were kept ignorant of . . . [warranty] credits, and the cost was ultimately passed on to the federal government,” the court said. United States ex rel. Fry v. Guidant Corp., No. 3:03-0842 (M.D. Tenn. Sept. 13, 2006).

U.S. Court In Pennsylvania Allows Qui Tam Case To Go Forward, Says Specifics Of False Claims Not Necessary
A federal court in Pennsylvania allowed a qui tam case to go forward, rejecting defendants’ claim that plaintiffs failed to plead fraud with particularity. In so holding, the court said that specifics as to “date, place, or time” are not required at this stage of the proceedings as long as defendants are on notice of the precise misconduct with which they are charged. A group of physicians initiated a qui tam action against Bradford Regional Medical Center, V & S Medical Associates, LLC, and two individual physicians (defendants) alleging False Claims Act violations for claims made seeking reimbursement for services rendered to patients unlawfully referred to defendant Bradford Regional Medical Center.

The U.S. District Court for the Western District of Pennsylvania refused to dismiss the action. The court rejected defendants’ argument that plaintiffs failed to provide specific information, including specific cost reports that were actually filed, when they were filed, and specific content that was false. According to the court, Federal Rule of Civil Procedure 9(b) does not require such strict scrutiny of fraud claims. The court held “Rule 9(b) requires plaintiffs to plead with particularity the ‘circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and charges of immoral and fraudulent behavior. It is certainly true that allegations of ‘date, place or time' fulfill these functions, but nothing in [Rule 9(b)] requires them.” In the court’s view, requiring relators to provide a single claim example would not put defendants in a better position to answer or defend against the claims. United States ex rel. Singh v. Bradford Reg’l Med. Ctr., No. 04-186 ERIE (W.D. Pa. Sept. 13, 2006).

U.S. Court In California Finds FCA Public Disclosure Bar Requires Dismissal Of Qui Tam Complaint
A federal trial court in California dismissed charges brought under the qui tam provision of the False Claims Act (FCA), finding the fraud allegations had been publicly disclosed in previous litigation. Thus, the court found it lacked jurisdiction under the FCA’s public disclosure bar. Plaintiffs Patricia Szerlip and Michael Meyer and former plaintiff Vickie Weatherford sued Horizon Health Corporation and others (defendants) under the FCA’s qui tam provision alleging a scheme involving Medicare fraud. After filing their third
amended complaint in the suit, plaintiffs notified the court that Vickie Weatherford was withdrawing from the action. Weatherford had previously brought an action against Horizon Health for breach of contract and defamation in connection with the alleged Medicare fraud committed by defendants. The third amended complaint filed by the instant plaintiffs alleged the same action by defendants.

The U.S. District Court for the Northern District of California first noted that under the FCA, a court lacks subject matter jurisdiction where the allegations in a qui tam complaint have been publicly disclosed unless the relator is an original source. The court concluded that the allegations in this case had been publicly disclosed in the prior civil litigation. The court further concluded that the instant allegations were “based upon” the information publicly disclosed in the prior suit because they “plainly share a substantial identity” with the Weatherford allegations. Finally, the court held neither Szerlip nor Meyers was an original source of the information contained in the complaint—they did not provide information about the alleged fraud to the government before bringing suit, they were not parties to the previous litigation, and they did not possess direct or independent knowledge of the alleged fraud. United States ex rel. Meyer v. Horizon Health Corp., No. CV 00 1303 SBA (N.D. Cal. Oct. 2, 2006).

U.S. Court in California Dismisses Whistleblower Action Alleging Misuse Of Medicaid Funds
A federal district court in California granted October 31, 2006 summary judgment in favor of the County of Los Angeles (County) in a False Claims Act (FCA) qui tam action alleging it made false claims when it requested supplemental funds under a state Medicaid waiver program and then used these funds for non-Medicaid and even non-healthcare purposes.

In reaching its decision, the U.S. District Court for the Eastern District of California reasoned that the federal government knew what the County was doing and implicitly approved of the County’s actions, thereby negating any intention by the County to defraud the government—a theory otherwise known as the “government knowledge defense” to FCA liability. In addition, the court found the relator failed to furnish evidence establishing any genuine issue of material fact so that a reasonable trier of fact could find the County knowingly submitted a false claim. United States ex rel. Englund v. Los Angeles County, No. S-04-282 LKK/JFM (E.D. Cal. Oct. 31, 2006).

Second Circuit Finds Government’s Attempt To Intervene Eight Years After Filing Of Original Qui Tam Complaint Is Time-Barred
A False Claims Act (FCA) qui tam action initially filed by a whistleblower in 1994, for which the government did not file complaints-in-intervention until 2002, is time-barred, the Second Circuit ruled November 16, 2006. A three-judge appellate panel therefore dismissed the action that was brought against 132 hospitals from thirty states based on allegations that the hospitals violated the FCA when they sought reimbursement for services involving investigational cardiac devices, in contravention of a provision in the Medicare reimbursement manual.
Kevin Cosens, the whistleblower in the case, was a former medical device salesman when he filed the action in March 1994 in the U.S. District Court for the Western District of Washington. In his original complaint, Cosens alleged that the hospitals defrauded Medicare by seeking and obtaining reimbursement for hospital services provided to patients participating in clinical trials involving investigational cardiac devices that had not received Food and Drug Administration (FDA) premarket approval. The government did not intervene in the case until 2002. Defendant-hospitals argued that all claims were time-barred. Concluding that the government’s FCA claims were timely, the district court reasoned that the controlling date for the statute-of-limitations period was the date of the original qui tam complaint, and that all claims had accrued within the applicable limitations period of that original complaint.

On appeal, defendant-hospitals argued that, under the six-year statute of limitations specified in 31 U.S.C. § 3730(b), the government’s FCA claims were time-barred. The Second Circuit agreed. “We conclude that the date the Government’s actions commenced (for statute of limitations purposes) was the date [2002] on which the complaints-in-intervention were filed . . . and that the Hospitals made their last false claims in 1995,” the appeals court said. The appeals court also rejected the government’s argument that its claims related back to the original complaint pursuant to Fed. R. Civ. P. 15(c)(2), which provides that “an amendment of a pleading relates back to the date of the original pleading when . . . the claim or defense asserted in the amended pleading arise out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading.” But the appeals court concluded the “secrecy required by § 3730(b) is incompatible with Rule 15(c)(2), because (as is well-settled) the touchstone for relation back pursuant to [that] Rule . . . is notice.” United States v. The Baylor Univ. Med. Ctr., No. 05-2951-cv (2d Cir. Nov. 16, 2006).

U.S. Court In Arkansas Finds Qui Tam Complaint Pled With Sufficient Particularity

A federal court in Arkansas found a relator pled her complaint with sufficient particularity to withstand a motion to dismiss. In so holding, the court distinguished a recent Eighth Circuit case laying out the requirements for Federal Rule of Civil Procedure 9(b). In July 2002, Misty Murphy filed a qui tam complaint against defendant Baptist Medcare, Inc., d/b/a Practice Plus (Practice Plus). Murphy alleged that Practice Plus submitted false claims to the Medicare and Medicaid programs in violation of the False Claims Act (FCA). Practice Plus moved to dismiss arguing Murphy failed to plead her complaint with the particularity required under Fed. R. Civ. P. 9(b).

The U.S. District Court for the Eastern District of Arkansas denied the motion. The court distinguished the Eighth Circuit’s recent holding in United States ex rel. Joshi v. St. Luke’s Hosp. Inc., 441 F.3d 552 (8th Cir. 2006), noting in Joshi the “plaintiff’s complaint was completely lacking any specificity,” whereas in the instant case Murphy’s allegations “are more specific and meet the ‘who, what, where, when, and how’ requirements.” The court rejected defendant’s suggestion that plaintiff should have knowledge of every relevant fact and that all facts should be included in the complaint. A burden that “onerous would eliminate the need for discovery and greatly surpass the standard

Eleventh Circuit Upholds Dismissal Of Qui Tam Lawsuit Against Two Psychiatrists And Several Skilled Nursing Facilities
The Eleventh Circuit affirmed December 1, 2006 the dismissal of a False Claims Act (FCA) qui tam lawsuit filed by an Alabama psychiatrist against two other psychiatrists and several skilled nursing facilities (SNFs), agreeing with the lower court’s conclusion that the fraud claims in the complaint were pled with insufficient particularity. The relator, Dr. Patrick Atkins, is an Alabama-licensed psychiatrist whose private practice includes providing psychiatric services to SNF residents in that state who are eligible for Medicare and Medicaid. After discovering questionable entries in the medical records of some of the residents he was attending at certain SNFs, Atkins conducted further review of the files. He discovered that two other psychiatrists serving SNF residents, Dr. Charles McInteer and Dr. Marilyn Lachman, had entered a number of false entries. Subsequently, Atkins brought his FCA qui tam action in the U.S. District Court for the Northern District of Alabama against McInteer and Lachman and their company, YHAP Psychiatric Services, as well as twelve other corporate owners/operators of SNFs, alleging they conspired to submit false and fraudulent Medicare and Medicaid claims for psychiatric services purportedly rendered to SNF residents.

The Eleventh Circuit found Atkins’ complaint failed to meet the particularity requirements of Fed. R. Civ. P. 9(b) because he did not “provide the next link in the FCA liability chain: showing that the defendants actually submitted reimbursement claims for the services he describes.” The appeals court also highlighted that Atkins never indicated that he had “firsthand knowledge” of defendants’ submission of false claims. As a psychiatrist, Atkins is “responsible for the provision of medical care . . . [not the] filing and submitting . . . [of] defendants’ claims for reimbursement,” the appeals court said. United States ex rel. Atkins v. McInteer, No. 04-16167 (11th Cir. Dec. 1, 2006).

Tenth Circuit Reverses Dismissal Of FCA Whistleblower Action Against Medicare Carrier And University Lab
A whistleblower could maintain a False Claims Act (FCA) action against her former employer, a Medicare carrier, and a university laboratory for causing false claims to be presented to the government involving allegedly improperly coded laboratory services, the Tenth Circuit ruled December 5, 2006. The case arose when Edyth Sikkenga brought a qui tam action against her former employer Regence Bluecross Blueshield of Utah (Regence), three of its managers, and Associated Regional and University Pathologists (ARUP). Regence is a Medicare carrier under contract with the Centers for Medicare and Medicaid Services and ARUP is a laboratory owned by the University of Utah Medical Center. Sikkenga alleged that Regence and ARUP violated the FCA when Regence paid claims for laboratory testing submitted by ARUP that were improperly coded and not medically necessary; that Regence directly submitted a false budget request in 1992; and that Regence fraudulently avoided Contractor Performance Evaluation Program score reductions. Sikkenga also asserted an FCA whistleblower retaliation claim and a state law wrongful discharge claim.
The Tenth Circuit reversed the lower court’s dismissal of Sikkenga’s claim against ARUP, her claim that Regence and its managers caused false claims to be presented, and her state law wrongful termination claim. The appeals court affirmed the dismissal of Sikkenga’s other FCA claims. As a threshold matter, the Tenth Circuit disagreed with the lower court’s conclusion that, as a Medicare carrier, Regence was immune from Sikkenga’s FCA claim regarding the allegedly improperly coded laboratory tests. Instead, the appeals court concluded that Regence would not be entitled to immunity if gross negligence or intent to defraud was involved. The appeals court also found that Sikkenga, at this stage of the litigation, sufficiently alleged that Regence “caused” claims to be presented by failing to stop ARUP from filing false claims after having knowledge that the claims were false. According to the appeals court, a defendant’s “ostrich-like behavior itself becomes ‘a course of conduct that allowed fraudulent claims to be presented to the government.’” The appeals court next concluded that ARUP was not an arm-of-the state and thus was subject to FCA liability. “We are convinced . . . that ARUP was designed to operate as a commercial enterprise, not as the alter ego of the State of Utah,” the appeals court said in reversing the dismissal of the FCA claims against the laboratory. United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, No. 05-4088 (10th Cir. Dec. 5, 2006).

U.S. Court In Texas Grants Attorneys’ Fees To Medical Device Company, Finds Government Acted In Bad Faith

The U.S. District Court for the Northern District of Texas in a December 7, 2006 decision ordered the government to pay attorneys’ fees to a durable medical equipment rental company after finding the government acted in bad faith in pursuing a False Claims Act (FCA) case against the company. The company sought an award of nearly $4.9 million, but the court referred the issue of the appropriate amount to mediation after the government claimed the charges were excessive or duplicative.

The case arose as a qui tam action under the FCA against Medica-Rents Co. alleging it overbilled the Medicare program between 1993 and 1995 for its anti-bedsore device. The government intervened and also alleged claims including unjust enrichment and payment by mistake. The dispute stemmed from how Medica-Rents coded its anti-bedsore device, which the government contended should have been billed under a code that paid much less. The court found that Medica-Rents had not fraudulently billed Medicare and therefore dismissed the FCA claims. The company asked, however, that the court exercise its discretion to award fees based on the government’s bad faith in pursuing the action.

Agreeing, the court relied on evidence indicating the government intervened in the qui tam action “based on information it knew could be faulty and unreliable” and “actively withheld crucial evidence from Medica-Rents” during discovery. “This case is troubling because the government put its full weight and authority behind a case that, upon examination, arises primarily out of personal animus and is based on shaky evidence,” the court said. “This case reveals the dangers of a government litigant set loose with no

Eleventh Circuit Finds Whistleblower’s Action Not Barred By “Release” Language In Severance Contract With Former Employer

A federal district court in Georgia erred in holding that a whistleblower’s False Claims Act (FCA) action against a hospital management company was barred by “release” provisions in a severance agreement signed by the whistleblower and the hospital authority for whom he worked, the Eleventh Circuit ruled December 13, 2006. The federal appeals court therefore reversed the lower court’s decision to grant summary judgment in favor of the hospital management company.

The whistleblower in the case, Ted R. Whitten, was employed by the Glynn Brunswick Memorial Hospital Authority (GBMHA) between 1980 and 2001, and during that time held a number of positions, including compliance officer. In 1989, the hospital management company, Quorum Health Resources, Inc., began providing the GBMHA with management services, including supplying the GBMHA with a chief executive officer and chief financial officer to manage the hospitals’ day-to-day operations. Quorum Health Resources Inc. subsequently reorganized into a limited liability company and merged with Triad Hospitals, Inc. in 2001 (collectively, Quorum). Prior to the merger, in September 2000, GBMHA terminated its relationship with Quorum. In early January 2001, Whitten resigned and entered into a severance agreement with the GBMHA; the agreement contained the “release” provisions at issue in the case. Shortly thereafter, Whitten initiated his FCA qui tam action against Quorum, alleging that the company, through its officers, was responsible for the submission of false claims for payment to the Medicare, CHAMPUS, and TRICARE programs. The federal government declined to intervene.

The U.S. District Court for the Southern District of Georgia granted Quorum summary judgment based on its argument that the action was barred by the "release" provisions in the severance agreement. The Eleventh Circuit reversed and remanded to the district court to determine whether Quorum was entitled to summary judgment based on its other arguments.

Applying Georgia contract law, the appeals court found the language of the release provisions was ambiguous in that, while a general provision applied the release to GBMHA and all “its officers, agents, trustees, servants and employees (‘Releasees’)” other specific language in the release referred to Quorum as distinct from the Releasees. Even assuming that Quorum was intended to be a Releasee, the Eleventh Circuit held other language in another release provision would preserve any claim “arising out of” Whitten’s employment. The appeals court rejected Quorum’s argument that this provision preserved only claims involving typical employment law issues, such as discrimination. “Simply because the drafters characterized the contemplated suit as 'arising from his employment' does not mean that Whitten is limited to suits involving employment law issues,” the appeals court said. Given that “Whitten worked as a compliance officer, and his knowledge of [Quorum’s] alleged fraud came by way of his
employment . . . [i]t is easy to see how this suit can be characterized as arising from Whitten’s employment, despite the fact that it does not involve traditional employment law claims,” the appeals court reasoned. Whitten v. Triad Hosps. Inc., No. 05-16422 (11th Cir. Dec. 13, 2006).

U.S. Court In Wisconsin Remands To State Court Challenge To Pharmaceutical Companies’ Allegedly Unfair Pricing Methods

The U.S. District Court for the Western District of Wisconsin agreed to remand to state court a lawsuit brought by the state of Wisconsin that challenged numerous pharmaceutical companies’ alleged unfair pricing methods, concluding that the defendant company failed to show removal was appropriate or timely. The district court also awarded costs and attorneys' fees to the state, noting that defendant companies had unsuccessfully attempted to remove the case to federal court on two prior occasions, and now, “relying on a theory of questionable merit,” had failed in a third removal attempt.

The state of Wisconsin originally filed its lawsuit in June 2004 in the Circuit Court of Dane County, alleging that defendant pharmaceutical companies violated state laws and unjustly enriched themselves by inflating the average wholesale price (AWP) of their drugs. Among other allegations, the state charged that defendant companies published false and inflated AWPs for their drugs and concealed their actual prices from payors, including the state (as a payor under Medicaid). Defendant companies twice attempted to remove the case to federal court. The first removal, dated July 14, 2004, asserted federal jurisdiction based on 28 U.S.C. § 1332 (diversity of citizenship), while the second removal, dated July, 13, 2005, asserted federal-question jurisdiction under 28 U.S.C. § 1331. The district court rejected both of these removal requests, and each time, remanded the case to state court.

Subsequently, in September 2006, the U.S. government intervened in a federal False Claims Act (FCA) qui tam action brought against Dey, Inc. (Dey), one of the defendant pharmaceutical companies in the present case. The complaint in that action (United States ex rel. Ven-A-Care of the Florida Keys Inc. v. Dey, Inc., Civil Action No. 05-11084-MEL (D. Mass. Sept. 11, 2006)) was based on FCA claims nearly identical to the claims alleged under state law in the present case, i.e., that Dey engaged in a scheme to report fraudulent and inflated prices resulting in substantial overpayments from Medicare and Medicaid. Dey then removed the case again to federal district court, arguing that the court had original jurisdiction under 37 U.S.C. § 3732(b), which states that the district court “shall have jurisdiction over any [state law] action . . . for the recovery of funds paid by a [s]tate or local government if the action arises from the same transaction or occurrence as an action brought under [the federal FCA].”

In rejecting defendants’ argument that the district court had original jurisdiction under 31 U.S.C. § 3732(b), the court noted that the state in this case could not have filed its original complaint in federal court because the complaint alleged no federal claim. “[O]f course, had Wisconsin pleaded a claim under the federal [FCA] in its complaint, this court would have had jurisdiction over the whole lawsuit under both § 3732(b) and 28 U.S.C. § 1331,” the court explained. The court then said that it also was “doubtful” that §
3732(b) supports as a ground for removal “the filing of the federal qui tam action three years after Wisconsin initiated its purely state law-based suit.” However, “[e]ven if the statute were to confer jurisdiction under these circumstances, defendant DeY’s removal would fail because it is untimely under 28 U.S.C. § 1446(b),” the court concluded. Under that statute, a notice of removal must be filed within thirty days after a defendant receives a copy of the initial pleading, the district court noted. Wisconsin v. Amgen Inc., No. 06-C-582-C (W.D. Wis. Jan. 16, 2007).

U.S. Court In Arkansas Dismisses FCA Qui Tam Action Against Hospital And Rehabilitation Services Provider On Finding Of Insufficient Evidence

The whistleblowers in a False Claims Act (FCA) qui tam action against a hospital and its acute rehabilitation services provider provided insufficient evidence to establish their allegations that the defendants knowingly submitted false claims to the federal government, a federal district court in Arkansas ruled January 29, 2007. The U.S. District Court for the Eastern District of Arkansas granted summary judgment in favor of the defendants on the whistleblowers’ claims that the defendants violated 31 U.S.C. § 3729, among other allegations.

One whistleblower in the case, Dr. Gregory Kersulis, formerly worked as the medical director of defendant RehabCare Group, Inc.’s (RehabCare's) acute rehabilitation unit (ARU) at co-defendant Baxter County Regional Hospital (BCH). RehabCare manages ARUs throughout the country. The other whistleblower, Jimmie Wilson, formerly worked as the charge physical therapist at the Baxter ARU. The federal government declined to intervene in the qui tam action. Kersulis and Wilson alleged fraud on behalf of the federal government, in particular that RehabCare and BCH violated 31 U.S.C. §§ 3729(a)(1)-(a)(3) by knowingly submitting false claims (and submitting false records in support of the claims) to Medicare for reimbursement of acute rehabilitation services, without complying with certain prerequisites for payment of such claims.

The district court first explained that Medicare reimbursement under Part A is typically made under the prospective payment system (PPS), but if acute rehabilitation units meet certain requirements, they may obtain reimbursement based on reasonable costs. One of the requirements for exempting out of the PPS system, the court continued, is known as the 75/25 Rule, which provides that a hospital qualifies as a “rehabilitation hospital” if “during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75%” required intensive rehabilitation services for the treatment of one or more conditions specified in the rule, including stroke, spinal cord injury, neurological disorders, and brain injury (42 C.F.R. § 412.23(b)(2)). Another requirement, as specified at 42 C.F.R. § 412.25(a)(7), is that the rehabilitation unit must “have beds physically separate from (that is, not commingled with)” the hospital’s other beds, the court noted.

In this case, Kersulis and Wilson alleged that the BCH ARU did not comply with either of these requirements, but nonetheless RehabCare and BCH submitted annual certifications and self-attestations that they did and submitted claims on a “reasonable cost” basis. “Summary judgment in favor of a FCA defendant is appropriate when the regulations at issue are ambiguous, such that no reasonable jury could find the defendant
satisfied the element of 'knowingly' submitting a false claim,” the district court said. According to the court, the 75/25 Rule has been subject to multiple interpretations and “did not unambiguously speak for itself.” In light of the evidence presented, defendants’ interpretation of the applicable regulations was reasonable, even if it was incorrect, the district court concluded, and therefore, a reasonable jury could not find that the defendants satisfied the element of “knowingly” submitting a false claim. United State ex rel. Kersulis v. RehabCare Group, No. 4:00-CV-00636 GTE (E.D. Ark. Jan. 29, 2007).

U.S. Court In Florida Denies Motion To Dismiss Qui Tam Complaint Even Though Not All Allegations Pled With Particularity
A federal trial court in Florida held February 15, 2007 that all claims contained in a qui tam complaint could go forward even though not all the allegations were supported. According to the court, because some of the claims were pled with sufficient particularity to survive defendants’ motion to dismiss, all of the claims could survive. Plaintiff Lanie Joe Heater was an employee at Holy Cross Hospital and in the course of his job he identified routine billing practices that failed to comply with Medicare and Medicaid requirements and allegedly resulted in false and fraudulent billing. His discoveries led Heater to file a qui tam complaint against defendants Holy Cross Hospital, Inc., Holy Cross Health Ministries, Inc., and fifty unnamed defendants alleging violations of the federal False Claims Act (FCA) and Florida False Claims Act. Defendants moved to dismiss plaintiff’s complaint under Fed. R. Civ. P. 9(b). The court granted the motion in part and denied it in part. Heater then submitted an amended complaint and defendants again moved to dismiss.

The U.S. District Court for the Southern District of Florida denied the motion. Because claim submission is an integral part of a valid FCA claim, “the Eleventh Circuit has held that a plaintiff in an FCA action must describe the billing scheme and the claim submission in detail,” the court noted. The court found that because Heater was employed as an Executive Director in Holy Cross' billing department for one month, his personal experience with the billing process could provide the “indicia of reliability” required to survive Holy Cross' motion to dismiss. Heater’s amended complaint added allegations regarding Holy Cross' billing process and documentary exhibits to support the contention that false claims were actually submitted, the court said. Although Heater failed to support all of his allegations in the amended complaint, at least some of the claims were pled with sufficient particularity, allowing the entire complaint to survive dismissal. United States ex rel. Heater v. Holy Cross Hosp., Inc., No. 03-62097-CIV-COHN/SNOW (S.D. Fla. Feb. 15, 2007).

U.S. Court In Nevada Dismisses FCA Action Against Physician, Finds No Intent To Defraud
The U.S. District Court for the District of Nevada dismissed March 1, 2007 the government’s action under the False Claims Act (FCA) against a physician who it alleged improperly billed Medicare for care provided to two dialysis patients. The action arose against Dr. Cyril A. Ovuworie and his medical practice Kappellini Medical, Inc. (defendants) in connection with dialysis services provided to two Medicare patients—Kathryn Hooker and Dorian Richmond—who had end stage renal disease as well as
numerous other medical problems. According to the court’s opinion, because of their unstable and violent behavior, all Medicare-certified outpatient dialysis centers in their area refused to provide them treatment.

As a result, Hooker and Richmond often ended up in UMC Valley Hospital’s emergency room, which was not a facility certified by Medicare to perform outpatient dialysis. Although other physicians refused to treat them, Ovuworie, a nephrologists, agreed to provide them care. UMC told Ovuworie to bill them as inpatients for the services he provided. According to the government, however, a twenty-three hour-admission did not qualify as an admission and therefore Hooker and Richmond should not have been billed as inpatients. Thus, the government contended, Ovuworie used the wrong code to bill Medicare for their care.

The U.S. District Court for the District of Nevada held the government failed to prove by a preponderance of the evidence that defendants knowingly violated the FCA or acted with deliberate ignorance or reckless disregard for the truth in the Medicare billings for the services provided to Hooker and Richmond. The court found unreasonable the government’s contention that Ovuworie should have billed the services under the code pertaining to outpatient care and then appealed the resulting denial for submitting an incomplete form (i.e. not including a code for a certified outpatient facility). “The alternative of inserting nonexistent codes for an uncertified outpatient facility would have required Dr. Ovuworie to knowingly commit fraud,” the court noted. Moreover, the government’s suggestion “that the doctor could have performed the medical services for free is too absurd to justify comment,” the court added. Even assuming that the billing was contrary to Medicare regulations and guidelines, of which the court was not convinced, defendants “cannot be liable under the Act for mere mistake or negligence.”


U.S. Court In Illinois Denies Motion To Dismiss FCA Qui Tam Action Against Nursing Home And Its Owner

The U.S. District Court for the Central District of Illinois refused March 2, 2007 to dismiss a False Claims Act (FCA) qui tam action against an Illinois nursing home and its owner involving allegations that the facility billed Medicare and Medicaid for substandard care or medications and services not provided to residents. Vanessa Absher and Lynda Mitchell (relators) are nurses formerly employed by defendant, Momence Meadows Nursing Center (MMNC), which is a 140-bed skilled nursing facility for the elderly and disabled. At all times pertinent to the action, MMNC was owned and operated by co-defendant Jacob Graff.

In their whistleblower action under the FCA and its Illinois counterpart, the Illinois Whistleblower Reward and Protection Act (WBA), the relators alleged they were directed to change patient and medication records to cover up MMNC’s grossly substandard care of its patients and/or request Medicare and Medicaid payments for medication and services not provided. In addition, the relators alleged they were ordered to falsify staffing records to show that minimum staffing levels had been satisfied. According to the relators, they complained to management about the alleged inadequate care provided
to MMNC residents, but received hostile treatment and were told to stop complaining. When one of the relators was fired, the other relator resigned shortly thereafter. The relators said MMNC then tried to prevent other employers from hiring Absher and fabricated charges against both of them with the Illinois Department of Professional Regulation. The relators ultimately asserted that defendants knowingly presented (or caused to be presented) thousands of false claims for Medicare and Medicaid reimbursement and unlawfully retaliated against them for reporting MMNC’s wrongdoing to MMNC management as well as various government agencies.

In denying defendants’ motion to dismiss pursuant to Fed. R. Civ. P. 9(b) (failure to plead fraud with particularity) and 12(b)(6) (failure to state a claim), the district court first rejected their argument that no false claim for payment had been identified anywhere in the complaint. The district court said it is well settled that the Rule 9(b) pleading requirement is relaxed where the plaintiff lacks access to all facts necessary to detail his claim. In this case, the district court noted, “the relators possess first-hand knowledge of the alleged incidents [of patient neglect and record falsification] by virtue of their employment . . . [b]ut as part of the nursing staff, they were isolated from the billing function and cannot have known the information within the defendants’ exclusive control—the precise billing dates that false claims were submitted.” The district court concluded that the complaint at issue “is far from a fishing expedition,” as it contained allegations that were highly specific and detailed. Even without pointing to specific dates on which false claims were submitted, the relators have “pled enough information to allow the defendants to respond to the allegations,” the district court said. In addition, contrary to defendants’ arguments, the allegations in the complaint were sufficient to support a claim against Graff individually, the district court concluded. Although Graff is a California resident and allegedly infrequently in Illinois, the mere allegation that Graff managed MMNC’s day-to-day operations was sufficient to tie him to the allegations of fraud involving MMNC, the court explained.

The district court also rejected the defendants’ argument that the relators failed to state a retaliation claim pursuant to the FCA because they did not allege the defendants knew the relators were investigating FCA violations before they were terminated. At this early stage of the litigation, the relators have alleged enough to sustain their retaliation claim based on allegations “that the defendants knew or should have known that they [the relators] were engaging in statutorily protected activities when they reported the substandard care to MMNC management and government agencies,” the district court concluded. United States ex rel. Absher, No. 04-2289 (C.D. Ill. Mar. 2, 2007).

U.S. Court In Massachusetts Refuses To Dismiss California’s FCA Action Against Drug Makers
The U.S. District Court for the District of Massachusetts refused March 22, 2007 to dismiss most of the claims the state of California brought against drug manufacturers under the state’s False Claims Act (FCA) alleging they defrauded Medi-Cal by reporting inflated drug prices used to set the program’s reimbursement levels. The case arose as a qui tam action filed by pharmacy Ven-A-Care of the Florida Keys on behalf of California against thirty-nine pharmaceutical companies (defendants), alleging they violated the
The California Attorney General intervened and the action was transferred to the federal trial court in Massachusetts as part of a multidistrict litigation. The complaint alleged defendants knowingly caused healthcare providers to submit false claims to Medi-Cal—California’s Medicaid program—by artificially inflating prices used to set reimbursement levels. Pharmaceutical companies marketed this price differential, or “spread,” to providers as a way of increasing their market share, the complaint contended. Defendants moved to dismiss the complaint.

First, the court held that, given the “sheer volume of drug reimbursements at issue,” the complaint met the specificity requirement of Fed. R. Civ. P. 9(b) by alleging the basic framework, procedures, and the nature of the fraudulent scheme giving rise to the state’s claims. Next, the court found the state’s allegations that drug manufacturers reported inflated Average Wholesale Prices (AWPs) and Direct Prices (DPs) for their drugs knowing full well that this would be the basis for Medi-Cal’s reimbursement were sufficient to connect the actual claim with the underlying fraud. The court also denied defendants’ argument that AWP and DP cannot be false because they are defined by state law as the price reported in the drug pricing compendia. “Defendants’ interpretation that they have carte blanche to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results,” the court noted.

The court found some merit to defendants’ argument that the state implicitly approved of their actions by continuing to pay claims despite knowledge of the allegedly inflated prices. But the court concluded dismissal would be improper on this ground because California alleged it did not know the extent of the false prices or approve them. The fact that medical providers, rather than the manufacturers themselves, submitted the allegedly false claims also was not fatal to the complaint since this was a “foreseeable” result of the allegedly fraudulent scheme.

Finally, the court refused to dismiss the state’s claim that defendants violated California’s anti-kickback statute, which in turn resulted in violations of the FCA. Defendants contended that the alleged reporting of inflated drug prices was not an “offer” or “payment” of remuneration as specified in the state’s anti-kickback law. But the court disagreed, noting defendants allegedly emphasized the spread between AWP and acquisition costs by giving physicians covert rebates and discounts to induce them to prescribe the companies’ drugs. “[T]hese rebates and other special incentives, if paid with corrupt intent, would be paradigm instances of behavior prohibited by anti-kickback legislation,” the court said. The court also concluded that, at least with respect to the alleged remuneration, the federal Anti-Kickback Statute did not preempt California’s law despite the difference in scienter requirements (with the federal statute requiring a “knowing and willful” mens rea and the state law containing no specific intent requirement). The court added that it reserved the right to revisit this issue after the state specified the specific theory of remuneration for each defendant. In re Pharmaceutical Ind. Average Wholesale Price Litig., No. 03-11226-PBS (D. Mass. Mar. 22, 2007).

U.S. Supreme Court Rules Former Employee Not “Original Source” In FCA Whistleblower Action
In a decision closely watched by the healthcare industry, the U.S. Supreme Court ruled March 27, 2007 that a former Rockwell International Corp. engineer should not have been allowed to proceed with his whistleblower action under the False Claims Act (FCA) because he was not an “original source” of the publicly disclosed information that formed the basis of the claims he asserted in his complaint. Reversing a Tenth Circuit ruling to the contrary, the Court’s 6-2 decision found engineer James B. Stone lacked “direct and independent knowledge” of the information underlying his qui tam allegations against Rockwell International and therefore did not qualify as an original source for purposes of avoiding the FCA’s public disclosure bar.

Stone previously had notified federal investigators of potential environmental crimes at a nuclear-weapons facility Rockwell operated pursuant to a contract with the Department of Energy (DOE). The Tenth Circuit held Stone met the statutory definition of an original source, even absent “direct and independent knowledge of the actual fraudulent submission to the government.” The decision stirred concerns, particularly in the healthcare sector, that the ruling would open the door to “opportunistic” relators.

While an employee of Rockwell from 1980 to 1986, Stone predicted that plans to mix cement with toxic pond sludge to create solid “pondcrete” blocks would not work because of a faulty piping system. After he was laid off from Rockwell in March 1986, the blocks began to leak toxic waste, although for a different reason than Stone had predicted. According to the opinion, Stone provided the Federal Bureau of Investigation (FBI) with 2,300 pages of documents, including the ones detailing his prediction about the defective piping system. The FBI obtained a search warrant for the Rocky Flats facility, based in part on the information allegedly obtained from Stone.

Stone filed a qui tam action against Rockwell in 1989, alleging it violated federal and state environmental laws and knowingly presented false claims to the government in order to continue receiving payments under its DOE contract. The government eventually intervened in the action. The jury found in favor of the government on the pondcrete allegations, awarding nearly $1.4 million, which the district court trebled under the FCA. Rockwell argued Stone’s claims should have been dismissed for lack of subject matter jurisdiction as he was not an original source under the FCA and his allegations were based on publicly disclosed information following the federal investigation rather than “direct and independent knowledge” in the first instance. But the district court and the Tenth Circuit disagreed.

As a threshold matter, the majority opinion, authored by Justice Antonin Scalia, concluded that the original source requirement is jurisdictional. The FCA defines an original source as an individual with “direct and independent knowledge of the information on which the allegations are based.” See 31 U.S.C. § 3730(e)(4)(B). Noting that the Court had not previously addressed the scope of this provision, the opinion clarified that the language in the statute requiring “direct and independent knowledge” referred to the information on which the relator’s allegations are based, not the publicly disclosed allegations that triggered the public disclosure bar. The opinion also concluded that the allegations relevant to the original-source determination include, at a minimum,
the original complaint as amended. To hold otherwise “would leave the relator free to plead a trivial theory of fraud for which he had some direct and independent knowledge and later amend the complaint to include theories copied from the public domain” or from the government. Based on these principles, the majority found Stone’s knowledge failed to qualify him as an original source of the information on which his allegations in the amended complaint were based.

“The only false claims ultimately found by the jury . . . involved false statements with respect to environmental, safety, and health compliance” over a period of time in which Stone no longer worked for Rockwell, the opinion observed. Stone’s prediction that the pondcrete would be insoloid did not amount to “direct and independent knowledge,” particularly given that he believed the problem would stem from the piping system when in fact it was due to a different issue. The majority also rejected Stone's contention that his original-source status on another claim not involving the pondcrete provided jurisdiction with respect to all of his claims asserted in the qui tam action. "Section 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim," Scalia wrote. Finally, the Court majority concluded that the government’s intervention did not cure the jurisdictional defect with respect to Stone. “An action brought by a private person does not become one brought by the Government just because the Government intervenes.” According to the opinion, Stone should have been dismissed from the action, leaving the government to proceed on its own.

A dissenting opinion, written by Justice John Paul Stevens and joined by Justice Ruth Bader Ginsburg, argued the language of the public disclosure bar and original source exception make “clear that it is the information underlying the publicly disclosed allegations, not the information underlying the allegations in the relator’s complaint (original or amended), of which the relator must be an original source.” Moreover, Stevens wrote, “the jurisdictional inquiry focuses on the facts in the public domain at the time the action is commenced,” not as the process of discovery proceeds and the complaint is amended. Rockwell Int’l Corp. v. United States, No. 05-1272 (U.S. Mar. 27, 2007).

**Tenth Circuit Finds PA Who Signed Form Granting Hospital Absolute Immunity From Suit Cannot Pursue Retaliation Claim**

A physician assistant (PA) who, upon resigning from his position at a hospital, signed a “Release and Immunity” form extending absolute immunity to the hospital cannot later sued the hospital for disclosing allegedly false and deliberately misleading information about him to a prospective employer, the Tenth Circuit ruled March 28, 2007. The appeals court therefore upheld a lower court’s summary judgment ruling in favor of the hospital in a lawsuit brought under the whistleblower provisions of the federal False Claims Act (FCA) by the PA, who claimed that the hospital’s allegedly false disclosures were in retaliation for the PA’s filing of an earlier qui tam suit against the hospital.

Vince DiMarco was working as a PA at Lincoln County Medical Center (LCMC)—a hospital owned and operated by Presbyterian Healthcare Services, Inc. (Presbyterian)—when he discovered that patients at LCMC were being billed for services they did not
receive. DiMarco initiated a qui tam suit against Presbyterian and LCMC, and then resigned. The qui tam suit was eventually settled, and approximately three years later, DiMarco obtained a provisional offer of employment at another hospital—Gerald Champion Regional Medical Center (GCRMC). The job offer was contingent upon receipt of DiMarco’s employment history at LCMC. To facilitate the transfer of this information, DiMarco signed two different release forms authorizing the disclosure of his employment history to the GCRMC. After receiving DiMarco’s information, however, GCRMC opted not to hire him, indicating its decision was based in part on Presbyterian disclosing that DiMarco failed to continuously render an adequate level of care. DiMarco then sought relief under the FCA’s whistleblower protections, alleging that Presbyterian retaliated against him for reporting its fraudulent activities.

The district court rejected DiMarco’s arguments, concluding instead that DiMarco had consented to Presbyterian’s disclosures by signing a broad Release and Immunity form. The court held that by signing the release, DiMarco extended absolute immunity to Presbyterian and thereby relinquished his right to sue for retaliation under the FCA. The Tenth Circuit agreed that, under New Mexico’s laws governing the disclosure of employment information, DiMarco granted Presbyterian absolute immunity from suit by signing the Release and Immunity form. Brock v. Presbyterian Healthcare Servs., Inc. No. 06-2192 (10th Cir. Mar. 28, 2007).

**U.S. Court In Hawaii Rejects FCA Action Alleging Clinic Violated Medicare “Incident To” Rules**

The U.S. District Court for the District of Hawaii rejected a qui tam lawsuit under the False Claims Act (FCA) alleging a medical clinic submitted false claims to Medicare by billing for chemotherapy administration under the Part B “incident to” rules when physicians were unaware they had been assigned to supervise the services. Physician James Lockyer filed a qui tam action under the FCA against defendants Hawaii Pacific Health (HPH), Kauai Medical Clinic (KMC), and Wilcox Memorial Hospital. Lockyer was employed by KMC, an outpatient clinic adjacent to Wilcox Memorial Hospital, as an internist. HPH is KMC’s parent entity.

KMC administered chemotherapy to patients at the clinic pursuant to its oncologist’s orders. Because KMC only employed one oncologist, the clinic would occasionally assign another physician from the clinic’s internal medicine department to supervise the administration of chemotherapy if the oncologist was unavailable. According to Lockyer, defendants violated Medicare’s “incident to” rules, and thereby submitted false claims to the program, by billing for chemotherapy services using his and other physicians’ provider numbers who were unaware they had been assigned to supervise the administration of chemotherapy at the clinic. In addition to his FCA claim, in which the federal government intervened, Lockyer also asserted that defendants improperly retaliated against him by lowering his salary for opposing and reporting the improper practices in violation of state common law and federal and state whistleblower protection laws.
The U.S. District Court for the District of Hawaii granted defendants’ motion for summary judgment. Under the Medicare Part B “incident to” rules, an outpatient clinic may bill for services and supplies “furnished under the direct supervision of the physician” so long as the physician is “present in the office suite and immediately available to furnish assistance and direction,” the court explained. The dispute at issue, the court noted, was whether the supervising physician must be aware he is supervising the services that are billed using his number. The court agreed with defendants’ interpretation that in a physician-directed clinic like KMC “any one of multiple physicians who are available in the office suite may be ‘deemed’ to be supervising the incident to service” and need not have “specific knowledge that [they are] the supervising physician for the purposes of submitting claims for incident to services to Medicare.”

Plaintiff did raise an issue of fact as to whether KMC billed Medicare for chemotherapy services using his provider number in instances when he left the office or went home sick. Although submitting claims for chemotherapy when no supervising physician was available in the office would violate the incident to rules, the court went on to find that plaintiff’s FCA claim still failed because KMC lacked the requisite scienter to commit fraud. Lockyer presented no evidence that defendants knew he had left the office or that the clinic knowingly billed Medicare for chemotherapy services when it knew no supervising physician was available, the court determined.

The court also granted defendants’ summary judgment on Lockyer’s retaliation claims. A state common law claim of retaliation may stand only where no other statutory remedy exists. Here, both federal and state whistleblower protection laws provided Lockyer a remedy for unlawful retaliation. Therefore, Lockyer could not assert a retaliation claim under the common law. The court concluded that Lockyer’s retaliation claim under the FCA’s whistleblower protection provision failed because he presented no evidence that he had the requisite subjective belief that KMC was defrauding the government when he asked to review certain compensation documents. In addition, there was no evidence that defendants were aware that Lockyer was investigating them for fraud until he filed the qui tam action. Likewise, the court concluded Lockyer could not maintain a retaliation claim under the Hawaii Whistleblower Protection Act. “Plaintiff did not present any triable issues of fact that his request for compensation documentation was motivated by anything other than a desire to see whether he was being underpaid by KMC,” the court wrote. United States ex rel. Lockyer v. Hawaii Pacific Health, No. 04-00596 ACK-LEK (Hawaii Apr. 17, 2007).

Physician Self-Referrals

South Carolina Supreme Court Upholds State Statute Prohibiting Physician-Owned Physical Therapy Services Arrangements

The South Carolina high court found that a state statute prohibits physical therapists from working as employees of physicians who refer them patients for therapy services. Accordingly, the high court lifted a temporary injunction that barred the state’s Board of Physical Therapy Examiners from enforcing the statute against physical therapists who violated the provision.
The statute at issue was enacted in 1998 and allows the Board to restrict or refuse to renew the license of a physical therapist who directly or indirectly divided fees with a referral source. From 1998 to 2004, the Board did not enforce the statute against a physical therapist who received referrals from a physician employer. In March 2004, the state Attorney General issued an opinion concluding that the statutory provision prohibited physician-owned physical therapy services, and the Board subsequently announced at an open meeting that it would begin enforcing the statute following a ninety-day grace period. Individual physical therapists and their physician employers challenged the Board’s action.

In a 3-2 opinion, the high court upheld the Board’s interpretation of the relevant statute. The high court also summarily rejected several arguments challenging the Board’s decision to enforce the statute, including one that focused on the six-year period in which the Board failed to apply the statute. The high court rejected the plaintiff-physicians’ claim that the Board’s decision to enforce the statute improperly infringed on the physicians’ statutory right to practice medicine and “usurped” their authority by prohibiting them from employing physical therapists. Although state statutes relating to the practice of medicine encompass the prescribing of physical therapy for a given injury or condition, this does not mean “a physician has an unfettered right to actually provide the therapy by directly employing physical therapists,” the high court said. In addition, the high court rejected plaintiff-physical therapists’ equal protection and due process claims. *Sloan v. South Carolina Bd. of Physical Therapy Exam’rs*, No. 26209 (S.C. Sept. 25, 2006).

**U.S. Court In Louisiana Holds HHA Violated Stark, Liable To Medicare For Payment By Mistake, Unjust Enrichment**

A federal trial court held February 16, 2007 that compensation arrangements between several physicians and a home health agency (HHA) violated Stark II and therefore the HHA was liable to Medicare for $427,503 under theories of payment by mistake and unjust enrichment. The case arose as a whistleblower action under the False Claims Act (FCA), alleging Aging Care Home Health, Inc. and its principals knowingly and willfully submitted false claims to Medicare. The government intervened, contending that defendants submitted to Medicare false certifications and false or fraudulent claims for services by five physicians that resulted from illegal relationships in violation of the Stark Law and the Anti-Kickback Statute.

From September 1999 to November 2003, Aging Care compensated five physicians for performing advisory services pursuant to medical service agreements. Aging Care then billed Medicare and was reimbursed $427,503 for services furnished to patients of these physicians. According to the government, Aging Care violated Stark II because it obtained “referrals” from physicians with whom it had a financial relationship. The government moved for partial summary judgment on its claims of payment by mistake and unjust enrichment.
As an initial matter, the U.S. District Court for the Western District of Louisiana rejected a federal magistrate’s recommendation that the government’s summary judgment motion be denied on the ground that Stark II was not enforceable until the Department of Health and Human Services (DHHS) published final regulations in 2001. According to the magistrate, because a confusing, contradictory regulation—namely, 42 C.F.R. § 424.22(d)—existed before that time, it would be unfair to hold defendants liable for violating Stark. Before 2001, § 424.22(d) prohibited an HHA from billing the Medicare program if certifying physicians received more than $25,000 or 5% of an HHA’s operating expenses for the year, whichever was less. Stark II, which Congress enacted in 1993, prohibits an HHA from billing the Medicare program for services provided to patients who have been referred by physicians with whom the HHA has any financial relationship, barring an exception. Discounting the magistrate’s reasoning, the court held defendants were required to simultaneously comply with § 424.22(d) and Stark II prior to 2001. “While Stark II and § 424.22(d) overlap, they are not mutually exclusive . . . and nothing in the statute or case law indicates that Stark II was not self-executing.”

Next, the court determined that defendants violated Stark II by billing Medicare for services furnished pursuant to a prohibited referral. In so holding, the court found none of the arrangements met the personal service arrangement exception to Stark II, noting the physicians’ testimony that they did not provide any legitimate advisory services to the HHAs and were compensated for providing standard care to their patients or for doing nothing.

The court then found the government was entitled to recover under the common law theories of payment by mistake and unjust enrichment. The cost reports at issue “contained express and implied certifications of compliance with Stark II . . . As these certifications were false and material to the Medicare program’s decision to pay, Aging Care was mistakenly paid,” the court said. The court also found defendants were unjustly enriched, rejecting defendants’ argument that the government had alternative legal remedies, including breach of contract, administrative remedies under Stark II, criminal penalties and fines under the Anti-Kickback Statute, and monetary damages under the FCA. "While Defendants claim that the Government has alternative legal remedies available, they have not shown how these remedies are adequate and thus preclude equitable relief," the court said. Thus, the court concluded that, under a theory of unjust enrichment or payment by mistake, the government was entitled to recover the value of the claims Aging Care submitted in violation of Stark II. United States ex rel. Roberts v. Aging Care Home Health, Inc., No. 02-2199 (W.D. La. Feb. 16, 2007).

**CMS Extends Deadline For Publication Of Phase III Physician Self-Referral Final Rule**

The Centers for Medicare and Medicaid Services (CMS) extended its timeline for publication of the Phase III physician self-referral final rule from March 26, 2007 to March 26, 2008, under an interim final rule in the March 23, 2007 Federal Register (72 Fed. Reg. 13710). CMS published its Phase II rule on March 26, 2004 (69 Fed. Reg. 16054) and, according to the original timeline, was supposed to respond to comments received on that rule and publish a final rule in three years. However, the agency said it
was “not able to meet the 3-year timeline for publication because [it] received extensive public comments requesting clarification of and revisions to the physician self-referral regulations.” In addition, “because the physician self-referral rules are jointly enforced by CMS, the Office of Inspector General, and the Department of Justice, substantial interagency coordination has been necessary,” CMS said. Therefore, the Phase II interim final rule will “remain in effect through March 26, 2008,” unless Phase III is published and becomes effective before then.

HEALTHCARE ACCESS

Census Bureau Revises Downward Uninsured Estimates For 2004 And 2005 By 1.8 Million

The U.S. Census Bureau issued March 23, 2007 revised 2004 and 2005 health insurance coverage estimates indicating about 1.8 fewer uninsured Americans for those years than reported earlier, according to a press release issued by the Census Bureau. “The revised estimates show that, in 2005, 44.8 million people, or 15.3 percent of the population were without health insurance—about 1.8 million fewer than the Census Bureau reported in August 2006,” the press release said. “Based on the Current Population Survey [CPS], the original 2005 estimate was 46.6 million, or about 15.9 percent of the population.” The Census Bureau found, conversely, “an estimated 249 million Americans had coverage [in 2005], up from 247.3 million reported in August [2006].” The Census Bureau also noted that, for both 2004 and 2005, the original and revised estimates “differ by less than one percent—0.6 percent for 2005 and 0.7 percent in 2004.”

HEALTHCARE SPENDING

Senate, House Pass FY 2008 Budget Resolutions

By a largely party-line vote of 52-47, the Senate passed March 23, 2007 a fiscal year 2008 budget resolution (S. Con. Res. 21) that includes $50 billion in funding for the State Children’s Health Insurance Program (SCHIP) as well as a number of amendments introduced in the past several weeks. The budget proposal includes an amendment offered by Senate Finance Committee Chairman Max Baucus (D-MT) and others that would put $15 billion toward renewal and expansion of SCHIP, which is set to expire this year, including $5 billion in surplus funds in 2012.

The Senate budget also includes an amendment offered by Senator Gordon H. Smith (R-OR) that allows for an increase in the federal tobacco tax to help fund and expand SCHIP. According to Smith, an increase of 61 cents on the federal excise tax on tobacco products is estimated to generate $35 billion in funds for the SCHIP program. An amendment proposed by Senator Edward Kennedy (D-MA) that would increase by $40 million the amount of funding the Food and Drug Administration receives for drug safety also was included in the budget resolution.

The budget includes several provisions advanced by Senate Finance Committee Ranking Member Charles Grassley (R-IA), including an amendment adding language to the reserve fund on Medicare physician payments to include financial incentives for
physicians to offer high quality care. Another provision urged by Grassley creates a reserve fund to allow the reform of the Medicare hospital wage index to better reflect labor costs. In addition, the budget resolution includes language that “creates a reserve fund to create a framework and parameters for the use of Medicare data for the purpose of conducting research, public reporting, and other activities to evaluate health care safety, effectiveness, efficiency and resource utilization in federal programs—such as Medicare’s prescription drug program—and the private health care system,” Grassley said.

Meanwhile, the House on March 29, 2007 passed its 2008 budget resolution (H. Con. Res. 99) by a vote of 216-210. The House version also contains $50 billion in funding over five years for SCHIP. The bill establishes reserve funds for the extension of the Transitional Medical Assistance program and for Medicare improvements. Rep. John Spratt (D-SC), Chairman of the House Budget Committee, noted the budget resolution “requires that any entitlement spending increases or tax cuts be offset, so that the bottom line of the budget, which is in deficit, is not worsened.”

HEALTH INFORMATION TECHNOLOGY

House Clears HIT Legislation
By a vote of 270-148, the House passed July 27, 2007 legislation (H.R. 4157) aimed at promoting the use of health information technology (HIT) to improve the safety and quality of the nation’s healthcare system. The “Health Information Promotion Act of 2006” codifies the Bush administration’s Office of the National Coordinator for Health Information Technology and creates statutory exceptions in the federal physician self-referral (Stark) law and safe harbors to the Anti-Kickback Statute that would allow hospitals to supply physicians with HIT software and hardware, or related services that are used for the electronic creation, maintenance, and exchange of clinical health information. The Senate passed by unanimous consent very different HIT legislation (S. 1418) on November 18, 2005. The Wired for Health Care Quality Act would provide for a paperless records system and would help rural areas adopt cutting edge information technologies in electronic health records to improve patient care and promote cost savings for healthcare providers. The Senate bill calls for awarding competitive grants to hospitals, group practices, and other healthcare providers to facilitate the adoption of HIT.

CMS, OIG Release Final Health IT Rules
The Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services Office of Inspector General (OIG) published final rules August 8, 2006 aimed at speeding the adoption of electronic prescribing and electronic health records. The CMS rule (71 Fed. Reg. 45140) creates two new exceptions under the physician self-referral (Stark) law and the OIG rule (71 Fed. Reg. 45110) establishes two new safe harbors under the Anti-Kickback Statute. The rules establish conditions under which (1) hospitals and certain other entities may provide physicians (and certain other recipients under the safe harbor) with hardware, software, or information technology and training services necessary and used solely for electronic prescribing; and (2) entities
furnishing designated health services (and certain other entities under the safe harbor) may donate to physicians (and certain other recipients under the safe harbor) interoperable electronic health records software, information technology, and training services.

**DHHS Recognizes CCHIT Criteria For EHRs, Releases Certification Guidance Document**
The Department of Health and Human Services (DHHS) officially recognized certain Certification Commission for Healthcare Information Technology (CCHIT) criteria for ambulatory electronic health record (EHR) functionality, interoperability, security, and reliability standards, the agency said in a notice issued in the August 4 Federal Register (71 Fed. Reg. 44295). The CCHIT criteria that have been recognized serve to establish the initial EHR certification criteria that are referenced in the final physician self-referral law and Anti-Kickback Statute rules. CCHIT was awarded a $2.7 million contract in fall 2005 to develop certification criteria and a certification process. CCHIT certification indicates that EHR products meet base-line levels of functionality, interoperability, and security in compliance with CCHIT’s published criteria.

**U.S. Court In D.C. Finds Association Lacks Standing To Sue DHHS Over Creation Of IT Advisory Committee**
The Association of American Physicians and Surgeons lacked standing to sue the U.S. Department of Health and Human Services (DHHS) over the creation of the American Health Information Community (AHIC), a federal trial court in the District of Columbia held October 6, 2006. The DHHS Office of the National Coordinator for Health Information Technology announced in July 2005 the establishment of AHIC as an advisory committee to develop recommendations on achieving interoperability for health information technology (IT). See 70 Fed. Reg. 40703 (July 14, 2005). The Association of American Physicians and Surgeons (association) challenged the establishment and composition of AHIC in federal court under the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2, §§ 1 et seq. According to the association’s multi-count complaint, AHIC is neither “fairly balanced” nor sufficiently independent of DHHS, in violation of the FACA.

To establish procedural standing, a plaintiff must assert that a statute offers a “promise of purposeful protection of the concrete interests,” the U.S. District Court for the District of Columbia said. But the court found no such promise afforded under FACA, and therefore held the association failed to establish a procedural injury. The court also concluded the association’s allegation of economic injury—that DHHS intended to use the federal government’s “market power” to force the medical profession and patients to adopt health IT—was speculative and insufficient to demonstrate injury in fact. Further, the court found no merit in the association’s contention that it suffered programmatic injury because DHHS impaired its advocacy on behalf of its members. Lastly, as to the association’s allegation of informational injury, the court found no evidence DHHS’ had refused to provide information to the association. Association of Am. Physicians and Surgeons, Inc. v. U.S. Dep’t of Health and Human Servs., No. 06-0319 (D.D.C. Oct. 6, 2006).
**NGA Launches State Alliance To Advance HIT**

The National Governors Association Center for Best Practices (NGA Center) announced October 19, 2006 a new initiative aimed at advancing the use of health information technology (HIT) through a State Alliance for e-Health. The alliance will bring together the nation’s governors and policymakers to identify inter- and intrastate-based HIT polices and best practices, the NGA Center said. The alliance, which was developed under contract with the U.S. Department of Health and Human Services Office of the National Coordinator for HIT, will serve an advisory role to facilitate collaboration among the states, resolve privacy and security issues involving the use and disclosure of electronic health information, and help move toward interoperable information exchange.

**DHHS Announces First Recognized Certification Body To Evaluate Electronic Health Records**

The first group to be designated a Recognized Certification Body (RCB) authorized to certify health information technology (health IT) products is the Certification Commission for Healthcare Information Technology (CCHIT), the Department of Health and Human Services (DHHS) announced in an October 26, 2006 press release. In September 2005, DHHS awarded a $2.7 million contract to CCHIT to develop an “efficient, credible, and sustainable mechanism” for certifying health IT products, the press release said.

Under the program developed by CCHIT, certification of health IT products will occur in three phases: (1) outpatient or ambulatory electronic health records (EHRs), (2) inpatient or hospital EHRs, and (3) building systems that enable the exchange of information between and among healthcare providers and institutions. CCHIT’s program already is in phase one, with thirty-three products that have been certified to date, according to the press release. As an RCB, CCHIT will continue to evaluate health IT products to ensure they “meet base-line requirements for functionality, interoperability and security,” the press release said.

**DHHS Advances Health IT Initiative**

The Department of Health and Human Services (DHHS) will begin supporting trial implementations of the Nationwide Health Information Network (NHIN), the Office of the National Coordinator for Health Information Technology announced December 8, 2006. “The trial implementations are a critical next step to move America closer to realizing an interoperable Nationwide Health Information Network,” said Interim National Coordinator for Health Information Technology Dr. Robert Kolodner. “By bringing together the significant expertise and work achieved this year by the current efforts with state and local health information exchanges, we can begin to construct the ‘network of networks’ that will form the basis of the Nationwide Health Information Network.” According to DHHS, the agency will solicit proposals to create the trial implementations and work toward integrating them with the broader NHIN initiative in spring 2007.

**Draft Model Antifraud Requirements For Electronic Health Records Released**
RTI International (RTI), a scientific research and technology development consulting firm under contract with the Department of Health and Human Services (DHHS) Office of the National Coordinator (ONC), has posted on its website a draft set of model anti-fraud requirements for electronic health records (EHRs). RTI asked all interested stakeholders to review and provide comments on the requirements by January 22, 2007. The model language includes recommendations that healthcare providers be required to maintain standardized audit logs to enable tracking of clinical entries and administrative and billing information in an EHR, as well as the specific individuals who are responsible for actions recorded in the EHR. Another provision in the model language requires demonstration of the EHR system’s ability to use the National Provider Identifier (NPI) in the EHR audit log. “A commonly known fraud scheme is for fraud perpetrators to steal provider identifiers and use them to submit false claims . . . [u]se of NPI in EHRs as well as claims will significantly reduce fraud losses,” RTI explained.

In addition, the model language requires demonstration of the EHR system’s ability to “support user ID/strong password as the minimum e-authentication level in 2008.” Among several other more technical requirements is a provision regarding payor use of EHR systems, which recommends that payors have access to EHR “according to agreed upon uses and only as a part of an identified EHR audit subject to appropriate authentication, authorization, and access control procedures.” The model language also recommends that patients be allowed to access their own completed records, and if requested, to provide comments in the EHR.

DHHS Secretary Accepts Thirty Consensus Standards For HIT From Contractor
Department of Health and Human Services (DHHS) Secretary Michael Leavitt has accepted thirty consensus standards recommended by the Healthcare Information Technology Standards Panel (HITSP), according to a January 25, 2007 press release issued by the American National Standards Institute (ANSI), which administers HITSP. HITSP, which is comprised of over 200 private- and public-sector members, was formed in 2005 to identify technical standards that will facilitate healthcare data interoperability. According to the press release, over the past year, the panel has completed standard harmonization in the areas of electronic health records, biosurveillance, and consumer empowerment. The American Health Information Community (AHIC) recommended that Leavitt accept the HITSP standards, which he did at the January 25 AHIC meeting. HITSP is under contract with the Office of the National Coordinator for Health Information Technology.

CCHIT Proposes Second Draft Certification Criteria For Inpatient And Ambulatory EHR Products
The Certification Commission for Healthcare Information Technology (CCHIT) issued its second draft certification criteria for inpatient (hospital) electronic health record (EHR) products, according to a February 12, 2007 press release issued by CCHIT. CCHIT is an independent, nonprofit organization recognized by the federal government as an official certification body for electronic health records. The draft certification criteria were open to public review and comment February 16 through March 16, and CCHIT also encouraged comments on its proposed 2007 test strategy for these products,
according to the release. In addition, CCHIT published February 14, 2007 its proposed final certification criteria and test scripts for certification of ambulatory (office-based) EHR products for 2007. The final public comment period on changes made since a previous publication was open from February 14 through February 28.

**Group Announces Development Of EHR Standard**
Health Level Seven, Inc. (HL7), an international healthcare information technology (IT) standards development organization, announced February 21, 2007 the healthcare industry’s first ANSI-approved standard that specifies the functional requirements for an electronic health record (EHR) system. The standard outlines important features and functions that should be contained in an EHR system, the company said in a press release. The standard’s Functional Model contains approximately 1,000 conformance criteria across 130 functions, including medication history, problem lists, orders, clinical decision support, and those supporting privacy and security, the release said. “This new standard is a ‘superset’ of functions that enables a standardized description and common understanding of functions, which is necessary when you’re working across care settings,” said Linda Fischetti, EHR Technical Committee Co-Chair. Functional profiles including the legal EHR, emergency services, long term care, behavioral health, child health, and regulated clinical research are currently in development.

**DHHS Awards Contract To Develop Guidance For State Health Information Exchange Organizations**
The Department of Health and Human Services’ (DHHS’) Office of the National Coordinator for Health Information Technology (ONC) has awarded a one-year, $800,000 contract to the American Health Information Management Association's (AHIMA's) Foundation of Research and Education (FORE). The contract is aimed at fostering collaboration among state leaders in health information exchange (HIE) to identify and share emerging best practices. The FORE contract also includes two subcontracts with eHealth Initiative (eHI) and the Healthcare Information and Management Systems Society (HIMSS). FORE will work to identify successful governance models that include defined operations, resources, and finances to generate, support, and amplify health information exchange, according to a press release issued by DHHS. The resultant guidance is intended to help state and local HIE efforts in developing a nationwide network that will enable healthcare transformation and lower costs, DHHS said.

**CMS Extends NPI Compliance Deadline**
The Centers for Medicare and Medicaid Services (CMS) announced April 2, 2007 that it is implementing a contingency plan for covered entities (other than small health plans) who will not meet the May 23, 2007 deadline for complying with the National Provider Identification (NPI) regulations. The standard unique health identifier is mandated by the Health Insurance Portability and Accountability Act of 1996 and will replace all "legacy" identifiers that are currently in use. CMS said covered entities that make a “good faith” effort to comply with the NPI provisions and implement contingency plans to move toward compliance will not be subject to enforcement actions for up to one year after the original compliance deadline. The agency decided to take this enforcement approach...
“after it became apparent that many covered entities would not be able to fully comply with the NPI standards by May 23, 2007,” CMS said. Contingency plans may not extend beyond May 23, 2008.

In January 2004, CMS issued a final rule requiring covered entities (healthcare providers, plans, or healthcare clearinghouses that transmit any data in electronic form for which the Department of Health and Human Services has adopted a standard) to use NPIs in standard transactions no later than May 23, 2007 (69 Fed. Reg. 3434). Small health plans have an extra year to comply. Use of the NPI is intended to reduce costs and improve efficiency in the healthcare system by eliminating the need for providers to maintain multiple identification numbers assigned by the various health plans they bill.

**CMS Launches Online Educational Tool To Assist Physician Offices With HIT Development**

The Centers for Medicare and Medicaid Services (CMS) announced April 11, 2007 the national launch of an online educational tool, known as Doctor’s Office Quality Information Technology University (DOQ-IT U), to assist physicians’ offices in developing their health information technology (HIT) initiatives, according to a press release issued by CMS. “DOQ-IT U is an interactive, Web-based tool designed to provide solo and small-to-medium sized physician practices with the education for successful HIT adoption, including lessons on culture change, vendor selection and operational redesign, along with clinical processes,” the press release said. Moreover, the e-learning system is available nationwide at no charge.

**Pilot Project Finds Three Of Six Initial E-Prescribing Standards Capable Of Part D Use**

Three of six “initial” test standards are capable of supporting e-prescribing transactions in Medicare Part D, according to a recent report issued by the Centers for Medicare and Medicaid Services (CMS) on a congressionally mandated pilot project. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the establishment of standards for the electronic transmission of prescriptions and certain other information for drugs covered by Medicare Part D. The MMA does not require prescribers to write prescriptions electronically, but if they do, they must use the adopted e-prescribing standards.

Effective January 1, 2006, CMS adopted three “foundation” e-prescribing standards, and recognized six “initial” standards that “might, pending confirmation from pilot testing, be suitable for adoption as additional final e-prescribing standards.” The pilot project, conducted through an interagency agreement between CMS and the Agency for Healthcare Research and Quality, tested the initial e-prescribing standards at five sites to determine readiness for widespread adoption. According to the report, three of the initial standards, which relate to providing physicians with patients’ formulary and benefit information, medication history, and the fill status of medications, “are technically able to convey the information needed to support these functions for use in Part D.” The report said the remaining initial standards involving indications and dosage, clinical drug terminology, and prior authorization messages are not ready to support these functions in
Part D at this time. The pilot project also found e-prescribing, with “some adjustment,” could be successfully implemented in a long term care setting, which has unique needs and workflows.

New Hampshire Law Prohibiting Disclosures of Prescription Data Found Unconstitutional
In a Memorandum and Order dated April 30, 2007, the U.S. District Court for the District of New Hampshire found that a first of its kind state law prohibiting pharmacies, insurance companies, and similar entities from transferring or using prescriber-identifiable data for certain commercial purposes was unconstitutional, violating the First Amendment. The practices targeted by this “Prescription Information Law” involved pharmacies and other entities allowing data management companies to install software on their computers that “de-identified” prescription information to remove information that would allow a patient’s identity to be determined, but which retained other information relating to the prescriptions—including the identity of the prescribing practitioners. This information would then be sent to the data management company, which would combine the data with other information and sell or license the product to pharmaceutical manufacturers and others.

The court found that the restrictions in New Hampshire’s Prescription Information Law were subject to intermediate scrutiny as restrictions on truthful commercial speech and failed under scrutiny because: (1) they did not directly serve the state’s substantial interests asserted (i.e., in promoting public health and containing healthcare costs), and (2) alternatives existed that would achieve the state’s interests as well or better without restricting speech (i.e., the restrictions were more extensive than necessary to serve the asserted interests). IMS Health Inc. v. Ayotte, No. 06-cv-280-PB (D.N.H. Apr. 30, 2007).

HEALTH POLICY
California Governor’s Plan Would Require All State Residents To Have Health Insurance
California Governor Arnold Schwarzenegger (R) issued a comprehensive plan January 8, 2007 that would require all state residents to have health insurance coverage sufficient to protect against catastrophic expenses and to minimize the “cost shift” that occurs when people are unable to pay their medical bills. Schwarzenegger said about 6.5 million Californians are uninsured for all or part of the year. The Governor’s press release cited a recent white paper that found the average family pays about $1,186 annually in “hidden taxes” through health insurance premiums to cover the uninsured. Those with low incomes would have expanded access to coverage through public programs like Medi-Cal or would receive extra financial help through a new state-administered purchasing pool. To help encourage provider participation in the state’s Medicaid program, the proposal calls for boosting Medi-Cal rates, which would be partially funded through a coverage dividend of 2% on physicians and 4% on hospitals. Under the proposal, employers of ten or more that fail to provide health coverage for their workers would be required to pay 4% of pay roll as an “in-lieu fee.”
Leading Health, Business, Labor Organizations Form Coalition To Spur Action On Healthcare
AARP, Business Roundtable, and SEIU announced January 16, 2007 that they will partner to urge politicians and the business community to look for ways to attain healthcare and long term financial security for all Americans. The partnership—dubbed “Divided We Fail”—will encompass traditional grassroots work, advertising in national outlets and in the primary states, and online activities encouraging public leaders to offer solutions, AARP said in a press release. “High health care costs threaten the long-term prosperity of America’s consumers, the economy and businesses,” said John J. Castellani, Business Roundtable President, “They are a top concern of America’s business leaders, and we’re pleased to join AARP and SEIU today to catalyze new thinking, and to urge our nation’s leaders to help find solutions.” The coalition recently launched a website, www.dividedwefail.org, where more information can be found.

President Bush’s Health Insurance Proposal Calls For Standard Tax Deduction, State Grants
President Bush during his State of the Union address January 23, 2007 outlined a two-prong proposal for expanding healthcare coverage that calls for changing the tax code to provide a standard deduction for health insurance and shifting existing federal funds to state programs that help the uninsured obtain private coverage. Under the President’s plan, those with health insurance, regardless of whether the policy was purchased individually or through an employer, would have a standard tax deduction of $15,000 for families or $7,500 for individuals. At the same time, health insurance would be considered taxable income. A fact sheet on the proposal said about 80% of those with employer-provided policies would see lower tax bills as a result of the plan. The remaining 20% with more generous plans, i.e. those worth more than the standard deduction, could see higher taxes.

The second prong of the plan, called the “Affordable Choices Initiatives,” would provide federal grants to states pursuing innovative programs to help their uninsured get basic private health insurance coverage. For example, states could use the grants to offer direct premium assistance to low-income or hard-to-insure residents to buy private health insurance or they could establish or expand high-risk pools for those deemed uninsurable because of their health status.

The healthcare tax proposal drew immediate criticism on several fronts. A number of Democratic lawmakers charged that the plan would mostly benefit well-off Americans and could undermine employer-sponsored coverage to the particular detriment of those with health problems who would have trouble finding affordable coverage in the individual insurance market. But at the same time others acknowledged the plan as a way to rectify inequities in the tax code that favor those who obtain expensive health insurance through their jobs.
Governor Spitzer Announces Health System Reform Plan To Achieve Universal Health Coverage For New Yorkers

New York Governor Eliot Spitzer (D) announced January 26, 2006 an ambitious healthcare reform plan aimed at achieving universal coverage for all state residents, while also transforming the state’s current “institution-centered” system to a “patient-centered” system. In a speech delivered at the State University of New York's Nelson A. Rockefeller Institute of Government, Spitzer described eight key healthcare reforms that will be included in his executive budget proposal for the upcoming year. The main features of Spitzer’s plan include: expanding Child Health Plus (New York's State Children’s Health Insurance Program (SCHIP)); removing enrollment barriers in the state’s Medicaid program; initiating Medicaid reform measures, including “strategic” freezing of Medicaid reimbursement rates paid to nursing homes and hospitals; reducing spending for pharmaceutical costs; improving coordinated care for Medicaid patients with multiple medical needs; implementing health information technology; increasing Medicaid anti-fraud efforts; and increasing funding for public health initiatives.

Major Employers, Union Team Up To Improve Healthcare System

Service Employees International Union (SEIU) has joined a number of major employers including Wal-Mart, AT&T, and Intel to launch the “Better Health Care Together” campaign, a new effort aimed at reforming the nation’s healthcare system. The coalition “will mobilize leaders from the business, labor, and political worlds—as well as individuals—in the growing movement to overhaul the nation’s health care system,” SEIU said. According to the release, the group will work off a set of shared principles to guide the overhaul of the healthcare system, committing to bring about fundamental change by 2012. The founding members said the campaign will: recruit selected business, labor, and civic leaders committed to making healthcare reform a reality; convene a national summit of the membership by the end of May 2007; enlist support for the principles from national, state, and local elected officials, policymakers, candidates, and opinion leaders; and, launch education initiatives to persuade workers and customers that the current healthcare system should be reformed to reflect the coalition’s principles.

HIPAA

Texas Appeals Court Finds HIPAA No Bar To Disclosure Made Under Public Information Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations allow for the disclosure of statistical information regarding abuse in state mental facilities requested by a reporter pursuant to the Texas Public Information Act (TPIA), an appeals court in that state ruled June 16, 2006.

The Texas Court of Appeals, Third District, held that requests for information made in accordance with the TPIA fall under HIPAA’s required-by-law exception, 45 C.F.R. § 164.512(a). The appeals court rejected the Department’s arguments that HIPAA’s required-by-law exception should not apply to information requests made pursuant to the TPIA because the Act neither defines public information to include protected health information nor sufficiently limits disclosure to specific individuals for specific purposes.
“Nothing in the [TPIA’s] definition of ‘public information’ expressly exempts health information,” the appeals court reasoned. Moreover, “there is nothing in the language of the Privacy Rule or HIPAA that limits the application of [the required-by-law exception] to statutes authorizing the disclosure of specifically enumerated types of information,” the appeals court said. *Abbott v. Texas Dep't of Mental Health*, No. 03-04-00743-CV (Tex. Ct. App. June 16, 2006).

**Georgia Appeals Court Finds HIPAA Preempts State Statute Requiring Medical Records Release Authorization In Medical Malpractice Action**

A Georgia statute requiring a plaintiff to file a medical records release authorization form with the complaint in a medical malpractice action is preempted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), an appeals court in that state ruled July 13, 2007. Because HIPAA pre-empted the statute, the trial court correctly denied a medical center’s motion to dismiss the malpractice action based on plaintiff’s failure to comply with the medical record release requirements. Linda Queen brought a medical malpractice action against Northlake Medical Center (Northlake) and others. Northlake moved to dismiss the complaint because Queen failed to comply with Ga. Code Ann. § 9-11-9.2, which states that a medical records release authorization form must be filed with the complaint in a medical malpractice action.

The Georgia Court of Appeals concluded that the authorization set forth in Ga. Code Ann. § 9-11-9.2 was contrary to HIPAA because it permitted the discovery of all of the plaintiff’s medical records, regardless of whether they were relevant to the medical malpractice case, did not provide for an “expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure,” and contained no notice of a right to revoke the authorization. *Northlake Med. Ctr. v. Queen*, No. A06A0540 (Ga. Ct. App. July 13, 2006).

**U.S. Court In Kansas Says Hospital Satisfied HIPAA Requirements In Seeking Order To Access Medical Records**

A federal court in Kansas granted August 16, 2006 a hospital’s motion seeking court authorized access to a patient’s medical records in a negligence action arising from the care she and her unborn child received there. The court also said the hospital was entitled to interview the patient’s treating physicians ex parte. According to the court, by seeking the court order, the hospital had complied with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). Deanna McCloud sued Geary Community Hospital and various physicians alleging violations of the Emergency Medical Treatment and Labor Act and negligence in connection with the care she and her unborn baby received following a car accident. McCloud was thirty-one weeks pregnant at the time and her baby died. Defendants sought access to the medical records of McCloud and her baby, arguing that the physician-patient privilege had been waived. Defendants also contended that they should be allowed to interview McCloud’s treating physicians ex parte. McCloud countered that defendants failed to comply with HIPAA and therefore their request should be denied.
The U.S. District Court for the District of Kansas first noted that because McCloud put her medical condition and that of her baby at issue in her personal injury and wrongful death lawsuit, she could not claim the physician-patient privilege. The court also found that prior case law consistently has allowed ex parte communications with treating physicians where a plaintiff’s medical condition is at issue and declined to deviate from those decisions. According to McCloud, HIPAA preempted any state provision governing the production of medical information unless the state law was “more stringent” than the HIPAA rules. The court said it need not delve into this argument because defendants, by seeking an order to allow the production of the medical information and the ex parte contact, complied with the HIPAA requirements set forth in 45 C.F.R. § 164.512(e)(1), which allows disclosure of protected health information in the course of any judicial or administrative proceeding pursuant to a court order or subpoena, discovery request, or other lawful process.

The court did conclude, however, that defendants failed to satisfy the statutory and regulatory requirements for production of information relating to whether McCloud had ever been diagnosed or treated for alcoholism or drug dependency. Under the Public Health Service Act, 42 U.S.C. § 290dd-2, such records that are maintained by federally funded programs must be kept confidential, absent a court order on a showing of good cause, which was not made here, the court found. McCloud v. The Board of Directors of Geary Community Hosp., No. 06-1002-MLB (D. Kan. Aug. 16, 2006).

U.S. Court In Nebraska Finds Physician Cannot Pursue Claims Against Hospital For Disclosing Drug/Alcohol Treatment

A physician does not have a private right of action under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) against a hospital where he worked for disclosing to a potential employer his past participation in a drug/alcohol treatment program, the U.S. District Court for the District of Nebraska ruled September 15, 2006. Scott Diering was an emergency room physician at Regional West Medical Center (Regional West) in Scottsbluff, Nebraska when he underwent, and successfully completed, a voluntary drug/alcohol treatment program. Nearly five years later, Regional West’s emergency room director disclosed to a potential employer that Diering had undergone the drug/alcohol treatment program. After he failed to secure a job offer, Diering sued Regional West, claiming the disclosure violated his right of confidentiality under state law and his privacy rights under HIPAA. The case was removed to federal court based on diversity.

The U.S. District Court for the District of Nebraska first held that Diering did not have a private cause of action under state law, which provides only that participation in a provided drug/alcohol treatment program shall not be reported to the director of regulation and licensure. In summarily rejecting Diering’s claim alleging violation of his privacy rights under HIPAA, the district court emphasized that every court considering this issue thus far has held that “HIPAA does not create of private cause of action for violation of the Act.” Diering v. Regional West Med. Ctr., No. 7:06CV5010 (D. Neb. Sept. 15, 2006).
Fifth Circuit Holds No Private Enforcement Of HIPAA

Becoming the first federal appeals court to rule on the issue, the Fifth Circuit held November 13, 2006 that private individuals cannot sue under the Health Insurance Portability and Accountability Act (HIPAA) for alleged privacy breaches. The case arose when Margaret Acara sued physician Bradley Banks under HIPAA for disclosing her medical information during a deposition without her consent. The U.S. District Court for the Eastern District of Louisiana granted Banks’ motion to dismiss, finding no subject matter jurisdiction because HIPAA does not give rise to a private cause of action. Reviewing the issue de novo, the Fifth Circuit affirmed, finding no express or implied provision in HIPAA creating a private right of action.

The appeals court noted that HIPAA contains no express language conferring privacy rights on a specific class of individuals; instead the statute regulates those who have access to personally identifiable health information and who conduct certain electronic healthcare transactions. The appeals court also found significant the fact that HIPAA limits enforcement of the statute to the Department of Health and Human Services Secretary. “While no other circuit court has specifically addressed this issue, we are not alone in our conclusion that Congress did not intend for private enforcement of HIPAA. Every district court that has considered this issue is in agreement that the statute does not support a private right of action,” the appeals court concluded. Acara v. Banks, No. 06-30356 (5th Cir. Nov. 13, 2006).

Agencies Release Final Rules On HIPAA Nondiscrimination Compliance

The Department of Health and Human Services (DHHS), in conjunction with the Department of Labor’s (DOL’s) Employee Benefits Security Administration (EBSA) and the Internal Revenue Service (IRS), published in the December 13, 2006 Federal Register (71 Fed. Reg. 75014) final rules that provide guidance on complying with the nondiscrimination provisions of the Health Insurance Portability and Accountability Act (HIPAA). The final rules also provide guidance on the implementation of wellness programs.

“HIPAA’s nondiscrimination provisions generally prohibit a group health plan or group health insurance issuer from denying an individual eligibility for benefits based on a health factor and from charging an individual a higher premium than a similarly situated individual based on a health factor,” the agencies explained. Health factors, as defined under HIPAA, include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of healthcare, medical history, genetic information, disability, and evidence of insurability.

The agencies said the final regulations generally do not change interim final rules or the proposed rule on wellness programs issued in 2001, but do “republish, and slightly modify, the special transitional rule for self-funded nonfederal governmental plans that had denied any individual coverage due to the plan’s election to opt out of the nondiscrimination requirements . . . in cases where the plan sponsor subsequently chooses to bring the plan into compliance with those requirements.” In addition, the final rules provide some clarification on how the “source-of-injury” provisions apply to the...
timing of a diagnosis of a medical condition. For example, the final rules do not change language from the interim final rules providing that a plan may not exclude coverage for self-inflicted injuries if the individual’s injuries are otherwise covered by the group plan and if the injuries are the result of a medical condition (such as depression). The final rules clarify, however, that benefits may not be denied for injuries resulting from such medical condition, even if the condition (such as depression) was not diagnosed prior to the injury. With regard to wellness programs, the final rules “clarify some ambiguities in the proposed regulations, make some changes in terminology and organization, and add a description of wellness programs not required to satisfy additional standards,” the final rules said. The final rules are effective February 12, 2007.

Hawaii Supreme Court Directs Issuance Of Protective Order For Health Information
The Hawaii Supreme Court granted a writ of mandamus directing a lower court to issue a comprehensive protective order for plaintiffs’ health information. The high court found that Hawaii law allows such protective orders to exceed protections offered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) when good cause is shown. Phillip and Delores Brende (plaintiffs) sued several parties in connection with a motor vehicle tort action. Plaintiffs asked the trial court for an order protecting the privacy of the health information that was produced in discovery. Their proposed stipulated order contained provisions patterned after HIPAA and some provisions grounded in Hawaii law. Ultimately, the trial judge agreed with defendants that plaintiffs failed to show good cause for an order that exceeded the protections afforded by HIPAA. Instead, the judge issued a "HIPAA Qualified Protective Order." Plaintiffs petitioned for a writ of mandamus.

The Hawaii Supreme Court found plaintiffs were entitled to mandamus relief. The high court first noted that in Hawaii “a medical information protective order issued in a judicial proceeding must, at a minimum, provide the protections of the HIPAA.” A protective order in excess of HIPAA protections may be issued, however, for good cause, the high court explained. According to the high court, under Hawaii law, “good cause” required a balancing between the harm resulting from disclosure of health information outside of litigation and the need for the information. Here, defendants had no legitimate need for plaintiffs’ health information outside of the present litigation, the high court found. Thus, the high court held that “petitioners have a clear and indisputable right to the revised protective order they seek, and good cause exists for the issuance of such order.” Brende v. Hara, No. 27964 (Haw. Nov. 27, 2006).

New York Appeals Court Declines To Compel Plaintiffs To Authorize Under HIPAA Defense Counsel’s Ex Parte Meetings With Treating Physicians
A New York trial court should not have ordered plaintiffs in a medical malpractice and wrongful death action to execute authorizations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to allow defense counsel to privately interview nonparty treating physicians who rendered care to the decedent, an appeals court in that state ruled December 5, 2006. On behalf of decedent Phyllis Arons, plaintiffs sued two of Arons’ physicians—Dr. Robert Jutkowitz and Dr. Robert Fulop—alleging they failed to
timely diagnose and inform Arons that she suffered from hydrocephalus. Defendants sought to interview nonparty treating physicians and moved to compel the production of HIPAA-compliant authorizations allowing them to do so.

The New York Supreme Court, Appellate Division, concluded that the relief requested in defendants' motion was “simply not authorized” by state statute. Neither N.Y. Civ. Prac. L. & R. article 31 nor the Uniform Rules for the New York State Trial Courts (Uniform Rules) include a provision authorizing defense counsel to meet privately with a plaintiff’s treating physician, the appeals court observed. Despite this general rule, the appeals court acknowledged the defense bar had apparently adopted the practice of conducting, after the notice of issue had been filed, ex parte meetings with plaintiffs’ treating physicians. The appeals court attributed this development to a line of New York cases holding that a treating physician’s testimony at trial should not be precluded on the ground that defense counsel had private discussions with him or her after the notice of issue was filed.

The instant case presented a more complex issue—and one of first impression—of how HIPAA requirements affect the defense bar’s informal practice of conducting private, post-notice of issue ex parte meetings with treating physicians, the appeals court explained. In light of HIPAA's Privacy Rule, “defense counsel have faced a practical dilemma in attempting to privately speak with plaintiffs’ nonparty treating physicians after a note of issue has been filed,” where plaintiffs have refused to execute HIPAA-compliant authorizations, the appeals court noted. As a result, defendants have resorted to filing motions in court to compel plaintiffs to execute such authorizations. State courts have resolved such motions inconsistently, the appeals court noted. “Although the specific reasoning of each of these courts varies, they share the general notion that our precedent ‘militates against granting the relief sought by the defendants on these applications because they call for directions outside the scope of discovery authorized by New York’s Civil Practice Law and Rules or the Uniform Rules,’” the appeals court said. Arons v. Jutkowitz, No. 2005-06762 (N.Y. App. Div. Dec. 5, 2006).

U.S. Court In Connecticut Says HIPAA Does Not Bar Ex Parte Interviews With Employees At Group Home Where Plaintiff Was Allegedly Neglected

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit expert witnesses retained by the defendants in a medical negligence action from conducting ex parte interviews with employees of a Connecticut group home where the plaintiff allegedly was neglected, a federal district court in that state ruled January 25, 2007. Eleanor Santaniello, who is nonverbal and has significant permanent disabilities, is a resident in a Westport, Connecticut group home for developmentally disabled adults. Santaniello, through her sister and conservator, Linda Quadrini, sued the owner and operator of the group home, CLASP Homes, Inc., alleging that Santaniello suffered injuries when the home neglected her health and dental needs. The original complaint filed with the U.S. District Court for the District of Connecticut was later amended to add Sybil Sweet, an official at the Connecticut Department of Mental Retardation (DMR), and DMR’s Commissioner, Peter O’Meara. The amended complaint requested that the court order DMR to initiate and carry out system-wide reforms in the area of residential group homes.
The DMR defendants hired three experts to tour the group home where the alleged negligence took place and observe the residents there, and conduct interviews with Quadrini as well as the employees of the home and DMR. The court rejected plaintiff’s HIPAA-based objections to the request by the DMR defendants’ experts to conduct ex parte interviews with employees of the group home as well as DMR employees. According to plaintiff, such ex parte interviews should not be permitted because they would involve unauthorized disclosure of medical information that is protected by HIPAA. Disagreeing with this argument, the court explained that, under HIPAA (45 C.F.R. § 164.512(e)(1)), the disclosure of medical records is permitted in response to a formal discovery request, as long as a qualified protective order has been entered. Here, such an order, as defined under 45 C.F.R. § 164.512(e)(1)(v), was in place, the court noted.

The parties in the case disagreed about the scope of the protective order “with the plaintiff arguing that it only applies to medical documents and does not adequately protect medical information [that might be] obtained in oral interviews.” But plaintiff conceded in oral argument that this shortcoming in the protective order could be easily resolved by allowing the parties to amend, if necessary, the order to state that medical information obtained during oral interviews was expressly protected, the court said. Santaniello v. Sweet, No. 3:04-cv-00806-RNC (D. Conn. Jan. 25, 2007).

**DHHS Grants HIPAA Subpoena Power To OCR**
The Department of Health and Human Services delegated to the Director of the Office for Civil Rights (OCR) the authority to issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in investigations of alleged violations of the Privacy Rule, according to an April 16 Federal Register notice (72 Fed. Reg. 18999). The notice also grants subpoena power under the Patient Safety and Quality Improvement Act of 2005.

**HOSPITALS AND HEALTH SYSTEMS**

**Oregon Health System Settles Charity Care Lawsuit**
Legacy Health System agreed to recalculate hospital bills going back five years and offer deeper discounts going forward to settle a class action brought by uninsured patients who alleged they were charged far more for their care than insured patients. The lawsuit is part of a nationwide effort by uninsured patients alleging various hospitals and health systems violated their charity care obligations.

Under the settlement, which requires court approval, Legacy must apply a 25% discount to uninsured patients’ hospital bills retroactive to December 2001. For the next four years, Legacy also agreed to provide uninsured patients who qualify for charity care with a 15% discount from its billed charges. In addition, Legacy for the next two years will provide the 15% discount to uninsured patients with incomes below $100,000 regardless of whether they qualify for charity care. Legacy also will apply its current charity care...
policy over the nine-year time span covered by the agreement to further reduce hospital bills based on a sliding-scale tied to income. Uninsured patients who have paid more than the recalculated bills will receive a refund. The settlement follows recent court approval of a similar agreement reached by the Providence Oregon Hospital System with uninsured patients.

**U.S. Court In New Jersey Rejects Lawsuit Against Health System For Overcharging Uninsured**

In an unpublished opinion issued July 19, 2006, the U.S. District Court for the District of New Jersey dismissed a proposed class action against a health system and one of its hospitals alleging breach of contract and consumer fraud with respect to its uninsured billing practices. Plaintiff Justin DiCarlo, who is uninsured, brought a proposed class action against Bon Secours Health System, Inc. alleging he was billed far more than insured patients would have been for treatment he received at its St. Mary’s Hospital. As a condition of treatment, plaintiff was required to sign a form guaranteeing payment of unspecified charges. St. Mary’s Hospital then billed plaintiff $3,483.04, its full chargemaster rate.

Plaintiff argued that his contract with St. Mary’s had an open price term and therefore the law implied an agreement to pay only a reasonable price. While acknowledging the “facial persuasiveness” of plaintiff’s contention, the court found that “all charges” as used in the payment guarantee plaintiff signed “unambiguously” could only refer to the hospital’s uniform charges set forth in its chargemaster. According to the court, the hospital context made including a more precise price term impractical given that at the time the guarantee was entered into, there was no way to know what condition the patient had or what treatments would be necessary. *DiCarlo v. St. Mary’s Hosp.*, No. 05-1665 (DRD-SDW) (D.N.J. July 19, 2006).

**JCAHO Issues Revised Medical Staff Standard For Comment**

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued another proposed revision to Medical Staff Standard MS 1.20, which deals with the medical staff’s self-governance and its accountability to the governing body. JCAHO said it further revised the standard in response to comments made in connection with a February 2006 field review on MS 1.20. Comments on the latest version were due October 27, 2006. According to JCAHO, stakeholders responding to the earlier version were concerned that the proposed standard would require resource-consuming compliance efforts, was too prescriptive as to what the medical staff bylaws must contain, and could undermine the role of the medical staff, among other things.

**Montana High Court Allows New License For Specialty Hospital That Changed Its Status To General Hospital**

A state court properly denied a hospital’s request for a preliminary injunction that would, in effect, void the license issued to a competing hospital that changed its status from a specialty to a “general” hospital when applying for a new license, the Montana Supreme Court ruled October 4, 2006. Specifically, the high court found no "manifest abuse of discretion" in the lower court’s conclusion that the plaintiff-hospital had failed to meet its
burden of showing it would suffer irreparable harm from the competing hospital’s switch from a specialty to a general hospital.

The plaintiff-hospital, Benefis Healthcare (Benefis), is a nonprofit corporation operating the sole community hospital (for purposes of Medicare and Medicaid) in Great Falls, Montana. The competing hospital, Central Montana Hospital, was originally licensed in October 2002 as a specialty hospital under the name of Central Montana Surgical Hospital (CMSH). CMSH sought to operate as a general hospital, rather than a specialty hospital, after its acquisition by a joint venture between a medical clinic and a health system. Montana’s Department of Public Health and Human Services (DPHHS) issued a provisional (general hospital) license to CMSH. Benefis then sought a preliminary injunction to void the new license and require DPPHS to institute a process for determining whether a license applicant was a specialty hospital. According to Benefis, it would suffer irreparable harm because CMSH would refer more lucrative procedures to itself, resulting in a loss of revenue that would ultimately force Benefis to reduce or discontinue its low margin and charity services.

In a 4-3 decision, the high court upheld the lower court’s refusal to grant the preliminary injunction. The high court said “Benefis’ novel argument that the community would suffer irreparable injury from a lack of available services should a preliminary injunction not issue” did not meet the statutory requirement that the applicant for the injunction be at risk of irreparable harm. The high court also rejected Benefis’ argument that DPHHS should have obtained public comments on the specialty to general hospital switch before proceeding. “[T]here is no express statutory requirement for DPHHS to permit public participation in licensing matters,” the high court noted. Benefis Healthcare v. Great Falls Clinic, LLP, No. DA 06-0240 (Mont. Oct. 4, 2006).

Illinois Appeals Court Dismisses Consumer Fraud, Unfair Business Practices Claim Against Hospital
An Illinois appeals court affirmed October 20, 2006 the dismissal of a claim alleging a hospital violated the state’s consumer fraud and deceptive business practices law by charging excessive prices and failing to disclose its billing policies. Rockford Memorial Hospital (RMH) sued Michael and Kathy Havrilesko (defendants) seeking payment for medical treatment it provided to one of their children. Defendants counterclaimed, on behalf of themselves and those similarly situated, for damages under the Illinois Consumer Fraud and Deceptive Business Practices Act (Act). According to defendants, RMH violated the Act by concealing facts about its charges and billing practices, charging for services not received, and billing for excessive charges.

The trial court dismissed defendants’ claim. The Illinois Appellate Court, Second District, affirmed, holding the claim was properly dismissed because defendants failed to allege RMH had knowledge of the facts allegedly omitted or to plead their allegations with the required specificity. Rockford Mem’l Hosp. v. Havrilesko, No. 04-AR-915 (Ill. App. Ct. Oct. 20, 2006).
U.S. Court In Florida Refuses To Dismiss Uninsured Patient’s Action Against Hospital For Unfair Billing

An uninsured patient who alleged a hospital charged her 600% more for services than its insured patients could proceed with her unreasonable pricing claims, a federal trial court in Florida ruled November 17, 2006. Plaintiff Barbara Colomar was treated at Mercy Hospital, Inc, part of Catholic Health East, Inc. (CHE), and received a bill totaling nearly $13,000. Colomar, who is uninsured, signed an “Authorization and Guarantee” before receiving treatment agreeing to pay all non-covered bills. Colomar paid $1,750 of the bill, which was then sent to collections. Colomar brought a class action on behalf of herself and other uninsured patients against Mercy, alleging the hospital charged inflated and unfair rates to uninsured patients as compared to those charged to insured individuals. Plaintiff alleged breach of contract and a violation of the Florida Deceptive and Unfair Trade Practices Act (FDUTPA) against the hospital, arguing the open price term in the contract she signed was unreasonable.

After her initial complaint was dismissed, Colomar added specific allegations that the actual costs of the services provided to her were $2,098; that Mercy charges uninsured patients 450% of Medicare reimbursement rates; that CHE hospitals rank among the top 13% of all hospitals nationwide in charges; and that CHE’s cost-to-charge ratio is 394%. Based on these additional allegations, the U.S. District Court for the Southern District of Florida refused to dismiss Colomar’s action claiming Mercy’s charges were unreasonable. The court noted that no single factor standing alone determined reasonableness, but Colomar’s allegations together were sufficient to survive a motion to dismiss. According to the court, Colomar’s allegations that Mercy charges in the top 13% of what all hospitals charge and that its cost-to-charge ratio is among the top 10% of all hospitals is sufficient to show Mercy’s charges are not “within the range” of the market. *Colomar v. Mercy Hosp. Inc.*, No. 05-22409-CIV-SEITZ (S.D. Fla. Nov. 17, 2006).

U.S. Court In Louisiana Remands Claims Related To Post-Katrina Patient Deaths And Injuries To State Court

The U.S. District Court for the Eastern District of Louisiana remanded November 21, 2006 a class action against a New Orleans medical center to state court, ruling that it could not exercise federal jurisdiction over claims relating to patient injuries and deaths following Hurricane Katrina. Patients and relatives of deceased and allegedly injured patients (plaintiffs) filed a state court action against Tenet Healthsystem Memorial Medical Center, d/b/a Memorial Medical Center (Memorial), as well as LifeCare Management Services (LifeCare), which leased space and operated an acute care unit on one floor of the hospital (collectively, defendants). In part, plaintiffs alleged that the facility’s back up electrical system was not adequate and that defendants failed to implement adequate evacuation and emergency preparedness plans. Plaintiffs set forth legal claims including negligence, intentional misconduct, reverse patient dumping under the Emergency Medical Treatment and Labor Act (EMTALA), and involuntary euthanasia.

The federal district court addressed the issue of federal jurisdiction *sua sponte*. Under the Federal Officer Removal Statute, 28 U.S.C. § 1422(a)(1), a civil action may be removed
to federal court if defendant LifeCare is a person that acted under color of federal authority when committing the allegedly tortious conduct, and can assert a colorable federal defense, the court explained. In this case, LifeCare argued that it conducted the evacuation of Memorial at the direction of a federal officer, the District Regional Coordinator for the U.S. Health Resources Services Administration (HRSA), who informed them that they must follow the Federal Emergency Management Agency (FEMA) evacuation plan, rather than implementing LifeCare’s own. The court disagreed and ruled that LifeCare did not act under color of federal authority, noting that the HRSA Coordinator was a volunteer, not a federal employee. Further, the HRSA Coordinator served as a conduit for information, and did not exercise direct and detailed control over LifeCare’s operations, the court reasoned. Thus, removal under the Federal Officer Removal Statute was improper.

The court next analyzed removal under the Multiparty, Multiforum Trial Jurisdiction Act (MMTJA), 28 U.S.C. § 1369. The MMTJA creates federal jurisdiction over civil actions that arise from a single accident, where at least seventy-five natural persons died at a discrete location, and where minimal diversity is present, the court found. The court concluded that the MMTJA did not confer federal jurisdiction here because, even if the levee breaches were accidents under the statute, the “discrete location” in this case was Memorial, where seventy-five deaths did not occur.

The Class Action Fairness Act of 2005 (CAFA), Pub. L. No. 109-2, broadly grants federal jurisdiction for class actions with more than five million dollars in controversy, but exceptions may bar a court’s ability to hear the case. In particular, the “local controversy” and “home-state controversy” carve-outs preclude federal jurisdiction where a case is “distinctly local in nature.” Accordingly, the court considered closely the citizenship of the plaintiffs in this case. Although a LifeCare investigator determined that forty-nine of 146 potential class members currently reside outside of Louisiana, citizenship is determined by looking at residence and intent at the date the suit was filed, the court noted, and evidence showed that at least some of the class members intended to return to New Orleans. Thus, the court concluded that because “more than two-thirds of the proposed plaintiff class are citizens of Louisiana, both Defendants are incorporated in Louisiana and hence citizens of this State, and the injuries took place in Louisiana,” CAFA did not confer federal jurisdiction.

Finally, the court examined LifeCare’s argument that plaintiffs’ claims of reverse patient dumping under EMTALA triggered federal jurisdiction. The court ruled that plaintiffs failed to state a valid claim under EMTALA. Even if such a claim existed, the court continued, state law claims predominated, making remand to state court appropriate. Preston v. Tenet Healthsystem Mem’l Med. Ctr., Civ. Action No. 06-3179 (E.D. La. Nov. 21, 2006).

San Francisco Judge Grants Final Approval To Settlement Of Uninsured Lawsuit
San Francisco Superior Court Judge Richard A. Kramer has granted final approval to the settlement of a class action against Catholic Healthcare West (CHW) for allegedly charging excessive and unfair prices to uninsured patients and engaging in aggressive
collection practices at its hospitals in California, Nevada, and Arizona, according to a statement posted by one of the law firms representing the plaintiffs in the case. The settlement entitles class members to make a claim for refunds or deductions of 35% from their prior hospital bills. CHW also has agreed to maintain uninsured pricing and collection policies for at least four years. The firm estimated the value of the settlement at $423 million. CHW denied any wrongdoing in settling the case.

**Texas Appeals Court Finds Hospital Not Obligated To Produce Variance, Investigative Reports In Premises Liability Action**

A Texas appeals court held January 18, 2007 that a lower court erred in ordering a hospital to produce reports to a slip and fall plaintiff that were subject to medical committee and work product privileges. The appeals court also found a discovery request for any and all employee handbooks to be overly broad and opined that such request could be better tailored to include only documents relevant to the lawsuit. Plaintiff Flora McDonald sued Christus Health Southeast Texas d/b/a Christus St. Mary Hospital after falling on hospital premises, claiming a dangerous condition caused her fall. The trial court ordered production of eighty-seven variance reports prepared for the hospital's Safety Committee, an investigation report prepared for the accident in this case, and employee handbooks. The hospital appealed.

The Court of Appeals of Texas granted conditional mandamus relief. The appeals court noted that the hospital had established the Safety Committee as a medical committee and therefore its “records that are not made in the regular course of business are confidential and not subject to discovery.” Because the investigation report was prepared in anticipation of litigation and plaintiff had not shown a substantial need for the materials and that substantially equivalent documents could not be obtained by other means, the investigation report also was not discoverable, the appeals court held. Lastly, the appeals court held that plaintiff’s request for “any and all employee handbooks” was overbroad because it did not describe with reasonable particularity the documents sought. *In re Christus Health Southeast Tex.*, No. 09-06-515 CV (Tex. Ct. App. Jan. 18, 2007).

**Illinois Supreme Court Holds Hospital Not Liable For Employee’s Disclosure Of Confidential Medical Information**

A hospital was entitled to summary judgment on a patient’s claim that it was vicariously liable for its employee’s disclosure of a patient’s confidential medical information, the Illinois Supreme Court ruled January 19, 2007. Reversing an appeals court’s decision, the high court found no reasonable person could conclude from the evidence that the employee, who disclosed the information to the patient’s sister at a bar, was acting within the scope of her employment.

Plaintiff Suzanne Bagent was a patient at Quincy Medical Group on September 4, 2003. Beginning on that date, blood samples and/or medical records were sent to Illini Hospital and were examined there by Misty Young who worked at the hospital as a phlebotomist. Young then inadvertently revealed the results of those tests (that Bagent was pregnant) to plaintiff’s sister at a tavern. Plaintiff sued Young and Blessing Care Corporation d/b/a Illini Community Hospital under a theory of respondeat superior alleging breach of
healthcare practitioner/patient confidentiality, invasion of privacy, negligent infliction of emotional distress, and intentional infliction of emotional distress. Reversing the trial court’s dismissal of the action, a divided panel of the Illinois Appellate Court held that a question of fact existed as to whether the purpose of Young’s disclosure was motivated, at least in part, by a purpose to serve the hospital.

The Illinois Supreme Court noted “uncontradicted evidence” that Young’s disclosure of plaintiff’s medical record was not the kind of conduct Young was employed to perform. Moreover, the hospital expressly forbade Young to reveal patient information. The high court also found no genuine issue of material fact that the disclosure was motivated to serve the hospital. “Regardless of whether Young was required to maintain patient confidentiality at all times and places . . . the evidence would still be insufficient to establish the hospital’s liability,” the high court held. *Bagent v. Blessing Care Corp.*, No. 102430 (Ill. Jan. 19, 2007).

**U.S. Court In Oklahoma Grants Hospital Summary Judgment In Breach Of Contract Action By Uninsured Patients**

A federal district court in Oklahoma held January 24, 2007 that a hospital was entitled to summary judgment in a breach of contract action alleging it billed certain patients more than the reasonable value of services they received. In so holding, the court found plaintiffs presented no evidence that the bills in fact exceeded the reasonable value of the services and also failed to show any damages. Plaintiffs Clayton Woodurm, Armando Martinez, Kenneth Thomas, and Mike Shannon entered into contracts and received treatment from defendant Integris Health, Inc. All plaintiffs were subsequently charged for the services. Plaintiffs filed a class action against defendant asserting breach of contract because defendant allegedly charged them more than the reasonable value of the services provided.

The U.S. District Court for the Western District of Oklahoma granted defendant’s motion for summary judgment, finding no evidence that plaintiffs incurred damages as a result of the alleged breach. Plaintiffs’ generalized evidence about billing the uninsured and the harms of outstanding medical debt were insufficient, the court said. “While plaintiffs may have shown that it is possible to suffer damages as a result of simply being charged too much (as opposed to actually paying too much), plaintiffs have failed to offer any evidence that they actually suffered such damages,” the court held. *Woodrum v. Integris Health*, No. NO. CIV-05-1224-HE (W.D. Okla. Jan. 24, 2007).

**CMS Says Texas Hospital Did Not Violate Specialty Hospital Moratorium, But Finds Non-Compliance With Medicare CoPs**

Responding to an inquiry from congressional lawmakers, the Centers for Medicare and Medicaid Services (CMS) said that West Texas Hospital in Abilene, Texas did not violate a statutorily mandated eighteen-month moratorium on specialty hospitals. At the same time, the agency said its investigation of West Texas Hospital revealed it was out of compliance with four Medicare Conditions of Participation—namely those applicable to the governing body, patient rights, nursing services, and emergency services. Citing evidence of a “serious and immediate threat to patient health and safety,” CMS said it
would pull the hospital's Medicare provider agreement unless it fixed these problems before March 17, 2007.

Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Charles Grassley (R-IA), along with Rep. Pete Stark (D-CA), asked CMS to scrutinize the facility following the January 23 death of a patient who suffered respiratory arrest after an elective spinal surgery. Hospital staff called 911 and the patient was transferred to a local community hospital for emergency services where he later died. In a February 8, 2007 letter to CMS, the lawmakers asked, among other things, whether the physician-owned facility received illegal Medicare payments during the eighteen-month moratorium on specialty hospitals imposed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

In response, CMS said its data analysis confirmed the hospital did not bill Medicare for any services based on prohibited referrals from physician investors before the moratorium expired in June 2005. At the same time, CMS acknowledged that its fiscal intermediary (FI) for Texas, Trailblazers, failed to follow the agency’s instructions to temporarily suspend the processing of specialty hospital enrollment applications after the moratorium ended with respect to West Texas Hospital, as well as on two other occasions. CMS told its FIs to obtain projections from applicant hospitals of all patient cardiac, orthopedic, or surgical discharges expected in the first year of operation. CMS considers a facility a “specialty hospital” if these projections indicate that 45% or more of inpatient cases fall into any of these categories. In the case of West Texas Hospital, Trailblazers failed to request this information, CMS said. CMS added that it is contacting all FIs to make sure they are complying with these instructions. Also in response to the lawmakers’ inquiry, CMS said its investigation revealed West Texas Hospital called 911 to transfer a patient to another hospital fifteen times since its opening in May 2005.

Following CMS’ response, Baucus and Grassley sent separate letters to CMS Acting Administrator Leslie Norwalk and Joint Commission President Dennis O’Leary, M.D. raising new questions about the hospital. In the letter to Norwalk, the lawmakers sought more details about how CMS responded to TrailBlazer’s mishandling of West Texas Hospital’s Medicare enrollment application, including any other instances since 2003 where TrailBlazer failed to follow the agency’s instructions.

In their letter to O’Leary, the lawmakers asked the Joint Commission to provide details on its accreditation of West Texas Hospital, including subsequent review activities and any response the accreditation group took following the January 23 patient death. “We find it disturbing that a Joint Commission accredited hospital has been found to be out of compliance with Medicare Conditions of Participation less than two years after receiving your accreditation,” the letter said.

**California Appeals Court Holds Physician Whose Privileges Were Terminated Cannot Sue For Damages Because He Failed To Meet Hospital Staff Requirements**

The California Court of Appeal, Fourth District, found in an unpublished decision issued March 9, 2007 that a physician whose medical staff privileges were terminated could not
maintain his action for damages against the hospital because he failed to meet hospital qualifications under a rule of general application to the entire medical staff. Plaintiff Bryan Tran is a licensed physician who practices obstetrics and gynecology, but is not board certified. In October 1999, Tran joined the staff of Mission Hospital and held full clinical privileges there after being reappointed to the staff twice. In 2002, the hospital amended its bylaws requiring all staff members to become board certified within five years of being admitted to the medical staff.

The hospital sent Tran a letter stating that the bylaws required him to become certified within five years of joining the medical staff; thus, if he did not provide the hospital with evidence of board certification, his medical staff privileges would terminate. Tran’s request for an extension was denied. Tran ultimately filed a claim for injunctive relief to prevent his staff membership from terminating, which the court denied. Tran then filed a complaint seeking various damages. The hospital filed a demurrer, which the court granted. Tran appealed.

The appeals court affirmed. The appeals court first noted that decisions regarding medical staff privileges generally fall into one of two categories—quasi-judicial or quasi-legislative. “Where a physician's medical staff privileges have been denied, suspended or terminated on the ground the physician has not demonstrated an ability to comply with established standards, that administrative decision is classified as ‘quasi-judicial’ . . . However, where the physician has had privileges denied or curtailed because of the implementation of a ‘policy’ of the hospital, the administrative action is classified as ‘quasi-legislative,’” the appeals court explained. Here, the appeals court found the hospital’s actions were quasi-legislative because it was implementing a rule of general application. As a result, the appeals court held Tran was not entitled to a hearing because the “requirement of a proceeding with minimal due process prior to termination of a physician's staff privileges is not applicable if it is the result of a quasi-legislative act by the hospital.” Tran v. Mission Hosp. Reg’l Med. Ctr., No. G036549 (Cal. Ct. App. Mar. 9, 2007).

West Virginia High Court Finds Nonprofit Hospital’s Executive Committee Meetings Must Be Open To Public

The meetings of a West Virginia hospital’s medical staff executive committee must be conducted in an open and public manner in accordance with West Virginia’s Open Hospital Proceedings Act (OHPA) [W.Va. Code §16-5G-1 to -7], the state’s highest court ruled March 1, 2007. Reversing the grant of summary judgment in favor of the hospital, the West Virginia Supreme Court of Appeals disagreed with the lower court’s conclusion that the OHPA, which provides that the meetings of a nonprofit hospital’s board of directors or “other governing bodies” be open to the public, applied only to the hospital’s Board of Trustees and not to its medical staff executive committee.

A group of physicians, including plaintiff Dr. R.E. Hamrick, Jr., filed a complaint in state circuit court alleging the Charleston Area Medical Center, Inc. (CAMC) was illegally denying them the right to attend meetings of its Medical Staff Executive Committee (MSEC). The state supreme court agreed with plaintiffs that the MSEC meetings fell
within OHPA’s purview. According to the high court, “the statute may be quite reasonably read to include the possibility that another group, in addition to a hospital’s board of directors, may function as a ‘governing body’” for purposes of the OHPA. Although the Board of Trustees bears the ultimate legal responsibility for CAMC and its actions, “the MSEC exercises primary authority over activities related to the functions of the medical staff, and other performance improvement activities regarding the professional services provided by individuals with hospital clinical privileges,” the state supreme court said. Moreover, this interpretation comports with the legislative purpose of the OHPA to ensure “all proceedings of the boards of directors or other governing bodies of such hospitals be conducted in an open and public manner so that people can remain informed of the decisions and decision-making processes affecting health care services on which they so vitally depend and which they help support.” *Hamrick v. Charleston Area Med. Ctr. Inc.*, No. 33107 (W. Va. Mar. 1, 2007).

**U.S. Court In Florida Dismisses Uninsured Patient’s Claims Against Hospital For Failing To Allege Injury**

An uninsured patient’s action contending a hospital charged her unreasonable rates for medical care must be dismissed because she failed to allege a specific injury to support her breach of contract and deceptive and unfair trade practices claims, a federal trial court in Florida ruled March 13, 2007. Plaintiff Una Urquhart sued Manatee Memorial Hospital, d/b/a Lakewood Ranch Medical Center, alleging that as an uninsured patient she was charged rates far exceeding those available to other payors. At the time of her treatment at Lakewood Ranch, plaintiff signed a “Conditions of Service Agreement,” acknowledging her obligation to pay the hospital’s “regular rates” and that the ultimate costs of the medical services could not be determined in advance. According to plaintiff, the hospital billed her $65,511 for services and supplies that actually cost approximately $16,805. Plaintiff also contended that Lakewood Ranch discounts its gross charges for managed care companies by about 66.8%. Plaintiff, who sought to bring her claims as a class action, alleged the hospital breached its contract with her by charging unreasonable rates; violated Florida’s Deceptive and Unfair Trade Practices Act; breached its duty of good faith and fair dealing; and was unjustly enriched.

The U.S. District Court for the Middle District of Florida dismissed the action, finding plaintiff failed to specify how she was injured by the hospital in any manner whatsoever, noting the complaint did not indicate whether she paid any portion of the bill or whether the hospital initiated any collection efforts against her. As to plaintiff’s statutory unfair and deceptive practices claim, the court agreed with other federal district courts that “deception does not occur simply because a pricing term in an open pricing agreement is left undefined.” The court added that while plaintiff could still potentially raise the issue of whether the conduct was “unfair” under the statute, the complaint’s failure to specify an injury was fatal to this claim as well. *Urquhart v. Manatee Mem’l Hosp.*, No. 8:06-cv-1418-T-17-EAJ (M.D. Fla. Mar. 13, 2007).
IMMIGRATION

Ninth Circuit Invalidates Certain Regulatory Provisions Affecting Resident Status Of Immigrant Doctors In Shortage Areas

Certain regulatory provisions of the Department of Homeland Security (DHS) conflict with statutory requirements governing the lawful permanent resident status of immigrant physicians practicing in medically underserved areas and are therefore invalid, the Ninth Circuit ruled recently. Four immigrant physicians sought an adjustment to lawful permanent resident (LPR) status based on their employment. The physicians sought “national interest waivers,” which provide an accelerated path to LPR status for immigrant doctors who practice in medically underserved areas. The physicians brought an action against the DHS Secretary in federal district court for declaratory and injunctive relief, challenging five sections of the regulations that implement the Nursing Relief for Disadvantaged Areas Act of 1999 (Act).

The Ninth Circuit struck down three sections of the regulations as in conflict with the Act—namely, that an immigrant doctor’s qualifying practice in a shortage area does not commence until the date of the notice approving the immigrant visa petition and national interest waiver request; the requirement that physicians who applied for a national interest waiver before November 1, 1998 but whose requests were denied before November 12, 1999 fulfill the five-year medical practice requirement instead of the shorter three-year requirement; and the imposition of a four- and six-year limitations period on the completion of the medical practice requirement following the approval of the immigrant visa petition and national interest waiver request (depending on whether the physician was subject to the three- or five-year aggregate practice requirement). Finally, the appeals court upheld the portion of the regulation establishing certain reporting obligations for complying with the medical practice requirement. Schneider v. Chertoff, No. 04-55689 (9th Cir. June 7, 2006).

INDIVIDUAL/PATIENT RIGHTS

Kentucky Supreme Court Rules Signed Consent Form Precludes Medical Battery Claim

A trial court did not err in finding the written consent form signed by a patient prior to colon surgery precluded her from establishing her medical battery claim against the surgeons who authorized and performed additional procedures to remove her ovaries and uterus, the Kentucky Supreme Court ruled June 15, 2006. The consent form in this case contained language authorizing additional procedures if medically necessary.

In a 5-2 opinion, the Kentucky high court found the patient failed to prove lack of consent as an essential element of battery. “The existence of a signed consent form gives rise to a presumption that patients ordinarily read and take whatever other measures are necessary to understand the nature, terms and general meaning of the consent,” the high court held. Moreover, “[t]o hold otherwise would negate the legal significance to written

**CMS Issues Final Rule Revising Patients' Rights Conditions Of Participation**
The Centers for Medicare and Medicaid Services (CMS) issued a rule in the December 8, 2006 *Federal Register* (71 Fed. Reg. 71378) finalizing the Patients' Rights Conditions of Participation applicable to all hospitals participating in Medicare and Medicaid. The rule addresses the many comments made on the July 1999 interim final rule. The eight standards specified in the final rule establish minimum protections and rights for patients. One standard, which addresses restraint and seclusion, was modified from the interim rule and now provides that a patient has a right to be free from restraint or seclusion, of any form, imposed by staff as a means of coercion, discipline, convenience, or retaliation. Among other changes, the definition of the word "restraint" was revised and clarified from the previous rule in response to comments. The final rule also adds a new standard requiring staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in certain specified areas. The regulations are effective January 8, 2007.

**New York High Court Says Organ Recipient Has No Property Right To Donated Kidney**
A specified recipient of a kidney has no common law property interest in the donated organ to support a claim of conversion, the New York high court ruled December 14, 2006. The high court also determined that the donee could not maintain a private cause of action under the state’s public health law because the donor's kidneys were eventually determined to be medically incompatible for his use.

The case arose after the death of Peter Lucia. His widow sought to donate his kidney to plaintiff, her husband’s long-time friend. The first kidney sent to plaintiff was unsuitable for transplantation and, by the time of this discovery, the second kidney had already been donated to someone else. Doctors eventually concluded that the other kidney would have been incompatible for plaintiff as well. Plaintiff sued the New York Organ Donor Network Inc. and the Good Samaritan Hospital where Lucia died, for fraud, conversion, and violations of New York Public Health Law Articles.

The New York Court of Appeals rejected the conversion claim, holding that plaintiff, as a specified donee of an incompatible kidney, had no common law right to the organ. The high court reviewed various court decisions, noting “none have strayed meaningfully from the doctrine that there is no common law property right in a dead body.” The high court also concluded that plaintiff had no statutory cause of action under New York’s Public Health Law because both kidneys were medically incompatible for plaintiff. *Colavito v. New York Organ Donor Network, Inc.*, No. 106 (N.Y. Dec. 14, 2006).

**U.S. Supreme Court Upholds Ban On Partial-Birth Abortions**
In a 5-4 decision, the U.S. Supreme Court upheld April 18, 2007 the federal Partial-Birth Abortion Act of 2003, rejecting numerous lower court decisions that ruled the Act was
unconstitutional. The majority opinion, written by Justice Anthony M. Kennedy, found the Act was not void for vagueness and did not present an “undue burden” on a woman’s right to an abortion as articulated in Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992). In upholding the partial-birth abortion ban, Kennedy also stressed the government’s “legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn.”

In her dissenting opinion, Justice Ruth Bader Ginsburg, joined by Justices John Paul Stevens, David H. Souter, and Stephen G. Breyer, called the majority decision’s “alarming,” arguing it “blurs the line, firmly draw in Casey, between previability and postviability abortions” and “blesses a prohibition with no exception safeguarding a woman’s health” for the first time since the landmark decision in Roe v. Wade, 410 U.S. 113 (1973).

The controversial measure signed into law by President George W. Bush in November 2003 criminalizes a certain type of procedure known as the partial-birth abortion. 18 U.S.C. § 1531. Physicians and advocacy groups challenged the Act in federal trial courts in Nebraska, California, and New York, which ruled the Act was unconstitutional and enjoined its enforcement. The Eighth, Ninth, and Second Circuits, citing the Supreme Court’s decision in Stenberg v. Carhart, 530 U.S. 914 (2000), which struck down a similar statute in Nebraska that also banned partial-birth abortions, affirmed the district courts’ rulings. Gonzales v. Carhart, No. 05-380 (U.S. Apr. 18, 2007).

INSURANCE

Pennsylvania Supreme Court Says Action Alleging Nonprofit Violated State Law By Maintaining Excess Reserves May Go Forward

The Pennsylvania Supreme Court found November 21, 2006 that an action alleging a nonprofit hospital corporation violated the state’s nonprofit law by maintaining excess reserves could proceed in court. In so holding, the high court rejected the lower courts’ conclusion that subject matter jurisdiction was lacking because the suit amounted to a challenge of matters exclusively within the province of the Pennsylvania Department of Insurance (Department). Jules Ciamaichelo and Rob Stevens (plaintiffs) filed a class action against Independence Blue Cross (IBC), a nonprofit hospital corporation, on behalf of themselves and other subscribers and policyholders for alleged violations of Pennsylvania’s Nonprofit Corporation Law of 1998. According to plaintiffs, IBC, as a nonprofit health insurer of last resort, violated the Nonprofit Law by accumulating reserves of as much as $438 million that were not needed for ongoing operations or financial solvency.

The Pennsylvania Supreme Court held that at this early stage of the proceedings it was not “clear and free from doubt” that plaintiffs’ claims amounted to a request that the court second guess an approved rate or assume the Department’s regulation of IBC’s reserves. In the high court’s view, plaintiffs’ claims raised questions of whether IBC violated the Nonprofit Law and breached contractual and fiduciary duties, matters that the legislature committed to the court’s jurisdiction, not to the Department. According to the high court,
plaintiffs’ complaint did not allege a “rate injury claim.” The high court added that the proper course was not to place the case in the exclusive jurisdiction of either the trial court or the Department. Instead, the trial court could refer to the Department any matters affecting its regulatory jurisdiction that may arise during the course of the litigation. *Ciamaichelo v. Independence Blue Cross*, No. 233 MAP 2003 (Pa. Nov. 21, 2006).

**Minnesota Supreme Court Says Contracts That Violate Corporate Practice Of Medicine Not Necessarily Void On Public Policy Grounds**

Three Minnesota chiropractic clinics that were operating in violation of the state’s corporate practice of medicine doctrine are entitled to proceed with their lawsuit seeking recovery from two insurance companies on outstanding claims for chiropractic services that the clinics provided to car accident victims under the state’s No-Fault Insurance Act, the Minnesota Supreme Court ruled December 7, 2006. The high court reversed the appeals court’s holding that, because the clinics were operating in violation of the corporate practice of medicine doctrine, all contracts between the clinics and their patients’ insurers were void as a matter of public policy. “Contracts made in violation of the corporate practice of medicine are not void per se,” the high court said, but rather such a contract must be examined separately, including the “circumstances surrounding the contract,” to determine whether the violation was knowing and intentional.

The underlying insurance claims at issue in the case dated back to 2000 when the three clinics—Isles Wellness, Inc., A Licensed Physical Therapy, Inc., and Licensed Massage Therapists, Inc. (the clinics)—first opened under the sole ownership of Jeanette Couf, an unlicensed lay person. From 2000 to 2003, the clinics provided chiropractic, physical therapy, and massage therapy services to forty-nine patients who had been involved in car accidents and had no-fault insurance coverage through Progressive Northern Insurance Company and Allstate Indemnity Company (insurers). Subsequently, each of the forty-nine patient assigned their claims against the insurers to the clinics. The clinics sued the insurers seeking to recover funds for unpaid services and alleging breach of contract and a violation of Minnesota’s Fair Practice Act. The insurers counterclaimed, alleging, among other things, that the clinics were operating in violation of the corporate practice of medicine doctrine.

The Minnesota Supreme Court noted the key factor was whether “the corporation’s actions show a knowing and intentional failure to abide by state and local law.” In this case, the clinics’ owner consulted with legal counsel and was told the law did not prohibit lay ownership of a corporate chiropractic practice. Because the record showed an obvious intent to comply with state law, the high court ruled the contracts should not be voided on public policy grounds. “Permitting insurance companies to avoid liability under their insurance contracts does little to protect patients from the ‘specter of lay control over professional judgment,’” the high court elaborated. *Isles Wellness Inc. v. Progressive Northern Ins. Co.*, No. A04-485 (Minn. Dec. 7, 2006).
LEGAL REPRESENTATION ISSUES

U.S. Court In Kansas Finds Insurer Waived Attorney-Client Privilege By Disclosing Legal Advice In Contract Negotiations With Hospital Network

A managed care insurer waived its attorney-client privilege by disclosing its attorneys’ legal concerns about certain exclusivity provisions during contract negotiations with a hospital network, a federal trial court in Kansas ruled February 6, 2007. The issue arose in connection with an antitrust lawsuit brought by Heartland Surgical Specialty Hospital LLC (Heartland) against CIGNA HealthCare of Ohio, Inc. (CIGNA). Heartland contended that CIGNA had waived the attorney-client privilege as to certain legal advice it received from its in-house counsel regarding contractual exclusivity provisions in its negotiations with Midwest Division, Inc., d/b/a HCA Midwest Division (HCA). HCA, in response to document discovery requests, produced to Heartland a memorandum it received from CIGNA about its attorneys’ legal advice regarding the exclusivity provisions in the HCA/CIGNA contract negotiations. According to Heartland, by disclosing this specific legal advice to HCA, and otherwise placing such advice at issue in the litigation, CIGNA waived any privilege that may have attached to the material.

The U.S. District Court for the District of Kansas concluded that CIGNA waived the attorney-client privilege as to the specific communications made in the memorandum, as well as to all other attorney communications on this issue. According to the court, “CIGNA did much more here than generically take a position on a legal issue” during business negotiations. Rather, the statements in the memorandum “reveal the precise advice of CIGNA’s attorney to CIGNA with regard to the contractual exclusivity language at issue.” In addition, the appeals court found CIGNA's waiver included all documents involving the subject of the exclusivity provisions as discussed in the memo to HCA. Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc., No. 05-2164-MLB-DWB (D. Kan. Feb. 6, 2007).

LONG TERM CARE

Missouri Appeals Court Upholds $240,000 Aggravating Circumstances Award Against Understaffed Nursing Home

A jury’s decision to award $240,000 aggravating circumstances damages against an understaffed nursing home in a wrongful death action brought by the daughter of a former resident was supported by clear and convincing evidence and was not excessive, the Missouri Court of Appeals ruled July 11, 2006. Pam Miller sued Levering Regional Health Care Center, and its affiliated owner, Reliant Care Management Company, for wrongful death and lost chance of survival after her mother, an Alzheimer’s patient, died following a head injury from a fall. The jury returned a verdict against Levering on the wrongful death claim for $10,000 actual damages and $240,000 aggravating circumstances damages. In addition, the jury returned a verdict against Reliant on the lost chance of survival claim for $150,000.

The Missouri Court of Appeals rejected Levering’s argument that the trial court erred when it submitted aggravating circumstances to the jury, finding the record “replete with
testimony” regarding Levering’s problem with understaffing. The appeals court also rejected Levering’s contention that the $240,000 aggravating circumstances award was unconstitutionally excessive. Finding Levering’s conduct to be reprehensible, the appeals court emphasized that the patient “was left unattended with a dangerous neurological health risk, and was not discovered until she had vomited on herself and suffered irreparable hemorrhaging that resulted in her death.” Miller v. Levering Reg’l Health Care Ctr., No. ED 86933 (Mo. Ct. App. July 11, 2006).

Sixth Circuit Affirms Civil Money Penalty Imposed On Nursing Home
The Sixth Circuit upheld a civil monetary penalty imposed by the Ohio Department of Health on a skilled nursing facility charged with violating Medicare program requirements. After a series of visits by the Ohio Department of Health, Harmony Court, a skilled nursing facility, was charged with twenty-nine violations of Medicare program participation requirements. Based on those violations, the Department levied fines of $77,100 against Harmony Court. Harmony Court challenged the fines administratively. An Administrative Law Judge (ALJ) found Harmony Court failed to comply with twelve participation requirements and therefore the fine was reasonable. Harmony Court appealed to the Departmental Appeals Board, which upheld the ALJ’s decision. Harmony Court appealed.

The Sixth Circuit first noted that even one violation may suffice to support the imposition of civil money penalties. After reviewing the relevant facts surrounding each type of violation, the appeals court concluded that substantial evidence supported the violation of the Medicare regulations and therefore affirmed the imposition of the $77,100 civil monetary penalty. Harmony Court v. Leavitt, No. No. 05-3644 (6th Cir. Aug. 1, 2006).

OIG Finds State Survey Agencies Failed To Investigate Serious Complaints At Nursing Homes Within Required Timeframes
Many state survey agencies in 2004 did not meet the required investigation timeframes for serious complaints set out in the Centers for Medicare and Medicaid Services’ (CMS’) procedural guidelines for nursing home complaint investigations—the State Operations Manual (SOM), according to a new report issued July 24, 2006 by the Department of Health and Human Services Office of Inspector General (OIG). The report, Nursing Home Complaint Investigations (OEI-01-04-00340), presents OIG’s findings from its analysis of 2004 data drawn from the ASPEN Complaints/Incidents Tracking System (ACTS), a database used by CMS to evaluate nursing home complaint investigations on a nationwide basis. Beginning in 2004, CMS required all state survey agencies to enter all nursing home complaint investigation information into the ACTS.

The OIG found that, during calendar year 2004, state agencies failed to investigate 7% of complaints alleging immediate jeopardy to a resident—the most serious complaint category—within the two-day timeframe required by CMS’ SOM. In addition, state agencies failed to investigate 27% of complaints alleging actual harm to a resident—the second most serious complaint category—within the ten-day timeframe required by the SOM, according to the report. “CMS regional offices and State agencies report that staff shortages and insufficient training limit State agencies’ ability to investigate complaints”
within the required timeframes, the report said. The OIG identified four specific limitations on CMS’ oversight of nursing home complaint investigations, and provided recommendations for addressing these limitations.

North Dakota Supreme Court Finds Wife May Be Liable For Nursing Home Bills Of Institutionalized Spouse If She Had Valid Contract With Home
The North Dakota Supreme Court reversed a lower court’s finding that a divorced spouse who had signed a nursing home admission agreement on her spouse’s behalf was not liable for his bills after the divorce, holding that the court must first make a finding as to whether the non-institutionalized spouse was a direct party to the contract. Colin Lovdahl moved into Mountrail Bethel Home (MBH) after suffering a stroke in December 2000. His wife, Bonnie, signed an “Admission Agreement” on his behalf. At the time of his admission, Lovdahl qualified for Medicaid, which paid the entire monthly cost of his care, except for a private room charge. In 2002, the Lovdahls divorced with no mention of the MBH contract in the divorce decree. Subsequently, Medicaid stopped paying for Lovdahl's care and MBH sued Colin and Bonnie Lovdahl seeking $35,626.57 for breach of contract.

Reversing a trial court decision, the North Dakota Supreme Court remanded for further proceedings on whether a contract existed between Bonnie Lovdahl and MBH. The question on remand was whether Bonnie was a direct party to the Admission Agreement as MBH argued or if she signed solely on her ex-husband’s behalf. *Mountrail Bethel Home v. Lovdahl*, No. 20060002 (N.D. Aug. 16, 2006).

New Hampshire Supreme Court Finds Nursing Home Reimbursement Changes Invalid
The New Hampshire Supreme Court found September 28, 2006 that changes made by the state reducing the amount of nursing home reimbursement were invalid because they were not promulgated in accordance with the state’s Administrative Procedure Act (APA). Bel Air Associates (Bel Air) operates a state-licensed nursing home in New Hampshire. In 2001, the state made two reductions to nursing home reimbursement through amendments to the state plan, which were not put through the APA process. Bel Air challenged both reductions, alleging the regulations violate the Social Security Act, the state and federal Constitutions, and the APA.

The New Hampshire Supreme Court held the amendments violated the state APA because the statute explicitly requires compliance with its provisions when adopting reimbursement rules for nursing home services. In so holding, the high court refused to give deference to the state’s “longstanding interpretation” of the statute finding the agency’s interpretation in clear conflict with the statute itself. *Bel Air Assocs. v. New Hampshire Dep’t of Health and Human Servs.*, No. 2005-522 (N.H. Sept. 28, 2006).

Mississippi High Court Finds Nursing Home Administrator And Licensee Did Not Have Duty Of Care, Fiduciary Duty To Nursing Home Residents
A husband and wife working as a licensee and administrator of a nursing home, respectively, did not owe a common law duty of care to nursing home residents under
Mississippi law, that state’s high court ruled October 26, 2006. The Mississippi Supreme Court also concluded that a fiduciary relationship did not exist between the nursing home residents and the individual administrator or licensee, and that they could not be held liable for medical malpractice in relation to the deaths of two residents who were allegedly neglected as a result of insufficient nursing personnel.

In the spring of 2002, representatives of the estate of Melvin Thead and the estate of Earline B. Harper (plaintiffs) each filed wrongful death and medical malpractice lawsuits against Benchmark Health Care, Inc. (Benchmark), the nursing home in Marion, Mississippi where both Thead and Harper had lived from 1997 until their deaths. At the same time, plaintiffs sued Joyce Howard in her capacity as administrator of Benchmark, and her husband, Guy Howard, in his capacity as licensee of Benchmark. In this suit, plaintiffs alleged that the Howards were negligent in failing to: provide a sufficient number of qualified personnel, including nurses and other staff; supervise and train the personnel; and prepare and maintain adequate records at the nursing home.

The high court declined to impose a common law duty of care on a nursing home administrator or licensee in “the absence of statutory law from the Legislature and the absence of case law calling for the expansion of this duty, as well as the fact that such expansion would be duplicative of the duty already owed by the nursing home business owner or proprietor.” The high court also rejected plaintiffs’ argument that the state's nursing home licensing statutes and regulations imposed a duty of care on administrators and licensees. While such statutes and regulations set standards in relation to the responsibilities of both the individual nursing home administrator and licensee, they do not “expressly create a duty by a licensee or an administrator to residents of a nursing home,” the high court concluded. The high court also rejected plaintiffs’ claims that the Howards, based solely on their positions as administrator and licensee, owed a fiduciary duty to Benchmark’s residents.

A dissenting opinion argued that the “practical effect of the majority’s ruling . . . is to render nursing home licensees and administrators virtually immune from civil suit . . . [and] [t]o grant such protection to those entrusted with the care of our loved ones is simply untenable.” Howard v. Estate of Harper, No. 2005-1A-00115-SCT (Miss. Oct. 26, 2006).

Sixth Circuit Affirms CMPs Imposed On SNF Following Immediate Jeopardy Citation
In an unpublished decision, the Sixth Circuit found substantial evidence to support the imposition of $80,300 in civil monetary penalties (CMPs) on a nursing home found to be out of compliance with Medicare and Medicaid provider requirements. The Centers for Medicare and Medicaid Services (CMS) imposed the CMP against Lakeridge Villa Health Center, a specialized skilled nursing facility, after the Ohio Department of Health (ODH) found the nursing home was not in substantial compliance with several provider requirements, including one immediate jeopardy violation. Both an administrative law judge and the Department of Health and Human Services’ Departmental Appeals Board (DAB) upheld the CMP.
Affirming, the Sixth Circuit accorded a “highly deferential” review of the DAB’s decision and held substantial evidence supported the imposition of the CMP. For the immediate jeopardy citation, the ODH found that Lakeridge attached restraints to immovable objects contrary to manufacturer warnings and also failed to supervise residents who were thus restrained. “[T]he ODH surveyors’ unchallenged observations of residents attempting to get out of bed and becoming suspended are sufficient evidence to support the DAB’s conclusion that Lakeridge’s supervision was inadequate,” the appeals court said. The appeals court also rejected Lakeridge’s contention that the citation was improper because no actual injury occurred. A finding of immediate jeopardy does not require actual harm, the appeals court said. “This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents,” the appeals court explained. *Lakeridge Villa Health Care Ctr.*, No. 05-4194 (6th Cir. Nov. 3, 2006).

**North Carolina Appeals Court Says Nursing Home Must Turn Over Incident Reports**

A nursing home must produce to a wrongful death plaintiff incident reports documenting a resident’s fall that were prepared by its nursing staff, a North Carolina appeals court ruled February 20, 2007. The appeals court found no evidence the incident reports were ever reviewed or considered by the nursing home’s quality assurance committee and therefore held they were not protected from discovery under the state’s peer review statutes. Plaintiff Freddy L. Hayes, the administrator of his mother Ina Hayes’ estate, sued Premier Living and Rehabilitation Center (Premier Living) for wrongful death. According to plaintiff, his mother fractured her hip and eventually died because of Premier Living’s negligence.

During discovery, plaintiff sought production of several incident reports documenting his mother’s falls while a resident at Premier Living. The nursing home refused to produce the reports and sought a protective order, citing the peer review privilege in N.C. Gen. Stat. §§ 90-21.22A and 131E-107. The trial court granted plaintiff’s motion to compel production of the three incident reports at issue, concluding that the reports were not privileged.

The North Carolina Court of Appeals affirmed, finding Premier Living failed to show the reports were part of the nursing home’s Continuous Quality Improvement (CQI) team proceedings. Premier Living’s nursing staff prepared incident reports to document the factual circumstances surrounding “unusual occurrences” like resident falls, the appeals court noted. Although the administrator of Premier Living indicated that incident reports were intended to “improve quality of care,” she acknowledged that the CQI team typically did not review individual incident reports, the appeals court added. The appeals court refused to adopt Premier Living’s interpretation of the peer review statute as protecting any record that could be subject to the CQI’s consideration. “We conclude that the plain language of section 131E-107 protects only those records which were actually a part of the team’s proceedings, produced by the team, or considered by the team,” the

**Minnesota Appeals Court Finds Sons Of Deceased Nursing Home Resident Not Responsible For Resident’s Unpaid Balance**

A state trial court properly rendered summary judgment against a Minnesota nursing home that argued the two adult sons of a former nursing home resident were responsible under state law for the resident’s unpaid balance upon her death, the Minnesota Court of Appeals ruled April 3, 2007. In May 2000, Brett Henderson admitted his mother, Helen Henderson, to a nursing home owned by Extendicare Health Services, Inc. (EHS) and signed a form “admissions agreement” on a line that designated him to be the “responsible party.” Neither Helen Henderson nor her other son, Craig Henderson, signed this agreement. The appeals court noted that Brett Henderson did not sign the line designating him to be a “guarantor” who agreed to be financially responsible for the resident’s care. Helen Henderson died with an unpaid balance due to EHS. Evidence in the record showed that her estate contained assets at her death sufficient to pay the unpaid balance, but EHS let the statutory period for making a claim expire.

EHS subsequently sued the two Henderson sons, alleging that each had violated Minn. Stat. § 144.6501, which states that “if the responsible party has signed the admission contract and fails to make timely payment of the facility obligation, or knowingly fails to spend down the resident’s assets appropriately for the purpose of obtaining medical assistance, then the responsible party shall be liable to the facility for the resident’s costs of care which are not paid for by medical assistance.” The state trial court granted summary judgment in favor of Brett and Craig Henderson, concluding that neither son qualified as a “responsible party” under the circumstances.

The appeals court agreed, noting that to be a “responsible party” under § 144.6501, an individual must both “have access to the resident’s income and assets, and either agree to apply the resident’s income and assets to pay for the resident’s care or agree to apply for medical assistance on behalf of the resident.” Although Craig Henderson satisfied the first element of this definition, he did not satisfy the second element, the appeals court concluded. Brett Henderson, on the other hand, satisfied the second element of the “responsible party” definition by signing EHS’ admissions agreement designating him as the party responsible for applying his mother’s assets to pay for her care, he did not satisfy the first element because he never “actually had access to his mother’s income or assets during her life or after her death.” The appeals court rejected EHS’ argument that Brett Henderson’s signature on the admissions agreement and his listing with EHS as the person to whom bills should be sent established a genuine issue of material fact as to whether Brett Henderson had access to his mother’s assets. “Minn. Stat. § 144.6501 requires that a responsible party actually have access to the resident’s income and assets, not that he merely hold himself out as having access.” *Extendicare Health Servs., Inc. v. Henderson*, No. A06-734 (Minn. Ct. App. Apr. 3, 2007) (unpublished).
MANAGED CARE

Michigan Appeals Court Says Insurance Commissioner May Not Disregard Findings Of Independent Review Organization
The Michigan Court of Appeals found that the state Insurance Commissioner was not authorized to substitute her judgment for that of an independent review organization regarding whether an insured’s treatment was an emergency or not. In so holding, the appeals court found the insurance company had to pay for certain treatment received by the insured at an out-of-network facility. Douglas Ross was insured through his employer by Health Maintenance Organization Blue Care Network of Michigan (BCN). It was determined that Ross suffered from multiple myeloma among other things. His condition became very grave and he underwent a bone marrow transplant at a non-network provider. BCN refused to pay for the treatment and following his death, Ross’ estate challenged the denial through the plan’s grievance process. When that was unsuccessful, plaintiff requested an external review with the Commissioner of the Office of Financial and Insurance Services (OFIS), which assigned the case to an independent review organization (IRO). The IRO determined that Ross’ care was an emergency and recommended that BCN’s payment denial be reversed.

However, the OFIS Commissioner questioned the IRO’s opinions and found that Ross’ treatment did not constitute an emergency. The Michigan Court of Appeals reversed the Commissioner’s findings, holding that “[b]y discounting the IRO’s medical recommendations and replacing them with her own independent conclusions, the OFIS Commissioner failed to comply” with the law and exceeded her authority. According to the appeals court, the language of the relevant statute “indicates that the Legislature intended the OFIS Commissioner to defer to the IRO’s recommendation on medical issues that do not implicate the language of the health plan itself.” Ross v. Blue Care Network of Michigan, No. 266240 (Jun. 13, 2006).

Federal Judge In Florida Rules In Favor Of HMOs In Physicians’ Long-Running Dispute Over Systematic Underpayments
Judge Federico Moreno of the U.S. District Court for the Southern District of Florida rejected June 19, 2006 physicians’ claims brought under the Racketeer Influenced and Corrupt Organizations Act (RICO) against United Healthcare, Inc. (United) and Coventry Health Care, Inc. (Coventry) alleging the companies participated in a scheme to defraud doctors through their automated claims processing system.

The long-running case arose as part of a larger action filed by over 700,000 physicians in 2000 against the nation’s major for-profit insurers for their alleged unlawful dealings with the physicians. The multidistrict litigation consolidated actions brought by the physicians alleging among other things that the managed care companies conspired together to underpay the physicians in violation of RICO. Aetna, WellPoint Health Networks, Inc., Humana Inc., CIGNA HealthCare, Health Net Inc., and Prudential Financial, which were other defendants named in the original action, have reached settlements with the physicians. In March, Judge Moreno dismissed the action as to defendant PacifiCare Health Systems, Inc. Judge Moreno likewise here found the
evidence insufficient to allow a jury to conclude that United or Coventry conspired to manipulate their claims processing software to systematically underpay doctors. In re Managed Care Litig., No. 1334 (S.D. Fla. June 19, 2006).

California Appeals Court Finds Provider Agreement Determines Whether Hospital Can Assert Lien Against Patient’s Third-Party Recovery
A court must look to the provider agreement between the hospital and insurer to ascertain whether the hospital reserved its right to assert a lien on an insured’s potential recovery from a third-party tortfeasor, a California appeals court said in an unpublished decision. Rafaela Rios’ son, Jeremy, was badly injured when he was struck by a van driven by Wilda Mae Simmons. Rios’ Blue Cross/Blue Shield (BCBS) policy covered her son’s treatment at Memorial Medical Center in Modesto, California, which is part of the Memorial Hospitals Association (MHA). Pursuant to its “preferred provider” agreement, BCBS paid only $10,196.28 of the hospital’s $63,000 bill. MHA then asserted a lien under California’s Hospital Lien Act (HLA) against Rios’ potential recovery against the tortfeasor for essentially the difference between the negotiated fee the hospital had been paid by BCBS and the hospital’s usual fee for the same care.

Rios sought a court order that MHA’s lien was invalid on the ground the hospital was bound by its agreement with BCBS to accept the negotiated fee as full payment for Jeremy’s care. The trial court ruled in favor of Rios. MHA appealed.

The California Court of Appeal, Fifth Appellate District, relying heavily on a recent decision rendered by the California Supreme Court, Parnell v. Adventist Health System/West, 35 Cal.4th 595 (2005), held the lien’s validity must be determined by examining the terms of the provider agreement between MHA and BCBS. Because the provider agreement was never made a part of the record, the appeals court agreed with MHA’s argument that the case must be remanded to the trial court for further proceedings to determine whether MHA reserved its right to balance billing in its agreement with BCBS. Rios v. Simmons, No. F047867 (Cal. Ct. App. July 5, 2006).

Florida Appeals Court Overturns Dismissal Of Hospital’s Action Seeking Reimbursement For Emergency Services Rendered To HMO Subscriber
A Florida appeals court found a hospital's request for a declaratory judgment regarding the interpretation of a specific provision of Florida’s Health Maintenance Organization Act (HMO Act) was proper. The case arose when an Adventist Health System hospital (Hospital) in Florida rendered emergency services to a subscriber of a Blue Cross and Blue Shield HMO known as Health Options. Health Options argued that, under the HMO Act, it was obligated to pay an amount equal to 120% of what Medicare would reimburse for the same services; the Hospital contended that it was entitled to full reimbursement for the services billed as this constituted the “usual and customary provider charges for similar services in the community” as defined in the statutory provision.

On appeal of the trial court’s dismissal, the Florida District Court of Appeal, Fifth District, said a private right of action could be implied under the statute given that it outlined a “methodology for use in establishing the amount of [civil] liability and the
applicable enforcement remedy.” But even if a statutory cause of action could not be implied, common law theories were available for pursuing a civil remedy through the court. *Adventist Health Sys. v. Blue Cross and Blue Shield*, No. 5D05-1735 (Fla. Dist. Ct. App. July 21, 2006).

**U.S. Court In Maryland Certifies Class Action Against HMO For Collecting Subrogation Claims**
A member of a health maintenance organization (HMO) suing her HMO based on allegations that it violated Maryland’s HMO statute by collecting payment from her as a subrogation claim against her recovery from a third party satisfied all the necessary elements to certify her lawsuit as a class action, a federal district court in that state ruled. Through her employer-sponsored health plan, Cindy J. Miller was a member of Optimum Choice, Inc. (OCI) when she was injured in a car accident for which she received treatment paid for by OCI. Subsequently, she received a settlement from the insurance of the third party who caused the accident and paid a portion of the recovery to OCI in response to a subrogation lien. Miller sought class certification for “[a]ll persons who . . . are or have been members or insureds of [OCI]; . . . have received medical or health care treatment . . . from [OCI]; and . . . [have] paid a subrogation claim to [OCI] in satisfaction of . . . a subrogation interest of [OCI] in any monies that the members or insureds had received or would receive from a third party.”

The U.S. District Court for the District of Maryland found Miller had satisfied the requirements of Fed. R. Civ. P. 23(a)—namely, numerosity (OCI had disclosed that during the relevant time period it had received subrogation payments from 1,509 members); commonality (each putative class member would have to show OCI was subject to Maryland’s HMO statute and that it collected subrogation in violation of the statute); typicality (because her claims stemmed from the same billing practice that gave rise to the claims of the other class members, and her claims were based on the same legal theory); and adequacy-of-representation (concluding that Miller was in a position to protect fairly and adequately the interests of the class). The court also found Miller satisfied both requirements of Rule 23(b)(3)—i.e. questions of law or fact common to the class members predominated over any questions affecting only individual members, and also that a class action was superior to other available methods for the fair and efficient adjudication of the controversy. *Miller v. Optimum Choice, Inc.*, No. DKC 2003-3653 (D. Md. July 28, 2006).

**Pennsylvania Supreme Court Finds HMO Is Exempt From Complying With Anti-Subrogation Provision Of State Automobile Insurance Law**
A health maintenance organization (HMO) operating in Pennsylvania can pursue a subrogation lien against a subscriber who sustained injuries in a car accident and later recovered a settlement from a third party, despite an anti-subrogation provision in a state law pertaining to automobile insurance claims, the Pennsylvania Supreme Court ruled August 22, 2006. Jonathon Wirth received medical care for injuries sustained in a car accident. His medical care was covered under an HMO contract issued by Aetna U.S. Healthcare to Wirth’s father. The HMO contract included a provision stating that the member acknowledged the HMO’s right of subrogation.
After Wirth recovered a settlement from the third party who caused the car accident, Aetna asserted a subrogation lien for its costs. Wirth paid $2,066.90 to release its lien, but then filed a class action in state court alleging unjust enrichment on the part of Aetna. In addition, Wirth alleged that Aetna’s subrogation lien violated a provision of the Pennsylvania Motor Vehicle Financial Responsibility Law (MVFRL), 75 Pa. Cons. Stat. § 1720, which provides that, “[i]n actions arising out of the . . . use of a motor vehicle, there shall be no right of subrogation or reimbursement from a claimant’s tort recovery with respect to workers’ compensation benefits . . . or benefits paid or payable by a program, group contract or other arrangement . . . .”

Answering a certified question of state law, the Pennsylvania Supreme Court concluded the state’s HMO law exempted an HMO operating in the state from complying with MVFRL § 1720. “When the General Assembly wishes to make insurance statutes applicable to HMOs, it does so by using the terms ‘health maintenance organization’ or ‘HMO’ or by referring to the HMO Act,” the high court said. Moreover, when the General Assembly intends to include HMOs within general terms such as “insurer” or “managed care plan,” it also does so “specifically and in exact terms,” the high court added. *Wirth v. Aetna U.S. Healthcare*, No. 28 EAP 2005 (Pa. Aug. 22, 2006).

**Illinois Supreme Court Strikes Down Percentage-Based Fee-Splitting Provision In Healthcare Company’s Participating Provider Agreements**

A provision in an Illinois healthcare company’s participating provider agreements that requires the provider to pay the company a percentage-based fee for administrative services violated the broad prohibition on fee sharing in Illinois’ Medical Practice Act (MP Act) and therefore was unenforceable, that state’s highest court ruled September 21, 2006.

The Illinois Supreme Court therefore affirmed the portion of the appeals court’s judgment finding the percentage-based fee violated the state MP Act. The high court reversed, however, the appeals court’s ruling that the company’s flat-fee arrangement with providers also was prohibited by the MP Act. In addition, the high court affirmed the appeals court’s ruling that the plaintiff-providers were entitled to recover neither percentage-based fees nor fixed flat fees previously paid to the company for administrative services.

HealthLink Inc. (HealthLink) is an Illinois company that creates provider networks by entering into participating provider agreements with physicians and other healthcare providers. HealthLink then makes these provider networks available to members of health plans offered by various health insurers. HealthLink entered into agreements with providers under which the providers agreed to offer medical services to HealthLink’s payor members at a discounted rate and to send their claims for reimbursement to HealthLink. Subsequently, HealthLink would process the claims and send them to the payor for benefit determination and payment. Vine Street Clinic (Vine Street) entered into a participating provider agreement with HealthLink in 1989, and maintained this contract through 2001. During this time period, Vine Street paid HealthLink a 5%
administrative fee, as required by the terms of the provider agreement. The total amount paid to HealthLink to satisfy this requirement was at least $21,720.28.

Following the expiration of Vine Street’s participating provider agreement with HealthLink in 2001, the Illinois Attorney General issued a March 2002 opinion letter finding that the provision imposing a percentage-based administrative fee in HealthLink’s participating provider agreements violated a specific section of Illinois’ MP Act and therefore was void. Subsequently, in May 2002, HealthLink notified its providers that, going forward, it would charge a fixed flat fee instead of a percentage-based fee.

Vine Street filed a putative class action lawsuit in state circuit court against HealthLink seeking a declaration that the “percentage fee” and flat fee provisions of HealthLink’s provider agreements violated the MP Act. Plaintiffs sought injunctive relief and recovery of all administrative fees previously paid to HealthLink.

The Illinois Supreme Court held the percentage-fee based contract with plaintiffs violated the MP Act and was void as against Illinois law, but upheld the flat fixed fee. “Nonphysicians can receive a fee for services rendered, apart from referral, but cannot receive a percentage of the physician’s profit, or its equivalent,” the high court explained. *Vine Street Clinic v. HealthLink Inc.*, No. 99790 (Ill. Sept. 21, 2006).

**Florida Appeals Court Allows Physician To Sue HMOs Over Reimbursement Rates For Emergency Service Providers**

A Florida appeals court ruled October 18, 2006 that an emergency services orthopedist can pursue class actions against four health maintenance organizations (HMOs) on the grounds that they reimburse emergency providers at rates less than what state law requires. Peter F. Merkle, M.D. provides emergency orthopedic services to members of four HMOs as a non-participating provider. Florida Statute § 641.513(5) sets the reimbursement rates for non-participating emergency service providers as the lesser of the provider’s charges, the usual and customary provider charges, or the charges agreed to by the HMO and the provider. Merkle sued the HMOs, arguing that the HMOs violated the statute by paying class members “artificially reduced payment amounts” equal to %120 of the Medicare fee schedule, rather than the usual and customary rates that law requires. The HMOs moved to dismiss, arguing that § 641.513(5) does not create a private right of action. The trial court granted the motion.

On appeal, the Florida District Court of Appeal held that § 641.513(5) does imply a private right of action, citing with approval the decision in *Adventist Health System/Sunbelt, Inc. v. Blue Cross & Blue Shield*, 934 So.2d 602 (Fla. Dist. Ct. App. 2006). Agreeing with the *Adventist* court that previous decisions refusing to imply a private cause of action under the state HMO Act were distinguishable, the appeals court here emphasized that § 641.513(5) was contained within another part of the state code. Further, unlike the HMO Act, which is aimed at protecting the public, § 641.513(5) is aimed at protecting non-participating providers who provide emergency services by ensuring fair compensation. The appeals court considered the legislative history of § 641.513(5) and found that it “clearly imposes a duty on HMOs to reimburse non-
participating providers according to the statute’s dictates, not based on Medicare reimbursement rates.” *Merkle v. Health Options, Inc.*, Nos. 4D05-4552, 4D05-4553, 4D05-4554, 4D05-4555 (Fla. Dist. Ct. App. Oct. 18, 2006).

**Florida Supreme Court Holds Providers May Qualify As Third-Party Beneficiaries Of Subscriber Agreements, Allows Prompt Pay Challenge**

The Supreme Court of Florida ruled a medical provider may sue a health maintenance organization (HMO) as a third-party beneficiary to an HMO-subscriber contract based on allegations that the HMO violated that state’s prompt pay provisions. Westside EKG Associates (Westside) provided emergency and non-emergency medical services to the subscribers of seven HMOs (defendants). Westside sued, claiming it was a third-party beneficiary to defendants’ subscriber contracts, and that defendants breached those contracts by failing to comply with the prompt pay provisions of Florida’s HMO Act, resulting in monetary damages to Westside.

Although the "HMO Act does not expressly authorize a private cause of action to enforce its provisions,” this does not preclude a common law cause of action based on the same allegations, the Florida Supreme Court said. Florida courts have “long-recognized” that statutory insurance requirements may be incorporated into insurance contracts, the high court noted. Likewise, the HMO Act governs HMO contracts, the high court reasoned. Thus, HMO contracts should be treated the same as insurance contracts, permitting the HMO prompt pay provisions “to be considered an implicit part of every HMO contract” unless the contract properly provides otherwise.

Turning to the issue of whether HMO contracts evince a clear intent to benefit nonparticipating providers, the high court pointed out that Florida law recognizes medical services providers as intended beneficiaries of insurance contracts and extended that recognition to HMOs. Citing support not only in the HMO Act, but also in a contract clause in this case, the high court concluded that nonparticipating providers are not precluded as a matter of law from establishing that they qualify as third-party beneficiaries to HMO subscriber contracts. *Foundation Health v. Westside EKG Assocs.*, Nos. SC05-870, SC05-871, SC05-872 (Fla. Oct. 19, 2006).

**U.S. Court In New York Allows Plaintiffs In Action Challenging Claims Processing To Add Antitrust And RICO Claims**

Multiple plaintiffs in protracted litigation challenging certain claims reimbursement processes used by United Healthcare Corporation (United) are entitled to amend their complaint to allege violations of the Racketeer Influenced and Corrupt Organizations (RICO) Act and antitrust laws that are based on injuries occurring after July 15, 2000, the U.S. District Court for the Southern District of New York ruled December 29, 2006. The original complaint was filed years ago, in 2000, by subscribers to certain health plans; out-of-network medical providers asserting claims as assignees of their subscribers’ benefit claims, and the American Medical Association and two state medical associations.
Plaintiffs alleged, among other claims, that defendants, including United, the Health Insurance Association of America, and other related entities, violated their fiduciary duty by relying on a database that defendants manipulated in determining “usual, customary, and reasonable” (UCR) reimbursement amounts. This manipulation generated flawed data that defendants then used to reimburse payments to plaintiffs below the amounts they should have received. Based on this alleged practice of improperly reducing reimbursement amounts, plaintiffs alleged violations of the Employee Retirement Income Security Act (ERISA), as well as breach of contract, bad faith, and deceptive acts in violation of New York law.

In the present case, the district court responded to plaintiffs’ motion to add fifteen new causes of action (ten alleging violations of federal and state antitrust laws on behalf of various plaintiffs, and five alleging violations of federal and state RICO laws on behalf of various plaintiffs). Defendants argued plaintiffs should be denied leave to amend because they unduly delayed, acted in bad faith, and the claims were futile because they were time-barred.

In granting plaintiffs’ motion, the district court determined plaintiffs had not unduly delayed in seeking to file a Fourth Amended Complaint based on their assertion that the proposed amendments were based on new information gleaned during discovery. The court also found no evidence plaintiffs had acted with bad faith in filing its proposed amendments. In rejecting defendants’ “futility” arguments, the court held plaintiffs’ RICO claims were not time-barred for any injuries that occurred after July 15, 2000. American Medical Ass’n v. United Healthcare Corp., No. 00 Civ. 2800 (S.D.N.Y. Dec. 29, 2006).

Third Circuit Upholds Arbitrator’s Class Certification Of Physician’s Payment Dispute Against Insurer

The Third Circuit upheld February 28, 2007 an arbitrator’s class certification award in an action brought by a physician alleging insurer Oxford Health Plans failed to pay medical claims in a timely and correct manner under New Jersey law. New Jersey pediatrician John Ivan Sutter, M.D. sued Oxford Health Plans alleging it failed to make prompt payments, improperly “bundled” procedures, and reduced payments through “downcoding.” Oxford sought and was granted its motion to compel arbitration of Sutter’s claims. In the arbitration with Oxford, Sutter sought class certification to represent all physicians who provided services to any Oxford-covered individual during a specific eight-year period. The arbitrator issued a partial final class determination award, where he defined the class of claimants and certified the class. Oxford appealed the arbitration award in the U.S. District Court for the District of New Jersey. The court denied Oxford’s motion to vacate the arbitration award.

The Third Circuit affirmed. As a threshold issue, the appeals court held the district court did not err in applying a highly deferential standard of review to the arbitration award given that the parties manifested no clear intent for a different standard to apply. The appeals court also concluded that the arbitrator’s award did not exceed his authority or manifest disregard of the law as Oxford contended. The arbitrator examined each of the
required elements set forth in the American Arbitration Association’s Supplementary Rules for Class Arbitrations. The arbitrator also considered the Eleventh Circuit’s decision in *Klay v. Humana, Inc.* 382 F.3d 1241 (2004) (holding class certification of physicians’ claims against various insurers for violations of state prompt pay statutes was improper because they involved extensive individualized issues of fact) and rejected its application to the instant action. Accordingly, the appeals court affirmed the arbitrator’s decision. *Sutter v. Oxford Health Plans, LLC*, No. 05-5223 (3d Cir. Feb. 28, 2007).

**MEDICAID**

*Regulatory and Legislative Developments*

**CMS Issues Rules Exempting Seniors, Disabled From Medicaid Proof-Of-Citizenship Requirement**


In the interim final rule, which was effective July 6, 2006, CMS concluded that seniors and disabled individuals who have Medicare or Supplemental Insurance Income will not be subject to citizenship verification requirement as they have already produced documentation to be eligible for those programs. CMS in June issued guidelines establishing a hierarchy of reliability for citizenship documents ranging from primary documents, such as a U.S. passport and certificates of naturalization or citizenship, to second, third, and fourth-level documentation. CMS accepted comments on the interim final rule until August 11, 2006. The interim final rule followed the filing of two lawsuits challenging the constitutionality of the citizenship verification requirement. One of those lawsuits was dropped after CMS issued the interim final rule.

**CMS OKs Landmark Massachusetts Healthcare Reform Plan**

Massachusetts Governor Mitt Romney announced July 26, 2006 that the Centers for Medicare and Medicaid Services (CMS) approved the state’s Medicaid waiver clearing the way for implementation of its landmark healthcare reform legislation enacted in the spring. The new law is aimed at achieving near-universal health insurance coverage of all state residents in three years and requires all state residents to obtain health insurance if they can afford it by July 1, 2007. According to Romney’s press release, the waiver “preserves $385 million in federal Medicaid funding during each of the next two years,” money that will be made available for premium assistance to help low-income state residents purchase private health insurance. Of the roughly 500,000 uninsured Massachusetts residents, about 100,000 are eligible for Medicaid, another 200,000 are expected to be eligible for premium assistance and health plans with no annual
deductibles, and another 200,000 with incomes over 300% of the federal poverty level will be able to purchase lower-cost policies.

**CMS Issues Interim Final Rule On Medicaid, SCHIP Improper Error Rate Estimation**

The Centers for Medicare and Medicaid Services (CMS) issued an interim final rule August 28, 2006 (71 Fed. Reg. 50150) detailing state requirements for providing the agency with the information needed to measure the improper payment rate for the Medicaid and State Children’s Health Insurance Program (SCHIP) programs. Required by the Improper Payments Information Act of 2002, the interim final rule sets forth the process for states to submit claims and policies to a federal contractor that will conduct fee-for-service and managed care reviews to estimate the Medicaid and SCHIP improper error rate. This is in accordance with a previous interim final rule that CMS issued on October 5, 2005. CMS plans to review a subset of state Medicaid programs each year and the interim final rule identifies the selected states for fiscal years 2006 through 2008. The latest interim final rule adds a new information collection from states to measure improper payments in managed care and a new section on the state requirements for measuring payment errors through eligibility reviews and providing this information to CMS. The interim final rule seeks further comments on state requirements for conducting eligibility reviews and estimating payment error rates caused by eligibility errors. Comments on the interim final rule were due September 27, 2006.

**CMS Proposes Changes In Medicaid Drug Reimbursements**

The Centers for Medicare and Medicaid Services (CMS) has proposed changes to how the government pays for prescription drugs under the Medicaid program. The changes, which implement provisions in the Deficit Reduction Act of 2005 (DRA), will save taxpayers $8.4 billion in state and federal funds over five years, the agency said in a press release. The federal government limits payments to state Medicaid agencies for the aggregate costs of prescription drugs when a generic substitute is available, the release explained. Under the DRA, the Federal Upper Limits (FULs) will be calculated based on 250% of the lowest average manufacturer price (AMP) in a drug class, instead of the current system of basing FULs on published drug prices. The DRA also requires CMS to disclose AMPs, which the agency says is “a major step towards providing greater transparency in the cost of health care.” CMS said it expects such data to be available in late spring. In addition, the proposed rule outlines new steps to allow Medicaid agencies to bill for rebates from drug manufacturers for drugs administered by physicians and ensures that manufacturers include “authorized generic” drugs in the calculation of their rebate amounts.

**CMS Proposes Rule That Would Reduce Medicaid Funding By $3.87 Billion Over Five Years**

The Centers for Medicare and Medicaid Services (CMS) published in the January 18, 2007 Federal Register (72 Fed. Reg. 2236) a controversial proposed rule that would reduce Medicaid funding by an estimated $120 million during the first year and $3.87 billion over five years. The rule establishes a limit on Medicaid payments to public hospitals in an amount “not to exceed cost,” and also includes a new definition for “unit
of government” that essentially defines more narrowly what entities qualify as a public hospital. The provisions of the proposed rule apply to all providers of Medicaid and State Children's Health Insurance Program (SCHIP) services, except that Medicaid managed care organizations and SCHIP providers are not subject to the cost limit provisions.

According to the proposed rule, CMS’ ongoing examination of Medicaid state financing arrangements across the country revealed many instances in which state financing practices did not comply with the Medicaid statute. For example, although “units of government” are permitted under § 1903(w) of the Social Security Act to participate in the financing of the non-federal share of Medicaid funding, in some instances states rely on funding from non-governmental entities for the non-federal share. In addition, CMS said it found several arrangements in which “providers did not retain the full amount of their Medicaid payments but were required to refund or return a portion of the payments received, either directly or indirectly.”

The proposed rule, whose comment period closed March 19, 2007, would effect the following changes:

- Redefine the term “unit of government” to include only state or local government entities that can demonstrate their taxing authority and healthcare providers that are operated by a state, city, county, or tribe;
- Clarify that only entities within the new definition are permitted to participate in financing the non-federal share of Medicaid payments;
- Establish minimum standards for documenting cost in support of a certified public expenditure (CPE), including a requirement that a CPE be supported by auditable documentation such as a form that would be issued by the Department of Health and Human Services (DHHS);
- Limit providers operated by “units of government” to reimbursement that does not exceed the cost of providing covered services to eligible Medicaid recipients;
- Eliminate statutory provisions allowing for payment flexibility to pay public providers in excess of cost;
- Authorize the Secretary of DHHS to determine a reasonable method for identifying allowable Medicaid costs that incorporates Medicare cost principles, e.g., for hospital and nursing facilities, a method such as required submission of a standard, nationally recognized cost report, and for other entities, required submission of cost documentation in a form approved by the Secretary;
- Require providers to receive and retain the full amount of their Medicaid payments for services furnished under an approved state plan (or the approved provisions of a waiver or demonstration, if applicable);
- Amend SCHIP regulations to conform to the provisions of the proposed rule.

**Bush Vetoes War Funding Bill That Contains Moratorium On Proposed Medicaid Rule**

President Bush vetoed May 1, 2007 an Iraq war spending bill that included a moratorium on the controversial Medicaid rule on intergovernmental transfers. The House passed the measure April 25, 2007 by a vote of 218-208; the Senate followed suit a day later in a 51-46 vote. The House was unable to muster enough votes to override the veto. On April 23,
2007, a group of hospital associations, including the American Hospital Association (AHA), sent a letter to Senate and House leaders asking them to retain the moratorium. According to the letter, the proposed rule “explicitly targets public and other safety-net hospitals by imposing sweeping funding cuts that will force these hospitals to eliminate vital services for patients, thus jeopardizing care for millions of needy Americans.” The bill also included a provision appropriating funds for states with shortfalls under the State’s Children’s Health Insurance Program (SCHIP). By a vote of 221-205, the House May 10, 2007 approved another supplemental Iraq spending bill, including the same emergency SCHIP funding and one-year moratorium on the Medicaid rule.

**CMS Will Modify Medicaid Rule Requiring Documentation For Newborns Born To Non-Citizen Mothers**

The Centers for Medicare and Medicaid (CMS) will modify its Medicaid eligibility documentation rule to allow automatic eligibility for one year to newborns born to non-citizen mothers receiving emergency “labor & delivery” services covered by Medicaid, the agency said March 20, 2007. The Medicaid statute currently provides that a child born to a mother receiving Medicaid will automatically be eligible for Medicaid for one full year, as long as certain conditions are met. Newborn eligibility for Medicaid typically is “deemed” as long as the mother remains Medicaid eligible, and the infant lives with the mother. “Under this ‘deemed’ status . . . the newborn’s eligibility is continued under the mother’s status for the first year,” after which the infant’s own eligibility must be established, CMS said.

In addition, the Medicaid statute provides that “[c]ertain non-citizens, who ordinarily cannot be eligible for Medicaid, can be eligible for emergency Medicaid services, including labor and delivery services.” However, in its July 2006 interim final rule, CMS stated that in these circumstances the “deeming” process would not extend to newborns born to mothers receiving such emergency Medicaid services. This aspect of CMS’ Medicaid eligibility documentation rule, which implements requirements set forth in the Deficit Reductions Act of 2005, was widely criticized by federal and state lawmakers. CMS said under the new rule, any newborn whose mother files an application and is determined eligible for emergency Medicaid for the delivery could be deemed eligible for his or her first year of life. “Documentation of eligibility would be required at redetermination in the same manner as for all deemed newborns,” CMS said.

**CMS Proposes Rule Reducing Provider Tax Rate To 5.5%**

The Centers for Medicare and Medicaid Services (CMS) published in the March 23, 2007 Federal Register (72 Fed. Reg. 13726) a proposed rule that would reduce the allowable amount that can be collected from a healthcare-related tax from 6% to 5.5% of net patient revenues received by the tax papers. The proposed rule would revise the threshold under the indirect guarantee hold harmless arrangement test pursuant to the Tax Relief and Health Care Act of 2006. The proposed rule also would clarify the standard for determining the existence of a hold harmless arrangement under the positive correlation test, Medicaid payment test, and the guarantee test.
The proposed rule provides that, under the positive correlation test, “a state or other unit of government will violate this test if they impose a healthcare-related tax and also provide for a direct or indirect non-Medicaid payment and the payment amount is positively correlated to the tax amount or to the difference between the Medicaid payment and tax amount.” Under the rule, CMS will “interpret the phrase ‘direct and indirect non-Medicaid payment’ broadly.” Under the Medicaid payment test, a hold harmless arrangement exists if all or any portion of the Medicaid payment varies based only on the amount of the total tax payment, the rule said. The proposal would revise the rule to use the standardized terminology “tax amount.” Lastly, under the guarantee test, a hold harmless arrangement exists if there is a direct or indirect guarantee that holds taxpayers harmless for any portion of their tax cost. The proposed rule would clarify this test to specify that a state can provide a direct or indirect guarantee through a direct or indirect payment.

CMS Issues Final Guidance On Employee Education About False Claims Recovery

The Centers for Medicare and Medicaid Services (CMS) issued March 22, 2007 final guidance to state Medicaid agencies on complying with § 6032 of the Deficit Reduction Act (DRA) of 2005, regarding “Employee Education About False Claims Recovery.” CMS issued initial guidance on § 6032’s requirements December 13, 2006, followed by a national teleconference for providers on January 11, 2007. Section 6032 requires entities making or receiving at least $5 million in Medicaid payments annually to establish written policies and procedures for employees, contractors, and agents detailing their fraud prevention efforts and informing them about federal and state false claims and whistleblower laws. The provision makes compliance a “condition of payment.”

The final guidance attached to a letter sent to state Medicaid directors is styled as seventy-one frequently asked questions (FAQs) discussing several key areas, including definitions of an entity, the $5 million threshold, and contractors and agents; policies and procedures; implementation (compliance deadlines); enforcement; and penalties. The letter also includes a Department of Justice “official description” of the federal False Claims Act, as requested by the states. The final guidance notes that entities must comply with § 6032 as of January 1, 2007, and that states have until March 31, 2007 to amend their Medicaid plans, unless the state has approval for delayed implementation.

Case Law Developments

Massachusetts Appeals Court Finds Medicaid Regulations Not So Vague As To Violate Due Process

A Massachusetts appeals court found June 8, 2006 that Medicaid regulations promulgated by the state Division of Medical Assistance (Division) did not violate due process and gave adequate guidance to hospitals for making medical necessity determinations. Plaintiff Massachusetts General Hospital (MGH) was denied reimbursement for inpatient services provided to three Medicaid patients. A Division hearing officer determined that the services were not "medically necessary" under the applicable regulations because they should have been provided in an outpatient, rather than an inpatient, setting.
The Massachusetts Appeals Court held that the Division’s regulations did not violate MGH’s due process rights because of vagueness and rejected the trial court’s conclusion that they were inconsistent with the federal legislative mandated. The appeals court found that the regulations defined the term “medically necessary” and provided hospitals with several sources of guidance in interpreting its definition. *Massachusetts Gen. Hosp. v. Commissioner*, No. 05-P-642 (Mass. App. Ct. June 8, 2006).

**Eighth Circuit Finds Plaintiffs Have Likelihood Of Success On Claim That Supremacy Clause Preempts State Medicaid Regulation**

A federal district court in Missouri improperly denied a preliminary injunction sought by plaintiff-Medicaid recipients to prohibit the state's Director of Social Services from enforcing a regulation that excludes many categorically needy Medicaid recipients from receiving certain durable medical equipment (DME) benefits, the Eighth Circuit ruled. Plaintiffs are several disabled Medicaid recipients who, along with a number of non-profit advocacy groups, filed a lawsuit challenging an emergency state regulation (Regulation) promulgated in September 2005 that eliminates the provision of specified DME, including orthotics, catheters, hospital beds, lifts, and wheelchair batteries and repair items, to most categorically needy Medicaid recipients. The Regulation allows Medicaid coverage of these DME items for blind or pregnant recipients, needy children, and those receiving home healthcare, but excludes coverage for the categorically needy who are aged or adult disabled.

The Eighth Circuit concluded that the Regulation violated the federal comparability requirement specifying that states provide an equal “amount, duration, and scope” of medical assistance to all categorically needy recipients. Thus, because Missouri accepted federal assistance in providing additional DME benefits to certain Medicaid recipients, the U.S. Constitution's Supremacy Clause preempted the Regulation as in conflict with federal requirements. According to the appeals court, Missouri's Medicaid plan and the Regulation did not provide a sufficient amount of DME services to meet Medicaid's basic objectives or a meaningful procedure for requesting non-covered DME items. *Lankford v. Sherman*, No. 05-3587 (8th Cir. June 22, 2006).

**Sixth Circuit Upholds Dismissal Of Most § 1983 Claims Against Michigan Officials For Failing To Provide Services Mandated By Medicaid Act**

A federal district court in Michigan correctly dismissed most of the claims brought against state officials under 42 U.S.C. § 1983 for allegedly failing to enforce specific provisions of the Medicaid Act that required the state to provide early and periodic screening diagnosis and treatment (EPSDT) services, the Sixth Circuit held July 17, 2006. However, because the district court erred in dismissing one of the plaintiffs’ alleged claims—that state officials failed to effectively inform plaintiffs of the availability of EPSDT services as required under the Medicaid Act—the case must be remanded for further proceedings, the appeals court concluded. In 1999, Westside Mother’s Welfare Rights Organization, based in Detroit, Michigan, as well as other advocacy and professional organizations and five named individuals sued various Michigan health department officials alleging that the state failed to provide EPSDT services mandated by the Medicaid Act under 42 U.S.C. § 1396(a)(4)(B).
The district court concluded that specific provisions of the Medicaid Act, 42 U.S.C. §§ 1396(a)(8) & (a)(10), require the state to pay some or all of the costs of certain medical services available to eligible individuals, but do not require the state to provide the services directly, the Sixth Circuit explained. While agreeing with that interpretation, the appeals court acknowledged plaintiffs’ argument that the opportunity for eligible individuals to receive covered medical services was essentially foreclosed because payments were insufficient to enlist an adequate number of providers and therefore modified the district court’s order to reflect a dismissal without prejudice so plaintiffs could file a motion to amend the complaint.

The appeals court then considered whether the lower court erred in dismissing plaintiffs’ claim that the defendant-state officials developed a Medicaid program that did not provide access to eligible children to the care and services available under the plan in violation of 42 U.S.C. §§ 1396a(a)(30). “Because the text of § 1396a(a)(30) does not focus on individual entitlements, nor is the ‘broad and nonspecific’ language of this provision amendable to judicial remedy, we are not persuaded that Congress has, with a clear voice, intended to create an individual right that either Medicaid recipients or providers would be able to enforce under § 1983,” the appeals court reasoned. The appeals court therefore affirmed the lower court’s dismissal of the plaintiffs’ § 1396a(a)(30) claim. Finally, the Sixth Circuit concluded that the plaintiffs stated a cognizable claim under § 1983 for violation of 42 U.S.C. §§ 1396a(a)(43)(A), which obligates states to provide for written and oral methods designed to effectively inform all eligible individuals about the EPSDT program. *Westside Mothers v. Olszewski*, No.05-1669 (6th Cir. July 17, 2006).

**New Hampshire Supreme Court Says State's Temporary Reduction Of Medicaid Reimbursement Rate For Pharmacies Exempt From Rulemaking Process**

A letter issued by the Commissioner of the New Hampshire Department of Health and Human Services (HHS) that announced a new and reduced reimbursement rate for pharmacy providers participating in the Medicaid program qualified as a rule but was exempt from formal rulemaking procedures, the New Hampshire Supreme Court found August 22, 2006. In January 2004, the state’s HHS Commissioner John A. Stephen issued a letter declaring that a “temporary rate change” would become effective in January to address an overcharging problem, and would remain in effect for a minimum of six months. The “temporary rate change” would lower Medicaid reimbursement rates from the average wholesale price (AWP) minus 12%, plus a $2.50 dispensing fee, to the AWP minus 16%, with a $1.75 dispensing fee. A group of five pharmacy providers sought a declaratory judgment in state court to the effect that the new reimbursement rate set out in the January 2004 letter was invalid because it was unilaterally promulgated by the HHS Commissioner without adhering to the mandatory rulemaking procedures of the state’s Administrative Procedure Act (APA).

On appeal, the New Hampshire Supreme Court disagreed with the state trial court’s conclusion that the January 2004 letter was not a rule. “Because [the letter] ‘institut[es] a temporary rate change’ applicable to all pharmacy providers seeking reimbursement
pursuant to the state [Medicaid] plan, it is plainly a ‘statement of general applicability adopted by an agency,’” the high court said. Therefore, the letter fell within the state APA’s definition of a “rule.” But the high court found that, because the new rule was aimed at establishing reimbursement rates for participating providers in the state Medicaid program, it was exempt from the rulemaking requirements of the APA. A dissenting opinion argued that the January 2004 letter should not be exempt from rulemaking requirements because it changed the methodology used to calculate that rate. *Maxi Drug North, Inc. v. Commissioner*, No. 2005-765 (N.H. Aug. 22, 2006).

**Federal Judge Dismisses Challenge To New Medicaid Citizenship Verification Requirement On Procedural Grounds**

In a twenty-one page interim ruling issued September 14, 2006, a federal judge held individuals challenging new Medicaid rules requiring them to verify their U.S. citizenship with documents such as passports and birth certificates did not have standing to bring the action. Dismissing the challenge for lack of subject matter jurisdiction, U.S. District Court Judge Ronald A. Guzman of the Northern District of Illinois did not reach the issue of whether the proof-of-citizenship requirement was unconstitutional as alleged in the complaint filed in June 2006 by the Sargent Shriver National Center of Poverty Law as a class action on behalf of Medicaid recipients and applicants.

The Centers for Medicare and Medicaid Services (CMS) issued interim final regulations in July 2006 (71 Fed. Reg. 39214), which implemented the Deficit Reduction Act’s (DRA’s) citizenship verification requirement for Medicaid eligibility. Those regulations exempted seniors and the disabled who received Medicare or Supplemental Security Income from the documentation requirement as they already had to show proof-of-citizenship to qualify for those programs. Judge Guzman found plaintiffs lacked standing because the alleged threat to their benefits was too speculative, noting no evidence that the individuals at issue would be unable to produce proof of citizenship or that the states would be unwilling to help them obtain the necessary documentation or waive the requirement in certain circumstances.

In addition, according to Guzman, plaintiffs sought to enjoin enforcement of the implementing regulations but even if he granted the injunction, the statutory requirement in the DRA would still be in place. Judge Guzman did note that the regulations may be invalid to the extent they apply the citizenship verification requirement to adopted and foster children in contravention of the DRA. “If, as it appears, the regulation contradicts the statute, the Secretary has abused his discretion to promulgate regulations and violated the [Administrative Procedure Act].” Thus, Guzman agreed to certify as a class the over 523,000 foster and adopted children affected by the regulation.

**Tenth Circuit Finds Medicaid Statute Does Not Require States To Provide Certain Services To Developmentally Disabled**

The state of Colorado did not violate the Medicaid statute’s reasonable promptness and comparability requirements or provide an insufficient level of funding to ensure the availability of certain services sought by six developmentally disabled individuals, the Tenth Circuit ruled September 21, 2006. Plaintiffs are developmentally disabled
individuals who are on waiting lists for comprehensive residential services in Colorado. The Colorado Association of Community Centered Board (CACCB), whose members provide a different type of residential setting for the developmentally disabled, intervened in the action on the side of plaintiffs. CACCB also alleged that Colorado’s payment rates for Medicaid services for the developmentally disabled are too low to meet the Medicaid statute’s requirement of sufficient payments.

Affirming the district court’s in the state’s favor, the Tenth Circuit found “medical assistance,” as defined by the Medicaid Act, refers to financial assistance rather than to actual medical services. Agreeing with other appeals courts’ decisions of relevance, the Tenth Circuit said that “the Medicaid statute does not require states to be service-providers of last resort.” The statute requires states to pay for medical services, but not to provide them, the appeals court emphasized. As to CACCB’s argument that Colorado’s payment rate for the services at issue are insufficient to comply with the Medicaid Act, 42 U.S.C § 1396a(a)(30)(A), the appeals court concluded that no private right of action existed under this provision. “We join the First, Sixth, and Ninth Circuits in concluding that [§ 1396a(a)(30)(A)] does not create a federal enforceable right under § 1983,” the court said. Mandy R. v. Owens, No. 05-1148 (10th Cir. Sept. 21, 2006).

Maryland High Court Says Minors Who Are Resident Legal Aliens Entitled To Preliminary Injunction After State Cut Medical Assistance Benefits

Minors in Maryland with lawful permanent resident status had a substantial likelihood of success on their claim that their equal protection rights were violated when the state cut funding for its medical assistance program that provided children under eighteen and pregnant women with coverage, the Maryland high court ruled October 12, 2006. While affirming the preliminary injunction granted to plaintiff minors, who immigrated to the United States after August 4, 2003, the high court held the lower court erred in ordering reinstatement of the medical benefits back to the time funding was cut, saying this amounted to an award of damages before final disposition of the case.

Plaintiffs sued various Maryland officials alleging the state’s failure to provide funding in fiscal year (FY) 2006 for their medical benefits under the Medical Assistance Program discriminated against them in violation of Article 24 of the Maryland Declaration of Rights. Under the Personal Responsibility and Work Opportunity Reconciliation Act (Welfare Reform Act), Congress implemented a five-year residency requirement for qualified aliens who immigrated to this country on or after August 22, 1996 to be eligible for Medicaid. The Welfare Reform Act left to the states' discretion whether to offer Medicaid coverage for this group of immigrant aliens provided only state funds were used. Maryland’s Medical Assistance Program provides such medical benefits for minors and pregnant women who are lawful permanent residents and who immigrated after August 22, 1996 “subject to the limitations in the State budget.” See Maryland Health General Code § 15-103(a)(2)(viii). The state budget for FY 2006 cut funding for the Medical Assistance Program causing plaintiffs to lose their medical coverage. Defendants contended the cut was aimed at achieving $7 million in savings.
The Maryland Court of Appeals found defendants’ reason for cutting the funding—i.e. cost savings—was insufficient under a strict scrutiny review to justify discriminating in the provision of medical assistance based on alienage classification or sub-classification. But the high court went on to conclude that the lower court erred in providing retroactive reinstatement of plaintiffs’ medical benefits back to July 1, 2005, when the funding cut was made, because the order did not preserve the status quo, but instead amounted to an award of past damages. The high court did, however, affirm the order compelling the state to provide plaintiffs with medical benefits prospectively from October 26, 2005—the date the complaint was filed. *Ehlrich v. Perez*, No. 137 (Md. Oct. 12, 2006).

**Indiana Appeals Court Rejects Private Causes Of Action Challenging Medicaid Transportation Rates**

Medicaid beneficiaries and providers in Indiana could not sue to challenge the rate of reimbursement for transporting beneficiaries to and from healthcare services because federal law does not provide a private cause of action, the Indiana Court of Appeals ruled November 8, 2006. In response to rising costs, and on the recommendation of federal officials, the Indiana Medicaid agency announced lower rates for transportation providers beginning in 1993. Because of the reduced rates, transportation providers experiencing operating losses reduced and/or eliminated services, leaving the disabled population in at least fifteen counties with little or no Medicaid transportation.

A group of Medicaid transportation providers, together with a group of Medicaid beneficiaries, sued state officials on the grounds that the inadequate reimbursement rates violated 42 U.S.C. § 1983 by depriving them of equal access to rights and/or privileges under color of state law. In support of their argument, plaintiffs pointed to 42 U.S.C. § 1936(30)(A), which requires state Medicaid plans to “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available . . . .”

The appeals court analyzed whether § 30(A) creates a private right of action under § 1983. Noting that the U.S. Supreme Court narrowed the potential for private rights of action under § 1983 in *Gonzaga University v. Doe*, 536 U.S. 273 (2002), the appeals court explained that the question is no longer whether a plaintiff is an intended beneficiary of the statute, but whether Congress intended to create a private right of action. Looking at the statutory language in § 30(A) for an unambiguously conferred right, the state appellate court instead found an aggregate focus that does not evince congressional intent to confer an individual right, broad and nonspecific language ill-suited to judicial remedy, and general language on methods and procedures rather than particular services. Finding fault with an Eighth Circuit decision to the contrary, the appeals court chose to follow the First, Sixth, Ninth, and Tenth Circuits and ruled that providers do not have enforceable rights in the Medicaid program under § 30(A). *Roob v. Fisher*, No. 49A02-0602-CV-103 (Ind. Ct. App. Nov. 8, 2006).
Alaska Supreme Court Finds Private Action Available To Enforce Medicaid “Balance Billing” Prohibition

A private individual can sue a hospital to enforce Medicaid billing standards as a third-party beneficiary of the provider agreement between the hospital and the state, the Alaska Supreme Court held November 17, 2006. John L. Smallwood, a Medicaid recipient, receives ongoing medical care from Central Peninsula Hospital, which is under a “provider agreement” with the state of Alaska. The hospital sent Smallwood an unitemized bill of $743.46, which he refused to pay. With a small claims action pending against him, Smallwood sued the hospital, alleging it was “balance billing” him in violation of federal and state law. The small claims action was later dropped and the hospital readjusted the balance due to $483.63.

While the Alaska Supreme Court found no express private right of action to enforce Medicaid’s “balance billing” prohibition, it held Smallwood could proceed as a third-party beneficiary of the hospital’s provider agreement with the state. The high court rejected the hospital’s contention that Smallwood’s rights as a third-party beneficiary were foreclosed because he had an alternative administrative remedy through the state’s “fair hearing process.” On this point, the high court observed that a claim of balance billing may not even fit within the hearing process. The high court also found questionable the hospital’s argument that other potential sources of enforcement existed given the lack of evidence that the state would initiate an inquiry into balance billing.


Seventh Circuit Upholds Dismissal Of Hospital’s Action Challenging State Medicaid Plan Amendment

A federal district court in Illinois properly concluded that the mootness doctrine barred a hospital’s action against the Director of the state’s Medicaid agency and the Centers for Medicare and Medicaid Services (CMS) for initiating and approving an allegedly unlawful Medicaid state plan amendment, the Seventh Circuit ruled on December 6, 2006. The appeals court affirmed the lower court’s holding that the hospital’s challenge of the state plan amendment was moot because, by the time that court was prepared to render its ruling in the case, all funds to be distributed under the amendment had already be disbursed and the amendment was no longer in effect.

In February 2004, the Illinois legislature enacted a new law amending the state Medicaid program by imposing a tax on healthcare providers. In addition, the legislation provided adjustments that increased payments from the state to certain hospitals; the payments were to be above the basic rate for inpatient hospital services, including a “Medicaid inpatient utilization rate adjustment.” These payments were to be funded through the new tax imposed by the legislation. The Illinois Department of Public Aid (IDPA) subsequently submitted to CMS for approval a state Medicaid plan amendment that would permit the state to receive federal matching funds for the increased payments to certain hospitals that would be provided for under the new state law. CMS approved the plan amendment in December 2004, which was to cover retroactively the period from May 9, 2004 until June 30, 2005.
In early January 2005, the plaintiff-hospital, Protestant Memorial Medical Center (Protestant Memorial), challenged the state plan amendment in the U.S. District Court for the Southern District of Illinois, alleging that the amendment violated various Medicaid regulatory and statutory provisions. By April 15, 2005, IDPA had already disbursed all of the increased payments to certain hospitals called for under the plan amendment. Two-and-a-half months later, on June 30, 2005, the plan amendment expired by its own terms.

The Seventh Circuit rejected Protestant Memorial’s argument that its claims fell within an exception to the mootness doctrine for cases that are “capable of repetition, yet evading review.” The appeals court first concluded that, even though Protestant Memorial had a period of only six months (from late December 2004 through June 2005) in which to seek review before the amendment expired, the hospital’s claims were not, “by [their] nature, necessarily . . . incapable of review.” If Protestant Memorial had requested a preliminary injunction, instead of declaratory relief that the state plan amendment was invalid, seeking to stop implementation of the state plan amendment, “judicial review well might have been possible before all of the funds were distributed,” the appeals court explained. The appeals court said it has “declined to determine that a controversy falls under the ‘capable of repetition, yet evading review’ exception when it is the plaintiff’s procedural missteps that prevent judicial review.” The appeals court then rejected Protestant Memorial’s contention that it was likely to be injured by a new state plan amendment that was pending before CMS. Relying again on its own precedent, the appeals court “declined to apply the ‘capable of repetition, yet evading review’ exception when the plaintiff fails to show that it necessarily will be subjected to ‘precisely the same treatment’ that it received in the earlier controversy.” Protestant Mem’l Med. Ctr. Inc. v. Maram, No. 05-4193 (7th Cir. Dec. 6, 2006).

Missouri Appeals Court Rejects Requirement That “Institutionalized Spouse” Reside In Medicaid-Certified Bed

The Missouri Department of Social Services, Family Support Division (agency) overstepped its authority under state law in requiring a nursing home resident to occupy a Medicaid-certified bed to meet the definition of an “institutionalized spouse,” a Missouri appeals court ruled December 12, 2006. The appeals court said state law required the agency in determining Medicaid eligibility of an institutionalized spouse to mirror federal statutes and regulations, which contain no requirement that the individual reside in a Medicaid-certified bed.

Lillian Gee entered a nursing facility in Kansas City and contacted the agency for a division of assets between the “institutionalized spouse” and the “community spouse.” The agency subsequently deactivated this division of assets after it discovered Gee was not in a Medicaid-certified bed as required to meet the definition of an “institutionalized” spouse under Mo. Code Regs. Tit. 13, § 40-2.03(13)(A(3)(B). Following an administrative appeal, Gee sued in state trial court, which reversed the agency’s decision.

The Missouri Court of Appeals held that the agency unlawfully altered the definition of an “institutionalized spouse” found in federal Medicaid law (42. U.S.C. § 1396r-5) by requiring the individual be in a Medicaid-certified bed. State law specifically requires the
agency to “comply with the provisions of the federal statutes and regulations” when determining the Medicaid eligibility of institutionalized spouses. See Mo. Rev. Stat. § 208.010.6. Federal law contains no requirement that an “institutionalized spouse” reside in a Medicaid-certified bed to be eligible for a division of assets, and the agency did not have the statutory authority to deviate from this definition, the appeals court concluded. The appeals court noted the issue of whether the institution where Gee resided was entitled to Medicaid reimbursement was separate from the question of dividing her assets for purposes of Medicaid eligibility. Gee v. Missouri Dep’t of Social Servs., Family Support Div., No. WD65693 (Mo. Ct. App. Dec. 12, 2006).

**New Hampshire Supreme Court Says State May Not Seek Recoupment From Providers For Paid Dual Eligible Claims**

The New Hampshire Department of Health and Human Services (DHHS) has no legal authority to withhold payments from Medicaid providers as a way to recoup Medicare reimbursements the agency was obligated to collect directly from Medicare, the New Hampshire Supreme Court ruled December 28. Under federal statutes and regulations, state Medicaid agencies may not treat payments to providers as overpayments where a third party is liable for all or part of the claim, the high court said. Instead, the state agency may either reject the claim from the provider initially (“cost avoidance”) or pay the claim and later seek to recover directly from the third party (“pay and recover later”), the high court explained.

The dispute arose when DHHS, the state Medicaid agency, underpaid a group of pharmacies and pharmacy trade associations for medical supplies and durable medical equipment they provided to Medicaid recipients as a way of recovering on prior claims for dual eligibles that were paid in full but for which Medicare was at least partially liable. The pharmacy providers sought a declaratory ruling by the Commissioner of DHHS that the agency’s recoupment procedure violated federal and state law. The Commissioner ruled DHHS had the authority under federal law to undertake the disputed recovery process, citing in support a letter from the Centers for Medicare and Medicaid Services (CMS) that indicated the agency could use the recoupment procedure.

The New Hampshire Supreme Court held the Commissioner “committed an error of law by determining that DHHS made overpayments to the pharmacy providers and was entitled to recover those purported overpayments by means of the regulatory recoupment process.” According to the high court, federal statutes and regulations make clear that the state Medicaid agency has the obligation to seek reimbursement from liable third parties when the providers already have been paid for a particular claim. The high court also noted those statutes and regulations establish that payment of a Medicaid claim for which third-party coverage was available is not considered an “overpayment” for purposes of the recoupment procedure. Finally, the high court said it need not defer to CMS’ letter, on which the state relied, because it was “legally erroneous.” Petition of Maxi Drug, Inc., No. 2005-473 (N.H. Dec. 28, 2006).
Tenth Circuit Reverses Finding That Oklahoma Officials Violated Medicaid Law By Setting Reimbursement Rates Too Low

A federal trial court erroneously concluded Oklahoma officials violated Medicaid’s “reasonable promptness” and “equal access” requirements by allowing system-wide delays in treatment of Medicaid-eligible children and by setting reimbursement rates that were too low to ensure an adequate supply of providers, the Tenth Circuit ruled January 3, 2007. According to the appeals court, the “reasonable promptness” provision at 42 U.S.C. § 1396a(a)(8) requires that a state pay promptly for medical services, not ensure that medical services are actually provided to Medicaid beneficiaries in a reasonably prompt manner. The appeals court also rejected the lower court’s conclusion that defendants ran afoul of the “equal access” provision at 42 U.S.C. § 1396a(30) by setting rates at levels that were insufficient to enlist enough providers to offer healthcare services to children of Medicaid to the extent available to the general population in the same geographic area. Citing its recent decision in Mandy R. v. Owens, 464 F.3d 1139 (10th Cir. 2006), the appeals court said it need not address the issue because § 1396a(30) does not afford Medicaid beneficiaries a private right of action.

The Oklahoma Chapter of the American Academy of Pediatrics, the Community Action Project of Tulsa County, Inc., and thirteen children and their parents brought a class action under 42 U.S.C. § 1983 against officials of the state and of the Oklahoma Health Care Authority alleging their policies and procedures violated the Medicaid Act. According to plaintiffs, defendants failed to provide Medicaid-eligible children in the state with necessary healthcare services, including early and periodic screening, diagnosis, and treatment (EPSDT) services. The district court found defendants violated 42 U.S.C. § 1396a(a)(8) by failing to ensure “medical assistance” was furnished with reasonable promptness to all eligible individuals. The district court recognized the distinction between the state’s obligation to provide financial assistance and the actual provision of medical services, but noted that without adequate reimbursement levels to attract a sufficient number of providers, “reasonably prompt assistance is effectively denied.”

While acknowledging that low rates of reimbursement could reduce the number of available providers and therefore increase wait times for Medicaid beneficiaries, the Tenth Circuit held that such a conclusion “does not mean that defendants failed (or will fail in the future) to be reasonably prompt in paying for services actually rendered by available providers, as required by § 1396a(a)(8).” In the appeals court’s view, the term “medical assistance,” as used in § 1396a(a)(8), refers to “financial assistance rather than to actual medical services.” Plaintiffs’ claims under 42 U.S.C. § 1396a(a)(10)(A) also fail, the appeals court said, because that provision requires a state plan only to pay for certain specified medical services, including EPSDT services, not directly provide them. Oklahoma Chapter of Am. Academy of Pediatrics v. Fogarty, Nos. 05-5100, 05-5107 (10th Cir. Jan. 3, 2007).
Fourth Circuit Affirms DHHS’ Denial Of West Virginia’s Proposed Homestead Exemption To Medicaid Estate Recovery

The Fourth Circuit affirmed January 19, 2007 a final decision by the U.S. Department of Health and Human Services (DHHS) denying, on “overbroadness” grounds, the approval of West Virginia’s proposed “homestead exemption” amendment to its Medicaid state plan that would exempt more than $50,000 of every homestead from estate recovery required under provisions of federal Medicaid law. Federal law requires states participating in Medicaid to attempt recovering costs of care after certain Medicaid recipients’ deaths, see 42 U.S.C. § 1396p(b)(1)(B). This provision generally is directed at individuals who received long term care and related benefits under Medicaid despite owning substantial assets (i.e., property). Under 42 U.S.C. § 1396p(b)(3), states must establish procedures allowing for “undue hardship” waivers of the estate recovery requirement based on criteria established by the Secretary.

In 2001, West Virginia proposed exempting from each homestead an amount equal to the statewide arithmetic mean appraised value of a West Virginia home, calculated annually by the state’s Department of Taxation and Revenue. At the time CMS reviewed this proposed amendment to West Virginia’s Medicaid plan, this exemption amounted to $50,735. After CMS disapproved the proposed amendment as overbroad, West Virginia sought administrative review before a CMS hearing officer, who subsequently affirmed the agency’s initial decision. CMS adopted the hearing officer’s proposed decision as its final decision.

On appeal, the Fourth Circuit rejected West Virginia’s argument that then DHHS Secretary Tommy G. Thompson’s decision to deny approval of the proposed “homestead exemption” amendment was arbitrary, capricious, and an abuse of discretion. “What has been represented as a hardship exemption for ‘homesteads of modest value’ would apply to every homestead, regardless of value, and without any means-testing of the recipients,” the appeals court said. West Virginia v. Thompson, No. 03-1841 (4th Cir. Jan. 19, 2007).

Massachusetts High Court Upholds State’s Transitional Regulations For Setting Medicaid Payment Rates For Nursing Homes

The Massachusetts Supreme Judicial Court upheld February 15, 2007 the validity of regulations established by the state’s Division of Health Care Finance & Policy (Division) to transition from a “prospective rates” to “standard rates” system for calculating Medicaid payment rates for nursing homes. Finding that the regulations were not arbitrary, capricious, or contrary to law, the state high court affirmed a lower court decision upholding the validity of the transitional rate-setting regulations. In addition, the high court found the lower court correctly determined the Division validly applied this transitional payment rate methodology to the nursing home challenging the regulations.

To facilitate the transition, the regulations governing the 1998 and 1999 transition years included a provision known as the total payment adjustment (TPA), “which was designed to answer the concerns of facilities that the new system might lower their payments without providing time to adjust,” the high court explained. During 1998, for example, if the 1998 rate calculated for a facility under the new methodology was lower than its 1997
payment rate, “the 1997 level would be maintained (positive TPA),” the high court elaborated. “To offset the cost of the positive TPA, the TPA provision also capped rate increases (negative TPA) . . . at nine percent [1997-1998], and . . . at six percent [1998-1999].”

Salisbury Nursing and Rehabilitation Center Inc. (Salisbury), a nursing home located in Worcester, Massachusetts, was subject to a negative TPA in both 1998 and 1999. In challenging the transitional regulations before the state’s Division of Administrative Law Appeals (DALA), Salisbury argued that the TPA provision, which effectively limited Salisbury’s payment rates for 1998 and 1999, violated a state law requiring that the base year used in calculating a facility’s actual costs from a calendar year be no more than four years prior to the rate year at issue. Although the Division stated that it had used the base year of 1996 in applying its transitional rate-setting regulations to Salisbury, the TPA provision, in effect, caused Salisbury to be subject to a base year of 1993 for rate determination purposes, Salisbury argued. In addition, Salisbury contended the regulations had resulted in the setting of 1998 and 1999 payment rates that were unfair, and that, in effect, punished it for being an economically efficient facility.

The DALA administrative magistrate affirmed the 1998 and 1999 rate calculations for Salisbury, concluding that the Division had not used an unlawful base year and that Salisbury had failed to show that its rates were unfair, inadequate, or unreasonable. The magistrate also found that DALA lacked jurisdiction over Salisbury’s case, noting that DALA has jurisdiction over challenges to the correctness of the application of regulations to a facility, but not over challenges to the substance of the rate-setting regulation itself.

On appeal, the state high court first rejected Salisbury’s argument that the application of the TPA provision to calculate its 1998 and 1999 payment rates subjected it to an illegal base year in violation of state law. The high court emphasized that the DALA magistrate had found as a matter of fact that the TPA provision was not applied “until after the division had done its base rate calculation using . . . the base year [of 1996]” and that this finding was supported by substantial evidence in the record. The high court next rejected Salisbury’s challenge to the validity of the TPA provision generally, finding “the cap on rate increases imposed by the TPA constitutes a rational method for fulfilling the statute’s instruction that the division ‘shall control rate increases,’” Moreover, the high court concluded Salisbury’s argument that the TPA provision unfairly punished “efficiently operated” facilities was “not sufficient to defeat the regulation.” Finally, the high court affirmed the lower court’s finding that DALA did not have jurisdiction over Salisbury’s appeal. “DALA, as this court has repeatedly held, is constituted to hear challenges to individual rate calculations, not to hear substantive attacks on the underlying regulations,” the high court said. Salisbury Nursing & Rehab. Ctr. Inc. v. Division of Admin. Law Appeals, No. SJC-09646 (Mass. Feb. 15, 2007).

**Missouri Appeals Court Reverses Ruling Finding Hospital Entitled To Additional $1.8 Million From Medicaid**

A Missouri appeals court reversed February 20, 2007 an administrative decision finding a psychiatric hospital was entitled to an additional $1.8 million in direct Medicaid
payments. The appeals court remanded to the state Administrative Hearing Commission (Commission) to determine whether the Missouri Department of Social Services, Division of Medical Services (DMS) abused its discretion in estimating the hospital’s Medicaid days for the year at issue. Little Hills Healthcare, L.L.C. bought Centerpointe Hospital, a psychiatric facility, in April 2003. Prior to its sale, the previous owner significantly curtailed the hospital’s operations, resulting in Centerpointe’s Medicaid services being at a historical low in 2003. After Little Hills acquired Centerpointe, its utilization of Medicaid services increased over 100% from state fiscal year (SFY) 2003.

In addition to a per diem reimbursement, hospitals in Missouri providing Medicaid services receive direct Medicaid payments calculated in part based on estimated Medicaid patient days. These direct payments are designed to mitigate the effect of a tax on Missouri hospitals known as the Federal Reimbursement Allowance (FRA). DMS notifies hospitals of Medicaid direct payments using estimated Medicaid days for that year since the actual number of days would not be known until the end of the SFY. DMS typically does not attempt to revise these estimates. Facing budget shortfalls in SFY 2003, DMS sought to adjust the FRA for that year but also agreed to update the estimated Medicaid patient days based on actual numbers for the first two-thirds of the year. While this update meant a higher number of patient days for most hospitals, it greatly reduced Centerpointe’s (which coincided with its pending sale), resulting in DMS seeking reimbursement of over $2.2 million in overpayments from Centerpointe. For the following year, SFY 2004, DMS projected Centerpointe’s patient days using the revised SFY 2003 numbers, which resulted in an initial estimate of 2,372. Subsequently, DMS did not revise this estimate, as it had done in the previous year. Had DMS done so, Centerpointe’s estimated Medicaid days would have been 4,802.

Ultimately, DMS determined that Centerpointe Hospital was entitled to $1.7 million in direct Medicaid payments for SFY 2004. Centerpointe filed a complaint with the Commission, arguing DMS’ computation of its Medicaid reimbursement for SFY 2004 was arbitrary, capricious, and unreasonable, resulting in a $1.8 million underpayment. The Commission agreed, concluding DMS “failed to promulgate a rule for the estimation of Medicaid days for purposes of determining direct Medicaid payments” and that Centerpointe was entitled to the additional reimbursement.

The Missouri Court of Appeals reversed, concluding the Commission erred in holding DMS was required to promulgate as a rule its internal guidelines for estimating Medicaid patient days. According to the appeals court, applicable regulations require DMS to estimate Medicaid patient days for purposes of the direct payment but leave to the agency’s discretion how to make this calculation. The appeals court agreed with DMS that the guidelines at issue were not a “rule” because they applied to a specific set of facts and had no future effect. Specifically, the appeals court noted that DMS selects the time period for estimating Medicaid patient days based on different data for each year. While the time frames being selected each year apply to all eligible hospitals for that SFY, the time frame affects Medicaid payments for the SFY at issue only and therefore the estimates do not have future effect, the appeals court concluded. Remanding, the appeals court said the Commission must consider “whether DMS’s use of a nine-month time
frame from SFY 2003, which was annualized and prospectively applied to SFY 2004, was an abuse of discretion.” *Department of Social Servs., Div. of Med. Servs. v. Little Hills Healthcare*, L.L.C., No. WD 66879 (Mo. Ct. App. Feb. 20, 2007).

**U.S. Court In Missouri Enjoins Enforcement Of State Medicaid DME Regulation**

The U.S. District Court for the Western District of Missouri March 2, 2007 enjoined Missouri’s Director of Social Services from enforcing a regulation that excludes many categorically needy Medicaid recipients from receiving certain durable medical equipment (DME) benefits. Plaintiffs are several disabled Medicaid recipients who, along with a number of nonprofit advocacy groups, challenged an emergency Missouri regulation (Regulation) promulgated in September 2005 that eliminated the provision of specified DME to most categorically needy Medicaid recipients. Missouri elected to cover DME as an optional Medicaid service, but excluded coverage for a number of items such as orthotics, catheters, hospital beds, lifts, and wheelchair batteries.

The district court initially denied plaintiffs’ request for a preliminary injunction. But on appeal, the Eighth Circuit reversed, concluding plaintiffs had a substantial likelihood of success on their claim that the Supremacy Clause preempted the Regulation because it conflicted with federal reasonable-standards requirements. Although acknowledging that a state has discretion to determine the optional services in its Medicaid plan, the appeals court said that “a state's failure to provide Medicaid coverage for non-experimental, medical necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid.” In addition, the appeals court found Missouri's Medicaid plan and the Regulation were inconsistent with the reasonable-standards requirement because they did not provide a meaningful procedure for requesting non-covered DME items. The appeals court remanded to the district court to determine whether the other factors for granting a preliminary injunction were satisfied. On remand plaintiffs moved for summary judgment on their permanent injunction claim.

Granting the motion, the U.S. District Court for the Western District of Missouri, deferring to the Eighth Circuit’s analysis, found plaintiffs showed actual success on the merits of their claim that the Regulation was preempted by Medicaid’s reasonable-standards requirement. The court rejected the state’s contention that a change in circumstances—namely, amending the Regulation to provide wheelchair accessories—rendered the Eighth Circuit’s analysis inapplicable. Wheelchair accessories was only one of numerous exclusions the appeals court considered; the “failure to cure the other exclusions renders the single change insubstantial,” the court said. The court also concluded plaintiffs showed irreparable harm resulting from the improper denial, noting that the exceptions process did not appear to provide a reasonable avenue to obtain non-covered items. The court further held that the balance of harms weighed in favor of granting plaintiffs the injunction. Plaintiffs “have incurred serious harm” from the denial of DME, while the comparative harm to the state is “small,” the court said. Finally, the court found the public interest was best served by enjoining the state from enforcing a preempted statute. *Lankford v. Sherman*, No. 05-4285-CV-C-DW (W.D. Mo. Mar. 2, 2007).

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California Appeals Court Orders State Reviews Of Medi-Cal Reimbursement Rates For Home Healthcare Services

The California Court of Appeal, Third District, ruled March 15, 2007 that the state Department of Health Services (DHS) must conduct reviews of Medi-Cal reimbursement rates paid to home healthcare providers between 2001 and 2005 as required under the state’s Medicaid plan. The appeals court also added that DHS was under no obligation at this point to adjust the rates based on the results of those reviews.

Plaintiffs, a home healthcare provider association, a home healthcare provider, and a disability rights advocacy group, sued DHS for not performing required annual rate reviews since 2000. Although the provision of the state plan requiring the annual reviews was repealed effective December 31, 2005, the appeals court said the case was not moot as to the years in question. Plaintiffs sought a writ of mandate ordering DHS to review the reimbursement rates for 2000 through 2005, determine whether they complied with federal and state law, and reimburse them for any shortfalls. The trial court ordered DHS to perform an annual review for the current year (2005) but refused to require retrospective rate reviews.

The appeals court held that DHS should be required to perform the rate reviews back to 2000, but that plaintiffs failed to show the agency was obligated to set new rates. The state plan provision at issue required DHS to perform the annual reviews of Medi-Cal home healthcare reimbursement rates to ensure they complied with a federal regulation, 42 U.S.C. § 1396a(a)(30)(A), which requires payments be “consistent with efficiency, economy, and quality of care” and sufficient to enlist enough providers to offer care at least to the same extent available to the general population in the geographic area. DHS argued plaintiffs lacked standing under federal law, but the appeals court said even if they could not bring an action under 42 U.S.C. § 1983 to enforce § 1396a(a)(30)(A), which other federal courts have held does not confer a private right of action, they could still seek mandamus relief under the broader Cal. Code Civ. Proc. § 1085 provided they had a “beneficial interest” over the public at large.

Finding both providers and Medicaid recipients had a special interest in ensuring appropriate Medi-Cal reimbursement rates, the appeals court concluded plaintiffs could compel the state to carry out the annual reviews to determine whether the rate schedule complied with § 1396a(a)(30)(A). But the appeals court also added that “it is not a function of the writ of mandamus in this setting to compel the setting of rates, regardless of plaintiffs’ showing of inadequacy.” Thus, the appeals court ordered the state to perform the annual reviews retroactive to 2000. “It is only when the state has performed that function that a challenge to any determination by the state may be made,” the appeals court said. California Ass’n for Health Servs. at Home v. Department of Health Servs., No. C051294 (Cal. Ct. App. Mar. 15, 2007).

Sixth Circuit Finds State Medicaid Program Not Required To Comply With Certain Pharmacy Benefit Plan Restrictions

The Sixth Circuit held March 13, 2007 that third-party claims by TennCare were not subject to certain “card presentation” and “timely filing” restrictions contained in the
When a plan has a card presentation restriction, Caremark will decline to provide any prescription drug benefits if the participant does not identify himself or herself as a Caremark plan participant at the time of sale. When a Caremark pharmacy plan participant also is eligible for Medicaid, the beneficiary presents only his or her Medicaid card and Caremark sends a claim to TennCare. If TennCare then discovers that the beneficiary also is covered by a Caremark plan after a claim is paid, it submits a third-party reimbursement request to Caremark. However, when reimbursement is sought for a participant enrolled in a Caremark plan that has a card presentation requirement, Caremark will reject the reimbursement request on the ground that a Caremark card was not presented at the point-of-sale. In addition, when TennCare submits a reimbursement request for a participant enrolled in a Caremark plan with a timely filing requirement, Caremark routinely denies TennCare’s request as untimely.

Affirming a lower court decision, the Sixth Circuit noted that, in February 2006, federal legislation (42 U.S.C. § 1396a(a)(25)(I)(iv)) went into effect stating that Medicaid reimbursement claims cannot be denied for violations of the type of card presentation or timely filing restrictions contained in the Caremark-administered plans. The appeals court agreed with the United States' argument, which intervened in the controversy, that the amendments were not new limitations, but simply clarified previously existing law.

The appeals court also concluded the statutory assignment of a Tennessee Medicaid beneficiary’s rights to TennCare occurs at the point-of-sale. The appeals court rejected Caremark’s argument that a Medicaid recipient could only make an assignment to the state after the recipient accepts payment of the cost of the prescription, finding "such an interpretation of the Tennessee statute is inconsistent with federal law." The appeals court opined that Caremark misconstrued the relevant statute and that any "lingering confusion" about its interpretation could be put to rest by looking at the statute's companion regulations, which "unequivocally spell out that assignment of rights to Medicaid is at the point-of-sale when a recipient uses a Medicaid card to get prescription drugs."

The appeals court next turned to Caremark's alternative argument that even if assignment of the right to reimbursement occurs at the point-of-sale, the beneficiary’s obligation to comply with the card presentation and timely filing restrictions still transfers to TennCare. According to the appeals court, because TennCare could never comply with the disputed requirements, “Caremark’s card presentation and timely filing plan restrictions impermissibly discriminate against Medicaid, and thus are invalid as applied.” Finally, the appeals court rejected Caremark’s argument that the Employee Retirement Income Security Act (ERISA) preempted any exemption of third-party reimbursement claims from the card presentation and timely filing plan provisions. According to the appeals court, (1) ERISA requires health benefit plans to reimburse state Medicaid programs; (2) ERISA specifically provides that its preemption provision does not apply to recoupment of Medicaid payments by states; and (3) the Department of Labor, which administers ERISA, concluded in an advisory opinion letter that ERISA
requires health benefit plans to reimburse Medicaid agencies and does not preempt reimbursement to a state. Caremark, Inc. v. Goetz, No. 05-6903 (6th Cir. Mar. 13, 2007).

Washington Supreme Court Says State’s “Shared-Living” Rule Violates Federal Medicaid Comparability Requirement

A Washington State Department of Social and Health Services (DSHS) regulation that reduces disabled Medicaid recipients’ benefits if they live with their paid caregivers is invalid because it violates federal comparability requirements, the Washington Supreme Court held May 3, 2007. Specifically, the high court noted the rule’s across-the-board 15% benefit reduction for all recipients living with their caregivers failed to take into account “the realities of the recipients’ individual situations.”

Three disabled Medicaid recipients, David Jenkins, Vennetta Gasper, and Tommeye Myers, who receive paid in-home personal care services to help them with basic activities of daily living challenged the so-called “shared living” rule, Wash. Admin. Code § 388-106-0130(3)(b). The shared living rule is based on the theory that the state should not pay for tasks like cooking, cleaning, and shopping that the caregiver would have to perform in their own household, the opinion explained. Each of the three disabled Medicaid recipients saw their benefits reduced as a result of the rule.

The lower courts found the rule violated the federal Medicaid comparability requirement, 42 U.S.C. § 1396(a)(10)(B), which requires the medical assistance a state provides for any categorically needy individual “shall not be less in amount, duration, or scope” than the assistance provided to any other categorically needy individual. The high court agreed, declining to defer to DSHS' interpretation of the Medicaid statute’s comparability provision. The comparability provision focuses on parity between individuals, not merely between groups as DSHS argued, the high court established. The high court also found the rule flawed because it operated by presumption rather than as individualized determinations based on each recipient’s need for paid services. “DSHS has promulgated a rule where recipients like Jenkins, Gasper, and Myers will have certain needs unmet while others with comparable disabilities will receive adequate services,” the high court reasoned. “We conclude that no reduction is justified unless an individual determination is made supporting that reclassification,” the high court held.

A dissenting opinion argued the shared living rule should be accorded administrative deference because the factors that may be considered when assessing the relative needs of Medicaid recipients is not clearly addressed in the federal comparability provision. According to the dissent, the majority’s finding that the shared living rule violates the comparability provision because it reduces services without an individualized determination establishes a “sweeping precedent” that could affect the way all public assistance benefits are allocated. Jenkins v. Washington State Dep't of Social and Health Servs., Nos. 78652-6, 78931-2 (Wash. May 3, 2007).
Other Developments

North Carolina To Repay Federal Government $151.5 Million Of Medicaid Reimbursements
The state of North Carolina has agreed to repay the federal government $151.5 million in excess reimbursements made under its Medicaid Disproportionate Share Hospital (DSH) program, according to an August 18, 2006 joint announcement of North Carolina’s three U.S. Attorneys. The U.S. Attorneys said that while a two-year federal investigation uncovered substantial overpayments to the state, there was no evidence of criminal wrongdoing or civil fraud. Under the agreement, the state must repay the full amount over a four-year period. The agreement also identifies fifty-one hospitals who received some of the DSH reimbursements and requires them to pay the state roughly $91 million of the total settlement amount. According to the release, the overpayments to the state and, in turn, the hospitals, were due to a number of related factors including an "overly aggressive" plan to maximize federal healthcare dollars, a number of significant accounting errors, and the failure of state officials to ensure timely cost settlements. The state will make its first payment of $106.5 million by September 30, 2006 and subsequent annual payments of $15 million plus interest over the three remaining years.

CMS Launches Comprehensive Effort To Combat Medicaid Fraud And Abuse
The Centers for Medicare and Medicaid Services (CMS) announced July 18, 2006 new efforts to detect and prevent Medicaid fraud and abuse. The new Medicaid Integrity Program (MIP), created by the Deficit Reduction Act of 2005, will focus on: collaboration and coordination with internal and external partners; consultation with interested parties in the development of the comprehensive Medicaid integrity plan; targeting vulnerabilities to the Medicaid program; balancing MIP roles (between providing training and technical assistance to states while also conducting oversight of their activities and, between supporting criminal investigations of suspect providers while concurrently seeking administrative sanctions); employing lessons learned in developing guidance and directives aimed at fraud prevention; and developing effective return on investment strategies. MIP will use both full-time CMS staff and contractors to review the actions of those seeking payment from Medicaid, conduct audits, identify overpayments, and provide education on program integrity and quality of care.

Medicaid Commission Issues Final Report On Medicaid Reform
The Medicaid Commission said “fundamental reform” is needed to shore up the long term sustainability of the federal-state Medicaid program in a final report issued December 29, 2006 that details its recommendations for achieving that end. Allowing states more flexibility in benefit design, providing federal and state tax incentives to individuals who purchase long term care insurance, and creating a new Medicaid Advantage program are among the recommendations fleshed out in the report, which the Commission’s charter required it to finish by the end of 2006. The Bush Administration established the Commission in 2005 to recommend specific ways to cut spending and “modernize the Medicaid program” through short and long term program changes. As required by its charter, the Commission submitted its first report to the Department of
Health and Human Services Secretary in September 2005 on reducing the rate of federal Medicaid spending by $10 billion over five years.

In its final report, the Commission advocated further increasing state flexibility to tailor benefit packages, including the authority to establish separate eligibility criteria for acute, preventative, and long term care services. In addition, the Commission advised streamlining Medicaid eligibility, which it said consumes too many administrative resources. States should be allowed to consolidate and/or redefine eligibility categories without a waiver, provided such action is cost-neutral to the federal government, the Commission noted. The Commission also called for a study of a new “scaled match” funding formula under which states would receive an enhanced federal match for adding lower-income populations to Medicaid, with the rate scaling back as they expand to groups with higher incomes. With respect to dual eligibles, states should have the option of implementing a Medicaid Advantage program, modeled after the Medicare Advantage program, that integrates both programs’ benefits.

MEDICAL MALPRACTICE

Virginia Supreme Court Finds Medical Malpractice Act Does Not Cover Claims Related To Nursing Home Sexual Assault

The Virginia Supreme Court found the state’s medical malpractice law does not extend to claims related to a sexual assault that took place in a nursing home facility. Such claims involve issues unrelated to medical care as contemplated by the law, the high court said. After suffering a stroke, Delfina Alcoy was admitted to Woodbine Rehabilitation and Healthcare Center, a nursing home facility operated by Valley Nursing Homes, Inc. (Valley). Four days after being admitted, Alcoy was sexually assaulted by an unidentified assailant. Following Alcoy’s death eight months later, plaintiff Bennie G. Alcoy, Jr., who served as administrator of Alcoy’s estate, filed suit against Valley alleging, among other things, negligence, sexual assault, and battery.

Valley claimed Alcoy’s action was governed by the Medical Malpractice Act (Act), Va. Code §§ 8.01-581.1 –581.20:1, and asked the court to limit the evidence in the case to the issue of whether Valley “committed malpractice defined as a breach of the standard of care, which proximately caused damages to Mrs. Alcoy.” Reversing the lower court, the Virginia Supreme Court held plaintiff’s claims were not covered by the Act because they “do not involve the provision of health care or professional services as contemplated by the Act.” Instead, the claims involve administrative and security issues, which are distinct from care-related issues, the high court said. *Alcoy v. Valley Nursing Homes, Inc.*, No. 051701 (Va. June 8, 2006).

Virginia Supreme Court Allows Vicarious Liability Claim Despite Dismissal Of Underlying Claim “With Prejudice”

A medical malpractice plaintiff can proceed with her vicarious liability claim against a physician’s employer even though her negligence claim against the physician was dismissed “with prejudice,” the Virginia Supreme Court ruled June 8, 2006. The high court agreed that in general a dismissal of a claim “with prejudice” constitutes “an
adjudication on the merits,” but noted that the trial court order dismissing the action against the physician with prejudice specifically stated that the patient could continue to pursue her claim against his professional company. Thus, under the circumstances of the case, the dismissal “with prejudice” did not resolve the underlying issue of the physician’s negligence so as to bar the plaintiff’s vicarious liability claim. A dissenting opinion argued that the majority should not have strayed from the consistently followed rule that a dismissal of a claim “with prejudice” amounts to “an adjudication on the merits.” Shutler v. Augusta Health Care for Women, No. 0518512 (Va. June 8, 2006).

**Illinois Supreme Court Holds Detrimental Reliance Unnecessary To Establish Apparent Agency In Medical Malpractice Context**

A medical malpractice plaintiff who was injured by an independent contractor physician during surgery does not need to establish detrimental reliance to support a vicarious liability claim based on apparent agency against a hospital where the procedure was performed, the Illinois Supreme Court ruled June 22, 2006. Dr. James M. York suffered a spinal injury during knee replacement surgery at defendant Rush-Presbyterian-St. Luke Medical Center (Rush). York and his wife sued the anesthesiologists, Dr. El-Ganzouri, and his employer, University Anesthesiologists, S.C., for medical malpractice. York then amended his complaint to add Rush as a defendant on the theory that El-Ganzouri was Rush's apparent agent. A jury found all three defendants liable and awarded York and his wife over $12 million in damages. The appeals court affirmed the verdict.

The Illinois Supreme Court granted appeal only as to York's apparent agency claim against Rush and ultimately affirmed the judgment. Rush did not dispute the "holding out" element of the apparent agency theory—that the hospital failed to inform patients that care was provided by independent contractors—but argued that case law also required the Yorks to show detrimental reliance. According to Rush, a plaintiff who did not know the employment status of a physician but would nonetheless have selected the same hospital should not be allowed to recover under an apparent agency theory.

Resolving a split in the appellate courts, the high court rejected a requirement that medical malpractice plaintiffs show a "but for" causal connection between the holding out by the hospital and the injury suffered by the plaintiff. The high court found the unique nature of the relationship between patients and healthcare providers warranted different treatment of the apparent agency theory in the medical malpractice context. According to the high court, "the reliance element of a plaintiff's apparent agency claim is satisfied if the plaintiff reasonably relies upon a hospital to provide medical care, rather than upon a specific physician." Even where a patient selects a particular physician to perform certain procedures, the patient may nonetheless reasonably rely on the hospital to provide other support services such as radiology, pathology, and anesthesiology, the high court said. A dissenting opinion argued that the majority "dilute[ed]" the reliance element of apparent agency claims against hospitals to the point where "the fact a plaintiff sought care from a specific physician is now virtually inconsequential in determining whether a hospital is vicariously liable for the negligence of an independent contractor physician." York v. Rush-Presbyterian-St. Luke's Med. Ctr., No. 99507 (Ill. June 22, 2006).
Wisconsin Supreme Court Finds No Global Noneconomic Damages Cap For Medical Malpractice Cases Involving Wrongful Death

Overturning a previous ruling, the Wisconsin Supreme Court found no “global” noneconomic damages cap in medical malpractice cases resulting in death. Instead, the three-judge majority opinion held claimants could recover for pre-death and post-death pain and suffering claims up to the maximum allowed under the respective medical malpractice and wrongful death statutory caps. Helen Bartholomew went to a physician complaining of chest pain, arm and shoulder pain, shortness of breath, sweating, and fainting feelings. She subsequently suffered a heart attack that left her brain damaged and she was unable to return home. Bartholomew sued the physician for medical malpractice and after her death, her husband was substituted as plaintiff, asserting claims both individually and on behalf of his wife’s estate.

A jury found the physician negligent and awarded noneconomic damages as follows: $500,000 to the estate for pre-death pain and suffering, $350,000 to Bartholomew’s husband individually for his pre-death loss of his wife’s companionship, and $350,000 for his post-death loss of his wife’s companionship. Defendants, the Wisconsin Patients Compensation Fund, Compcare Health Services Insurance, and the physician argued that the awards should be collectively limited to the maximum allowed under the cap on wrongful death actions, or $350,000. The trial court reduced the $1.2 million total damages award to $422,632, the cap for medical malpractice under state law. Following the Wisconsin Supreme Court’s decision in Maurin v. Hall, 682 N.W.2d 866 (Wis. 2004), which held that when a victim of medical malpractice dies the cap for wrongful death actions limits all noneconomic damages, the trial court subsequently reduced the three jury awards to $350,000, the wrongful death cap.

The majority of the Wisconsin Supreme Court concluded Maurin was wrongly decided and must be overturned and plaintiff and the estate were entitled to the full amount awarded by the jury. According to the majority opinion, Maurin’s conclusion that Wisconsin’s medical malpractice and wrongful death statutes impose a single global wrongful death cap on all noneconomic damages was flawed “because it fails to take into account the well-established distinction in Wisconsin tort law between actions for noneconomic damages for pre-death claims and a ‘wrongful death’ claim . . . for noneconomic damages for post-death loss of society and companionship.” The majority concluded that the legislature had adopted two caps: a medical malpractice cap for noneconomic damages for pre-death claims and a wrongful death cap for noneconomic damages for post-death claims.

Plaintiff argued that, because the medical malpractice cap was declared unconstitutional in Ferdon v. Wisconsin Patients Compensation Fund, 701 N.W.2d 440 (Wis. 2005), no cap applied to the $500,000 in noneconomic damages awarded to the estate for pre-death pain and suffering claims. The high court agreed, noting that while the cap was later reinstated by the legislature effective April 6, 2006, there was no argument for retroactive application of the cap. Bartholomew v. Wisconsin Patients Compensation Fund, No. 2006 WI 91 (Wis. July 7, 2006).
Louisiana Appeals Court Finds Lack Of Notation In Medical Record Created Material Issue Regarding Whether Treatment Recommendation Was Made To Patient

A Louisiana appeals court reversed a trial court’s grant of summary judgment to a physician in a medical malpractice action, finding the lack of notation in the medical record was sufficient circumstantial evidence to create a material fact question as to whether the physician made certain treatment recommendations. Joseph Lee Amos sued Dr. Rebecca L. Crouch and her medical malpractice insurer, Louisiana Medical Mutual Insurance Company (defendants), claiming she breached the standard of care in failing to recommend and conduct the proper diagnostic testing called for by Amos’ symptoms, which delayed an accurate diagnosis and treatment of his colorectal cancer. Defendants argued that Crouch recommended the diagnostic testing but Amos refused.

The Louisiana Court of Appeal, Second Circuit, found a genuine issue of material fact precluded summary judgment regardless of the allegations made in Amos’ affidavit, who was now deceased. Instead, the appeals court found the “absence in Mr. Amos’ medical records of any notations indicating that Dr. Crouch recommended he undergo either a proctoscopy or colonoscopy is circumstantial evidence from which the trier of fact could reasonably conclude that Dr. Crouch never made any such recommendations.” Amos v. Louisiana Med. Mut. Ins. Co., No. 41,302-CA (La. Ct. App. Aug. 4, 2006).

Kansas Appeals Court Finds No Physician-Patient Relationship Between On-Call Physician And Patient

The Kansas Court of Appeals found September 1, 2006 that no physician-patient relationship was established between an on-call physician and a patient in the emergency room when the physician refused to come to the hospital because of fatigue. Thus, the appeals court affirmed the lower court’s decision that the patient’s medical malpractice claim against the on-call physician should be dismissed. Christopher Seeber was injured in a car accident and was airlifted to St. Francis Regional Medical Center (St. Francis). The emergency room physician determined that Seeber needed neurosurgical care and paged the on-call neurosurgeon, Dr. John Ebeling. Ebeling refused to come to the hospital citing fatigue. Seeber was eventually transferred to another hospital where it was determined that he had a C7 fracture with complete paraplegia.

Affirming the trial court’s grant of summary judgment to Ebeling in Seeber’s medical malpractice action, the Kansas Court of Appeals found Ebeling did not have a duty under the Restatement (Second) of Torts § 324A to come to the hospital and treat a patient while he was on call. Instead, the appeals court found only that Ebeling’s status as an on-call physician required that he was available for consultation and did not necessarily require him to come to the hospital to treat a patient. The appeals court also rejected Seeber’s argument that Kansas as a matter of public policy should recognize a duty on the part of an on-call physician to notify appropriate hospital personnel of his or her unavailability for on-call status. The appeals court distinguished a case relied on by Seeber, finding that unlike that case, Ebeling had not signed up to be on-call. Rather he was on call by default as he was one of only three neurosurgeons in Topeka, Kansas. According to the appeals court, “the mere fact that a physician has agreed to be on-call

**Indiana Appeals Court Finds Psychiatric Patient’s Claims Not Subject To Medical Malpractice Statute**

An Indiana appeals court affirmed September 21, 2006 a trial court’s denial of summary judgment to a psychiatric facility where one patient was injured by another, finding plaintiff’s claims were properly pled under premises liability and were not subject to the state’s medical malpractice statute. Plaintiff R.R.K., an inpatient at Madison Center, a psychiatric hospital, was injured during an altercation with another resident. Plaintiff sued the Center based on premises liability alleging that it failed to keep its property in a reasonable and safe condition. The Center moved for summary judgment, arguing that plaintiff’s claims were subject to the Indiana Medical Malpractice Act and that the court did not have subject matter jurisdiction because plaintiff failed to comply with the requirements of the Act. The trial court denied the motion and the Center appealed.

Affirming, the Indiana Court of Appeals noted “the fact that the alleged misconduct occurs in a healthcare facility does not, by itself, make the claim one for malpractice.” In the instant case, plaintiff’s injuries were not caused by any services that the Center provided or failed to provide to him as a patient, the appeals court found, “rather, they were caused by another resident whom the Center failed to medicate, restrain, or confine.” Thus, the appeals court held, “they arise not from the Center's medical treatment of R.R.K., but from his presence on the Center's premises.” *Madison Ctr., Inc. v. R.R.K.*, No. 71A03-0602-CV-52 (Ind. Ct. App. Sept. 21, 2006).

**Florida Appeals Court Allows Medical Malpractice Lawsuit Against Hospital Based On Independent Contractor Physician’s Alleged Negligence**

The parents of a newborn who suffered permanent brain damage after the hospital’s on-call neonatologist allegedly failed to timely order tests and resuscitative measures may pursue its medical malpractice action against the hospital, despite the fact that the neonatologist was an independent contractor, a Florida appeals courts ruled October 6, 2006. After Preston and Ginger Pope’s newborn son was born at Winter Park Hospital (Winter Park), it was discovered that he suffered from fetal-maternal hemorrhage. As a result, their son’s breathing became increasingly labored over the next several hours, and he ultimately required resuscitation. Because testing and resuscitative measures were allegedly not ordered in a timely manner by the on-call neonatologist, Dr. Michael McMahan, the Popes’ son suffered permanent brain damage. The Popes sued Winter Park and McMahan for negligence, alleging the hospital had a nondelegable duty to treat their newborn son with due care.

Reversing a the lower court’s directed verdict in the hospital’s favor, the Florida District Court of Appeals, Fifth District noted that while an express contract (i.e. a signed consent form) existed between the Popes and the hospital, “an issue remains unresolved concerning the scope of the express contractual undertaking which may have given rise to a duty to provide non-negligent neonatal care to the couple’s newborn son.” Despite the
general rule that a principal is not liable for the negligence of an independent contractor, “where the contracting party makes it her or his duty to perform a task, that party cannot escape liability for damage caused to the other contracting party by the negligence of independent contractors hired to carry out the task.” The appeals court found sufficient evidence in the record for this issue to go to the jury. Mrs. Pope’s acknowledgment, via signing the consent form, that the duty to provide “medical or surgical treatments” can be delegated to an independent physician did not constitute an agreement on the part of Mrs. Pope to discharge Winter Park from any contractual duty it assumed, the appeals court reasoned. Pope v. Winter Park Healthcare Group, Ltd., No. 5D04-3284 (Fla. Dist. Ct. App. Oct. 6, 2006).

Virginia High Court Upholds Medical Malpractice Damages Award Of $1.6 Million To Mother Of Severely Impaired Child For Her Injuries Arising From Birth
The Virginia Supreme Court upheld November 3, 2006 a state trial court’s medical malpractice damages award of $1.6 million to a mother of a severely neurologically impaired child for her injuries arising from the child’s. In affirming the trial’s court’s judgment and damages award in the action in which the mother alleged her obstetrician-gynecologist (ob-gyn) was negligent for failing to adequately monitor her labor and delivery, the high court found no error in the lower court’s jury instruction indicating that injury to an unborn child is physical injury to the mother.

Karyn Lester sued her ob-gyn, Dr. Robert L. Castle and his professional corporation, Fairfax OB-GYN Associates, P.C., for medical malpractice, alleging they were liable for injuries to both her and her son. Castle settled the alleged claims in relation to Lester’s son. The litigation continued, however, to determine the amount, if any, to be awarded to Lester for her injuries. At the close of evidence, the trial court gave a jury instruction, over Castle’s objection, stating that “injury to an unborn child in the womb of a mother is to be considered as physical injury to the mother.”

The Virginia Supreme Court held that the trial court did not err in giving the jury instruction that injury to an unborn child is physical injury to the mother, citing as “good law” precedent that “when a fetus sustains injury and is subsequently born alive, the mother and the impaired child each have a claim for damages resulting from the negligently caused, in utero, injury.” The high court also rejected Castle’s argument that Lester’s recovery should be limited to her mental anguish resulting from giving birth to her son, as opposed to her emotional distress arising from living with and caring for her son. “Castles has not advanced any reason why we should allow a mother to recover some, but not all, of the . . . damages that are proximately caused by his negligence,” especially when these damages are for “mental anguish she suffers almost every waking minute of her life,” the high court said. Castle v. Lester, No. 052679 (Va. Nov. 3, 2006).

Missouri Appeals Court Finds Absent On-Call Neurosurgeon Owed Duty To Patient Who Died After Sustaining Head Injury At Hospital
A neurosurgeon owed a duty to a patient who died from a head injury sustained at the hospital to provide reasonable notice to hospital personnel that he would be unavailable for his on-call shift, a Missouri appeals court ruled November 14, 2006. The Missouri
Court of Appeals affirmed a jury verdict against the physician in a wrongful death lawsuit brought on behalf of the patient. Dr. Greg Bailey was the scheduled on-call neurosurgeon at Forest Park Hospital, but arranged for an associate in his practice group to cover for him. The associate did not, however, have privileges at the hospital, and when the patient in question fell and sustained a head injury, he had her transferred to another facility where he did have privileges. The patient died and her children sued Bailey, alleging he was negligent in failing to inform Forest Park that he was unavailable for his on-call shift and failing to adequately delegate his on-call duties. After a trial, the jury returned a verdict in favor of plaintiffs in the amount of $400,800, and assessed 50% of the fault to Bailey.

The appeals court held that a physician-patient relationship was not needed to establish a claim for general negligence, noting that a “physician’s duty to a plaintiff may exist when public policy favors the recognition of a duty or when the harm to the patient is particularly foreseeable.” The appeals court concluded that Bailey, as the on-call physician at the hospital, “owed a duty to reasonably foreseeable emergency patients to provide reasonable notice to Forest Park personnel that he would be unavailable to respond to calls.” *Brown v. Bailey*, No. ED86387 (Mo. Ct. App. Nov. 14, 2006).

**Eleventh Circuit Finds Medical Center And Affiliated Hospital Are One Entity For Contribution Purposes In Relation To Malpractice Judgment**

Two nonprofit corporations—a health system and its affiliated hospital—are one entity for purposes of determining contributions owed in relation to a $2.5 million malpractice liability judgment entered against the system, the hospital, and a physician jointly, the Eleventh Circuit ruled November 27, 2006. The underlying malpractice action was filed by the husband of Tracy Bonner, a patient who died in August 2002 from complications that developed following a surgery performed at the Medical Center, Inc. (Medical Center) by Dr. Ronald Beck. It was undisputed at trial that the Medical Center is considered a wholly owned subsidiary of the larger health system, Columbus Regional Healthcare System Inc. (Columbus Regional). Moreover, prior to trial, both parties stipulated that the nurses and surgical staff who assisted Beck during the surgery on Bonner were employees of both Columbus Regional and the Medical Center.

Following a jury verdict in favor of plaintiff, the trial court entered its $2.5 million judgment against Columbia Regional, the Medical Center, and Beck jointly. Beck’s malpractice carrier then paid $1 million of the judgment, while Columbus Regional (on behalf of itself and the Medical Center) paid the remainder and interest. Subsequently, Columbus Regional brought an action seeking to recover additional funds from Beck based on the argument that it and the Medical Center should be considered one entity for contribution purposes and therefore liable for only half of the judgment. Beck filed a counterclaim arguing that Columbus Regional and the Medical Center are two separate entities and that each was responsible for one-third of the judgment.

The trial court granted summary judgment in favor of Columbus Regional, reasoning that case precedent, namely *St. Paul Fire & Marine Ins. Co. v. MAG Mut. Ins. Co.*, 433 S.E.2d 112 (Ga. Ct. App. 1993), required it to treat the health system and the hospital as
one unit. On appeal, the Eleventh Circuit explained in *St. Paul Fire & Marine Ins. Co.* the court held that when one of the parties subject to a judgment entered against joint tortfeasors is liable solely because of negligence imputed from another defendant, those two parties are treated as one party for contribution purposes. “While it is undisputed that multiple employers of negligent employees can be considered joint tortfeasors, that is not the issue in this case,” the appeals court said, adding that, instead, “the question is whether the same party is being held liable twice for the same set of acts.” The appeals court agreed with the lower court’s conclusion that no separate grounds existed for liability against either the health system or the hospital and, therefore, Columbus Regional and the Medical Center should be considered one entity for contribution purposes. *Columbus Reg’l Healthcare Sys. v. Beck,* No. 06-13444 (11th Cir. Nov. 27, 2006).

**Ohio High Court Finds Healthcare Practitioners Employed By State Immune From Malpractice Liability When Educating Residents Or Students**

Physicians and other healthcare practitioners who are employed by a state university medical school, but who also work in private practice settings, are entitled to personal immunity from medical malpractice liability for a plaintiff’s injury allegedly sustained during a surgery in which the defendant-physicians and other practitioners were educating a resident or student, the Ohio Supreme Court ruled December 13, 2006. The state high court disagreed with a lower court’s decision holding that Ohio Rev. Code §§ 9.86 and 2743.02(F), which protects state employees from personal liability in civil actions against them, were inapplicable to the defendants because they acted outside their state employment by billing the plaintiff through their private-practice plans. Instead, the high court concluded that, while financial considerations may be a factor in determining a health practitioner's status as a state employee qualifying for immunity under the relevant statutes, scope of employment turns on "what the practitioner’s duties are as a state employee and whether the practitioner was engaged in those duties at the time of the injury.”

Plaintiff Keith Theobald was taken to University Hospital in Cincinnati, Ohio after sustaining major injuries in a car accident. Theobald underwent ten hours of neurosurgery in which the surgeons and anesthesiologist (defendants) were assisted by hospital residents. Theobald suffered serious complications and he sued the physicians for negligence. Defendants claimed that, as state employees, they were immune from liability under Ohio Rev. Code § 9.86.

The Ohio Supreme Court first noted no dispute that the defendants were state employees for purposes of Ohio Rev. Code § 9.86. Thus, the only issue before the court was whether defendants were acting within the scope of employment when the cause of action arose. The high court declined to adopt a “bright-line test” based on a healthcare practitioner’s billing practices to determine whether the practitioners’ actions were manifestly outside the scope of employment. Rather, “proof of the content of the practitioner’s duties is crucial,” the high court said, finding that in this case the practitioners’ duties included the education of students and residents. *Theobald v. University of Cincinnati,* No. 2006-Ohio-6208 (Ohio Dec.13, 2006).
Virginia Supreme Court Allows Medical Negligence Claims Alleging Derivative Liability Of Physician Practice To Proceed Despite Dismissal Of Employee Claims

In a medical negligence case where the plaintiff’s claims against the employee of a physician practice have been dismissed on procedural grounds, the plaintiff is not precluded from bringing the claims against the practice on the basis of respondeat superior, the Virginia Supreme Court ruled in a 5-2 majority decision January 12, 2007.

Sidney Hughes brought a lawsuit against “Jane Doe” and the Pratt Medical Center, Ltd. (Pratt), a multi-specialty physician practice in Fredericksburg, Virginia, alleging that she was injured as a result of Doe’s negligence. Hughes asserted that as Doe’s employer Pratt was liable for her negligence under a theory of respondeat superior. After Hughes learned Doe’s identity as Melissa D. Lucas, she attempted to amend her complaint and add Lucas as a defendant. The court found Hughes claims against Lucas time-barred. Pratt then moved for summary judgment, asserting that because its liability was wholly derivative of Lucas’ negligence, the dismissal of Lucas with prejudice precluded further action against Pratt. The trial court agreed and dismissed the case.

Reversing, the high court reasoned that the derivative liability principle as “recited by Pratt” does not apply to claims against an employer when the employee was dismissed with prejudice on a procedural matter, but rather applies only “when a verdict or other finding that the employee was not negligent is the basis for exoneration of the employer in the same case.” Virginia law does not require a plaintiff pursuing a claim against an employer on a theory of respondeat superior to file a negligence action against the employee, the high court noted. “No judgment against the employee individually is necessary for recovery; only a finding that the employee was negligent,” the high court said. The high court explained that in this case the dismissal of claims against Lucas with prejudice was “not a holding on the merits” as to her negligence and therefore neither exonerated Pratt nor otherwise precluded Hughes from pursuing her claims against Pratt on a theory of respondeat superior. Hughes v. Doe, No. 060684 (Va. Jan. 12, 2007).

Louisiana Supreme Court Vacates Rulings Finding Medical Malpractice Cap Unconstitutional

The Louisiana Supreme Court vacated February 2 on procedural grounds a pair of appeals court rulings finding the damages cap in the state’s medical malpractice statute unconstitutional. In both cases, divided panels of the appeals court concluded that the damages cap was unconstitutional because it failed to provide an adequate remedy for injured plaintiffs and therefore violated La.Const. art. 1, § 22. But the high court said that plaintiffs in the cases did not plead La.Const. art. 1, § 22 as a ground for finding the damages cap unconstitutional and therefore the appeals court erred in striking down the cap on that basis.

In one case, plaintiffs, survivors of decedent William Arrington, sued his physicians and the medical center where he died alleging all were liable for his death. Plaintiffs settled with the physician for $100,000 and with the Louisiana Patient’s Compensation Fund for $500,000 pursuant to the Louisiana Medical Malpractice Act (Act). Plaintiffs then moved
for summary judgment asking the court to declare the $500,000 limit on damages in the
Act unconstitutional on a number of grounds including due process and separation of
powers. Plaintiffs did not argue the statute violated La.Const. art. 1, § 22 regarding access
to courts. The trial court denied the motion. The Louisiana Court of Appeal, Third
Circuit, over two dissents, reversed.

In the other case, plaintiffs Mr. and Mrs. Charles Ray Taylor, Jr., individually and on
behalf of their minor son, sued numerous defendants for medical malpractice. A jury
awarded plaintiffs damages in excess of the statutory limit. Although plaintiffs initially
alleged the damages cap was unconstitutional on the ground that it violated La.Const. art. 1,
§ 22, they failed to do so in their motion for summary judgment on which the trial
court ruled in favor of defendants. The appeals court again reversed.

“It is well-established that litigants must raise constitutional challenges in the trial court
rather than in the appellate courts and that the constitutional challenge must be specially
pled and the grounds for the claims particularized,” the high court noted. In the first
case, the high court found plaintiffs did not specially plead a violation of La.Const. art. 1,
§ 22, nor was it made an issue in the trial court. As for the second case, although
plaintiffs pleaded La.Const. art. 1, § 22 as a ground for unconstitutionality, they did not
rely on this basis in their motion for summary judgment and therefore the issue was never
06-C-2923, 06-C-2944, and 06-C-2968 (La. Feb. 2, 2007) and Taylor v. Clement, Nos.
06-C-2518, 06-C-2581, and 06-C-2600 (La. Feb. 2, 2007).

Virginia Supreme Court Reinstates Jury Verdict For Medical Negligence Plaintiff,
Finding Verdict Supported By Evidence
The Virginia Supreme Court reinstated an $850,000 jury verdict for a plaintiff in a
medical negligence action after it had been set aside by a trial court, finding that the
verdict was supported by sufficient evidence. Plaintiff John R. Doherty, who had a
history of quintuple bypass surgery and had a pacemaker, first visited podiatrist Debra J.
Aleck, D.P.M. for a callous on the side of his left great toe. Aleck began a course of
treatment that consisted of periodically shaving the callous until it eventually formed a
hole and started to bleed. Almost a year later, the callous was still not healed so Aleck
performed surgery to remove a bone spur from the foot. A week later, Doherty was
admitted to the emergency room where his toe was amputated due to gangrene.

Doherty sued Aleck and Podiatry, Ltd. (defendants), a limited liability company wholly
owned by Aleck, claiming Aleck was negligent in failing to “refrain from contraindicated
surgery.” A jury returned a verdict in favor of Doherty in the amount of $850,000.
Defendants moved to set aside the verdict on the grounds Doherty’s medical expert, Dr.
Noel P. Patel, had failed to testify to a reasonable degree of medical probability that
Aleck breached the standard of care and that the alleged breach proximately caused
Doherty's injuries. The trial court set aside the verdict and Doherty appealed.

The Virginia Supreme Court first found that defendants’ challenge to Patel’s testimony
was not timely made because they failed to object to the admission of the testimony in the
trial court. Thus, the high court said, “the trial court should not have considered this argument in deciding whether there was sufficient evidence to sustain the jury verdict and we will not consider it” in the instant appeal. Next, the high court turned to whether the surgery was contraindicated as Doherty had claimed. The court noted Patel testified that Doherty was a poor candidate for the surgery to remove the bone spur because of his medical history. According to the high court, “Patel’s testimony as supplemented by the medical records was clearly sufficient to make a jury issue of whether Dr. Aleck was negligent in performing the surgery at all.” The high court also reviewed the somewhat contradictory causation testimony and ultimately concluded that “the evidence was clearly sufficient to make a jury issue of whether the surgery Dr. Aleck performed on Doherty was a proximate cause of the amputation of his toe.” Doherty v. Aleck, No. 060959 (Va. Mar. 2, 2007).

Seventh Circuit Dismisses Physician’s Defamation Claims Against Expert Witness Who Testified Against Her In Malpractice Suit

A neurosurgeon cannot bring a lawsuit alleging defamation and breach of contract against an expert witness who testified for the patient in a medical malpractice suit against the neurosurgeon, the Seventh Circuit ruled February 27, 2007. The appeals court found the expert witness, who also was a neurosurgeon, was shielded from liability for defamation because his testimony was subject to an absolute privilege. In addition, the appeals court rejected the plaintiff-neurosurgeon’s contention that the expert witness had breached a contract by allegedly violating a rule of a professional association to which both neurosurgeons belonged.

Dr. Margaret MacGregor performed an operation on a patient that involved removing a herniated disk located at the top of the spine by making an incision at the front of the patient’s neck. During the operation, the patient’s esophagus was punctured. The patient later sued MacGregor for malpractice. In a deposition, Dr. L. David Rutberg testified as an expert witness for the patient and said that MacGregor had failed to exercise due care and that this failure was responsible for the puncture. Rutberg also testified that, during the operation, MacGregor had placed surgical retractors in the wrong position. Nonetheless, MacGregor ultimately prevailed in the malpractice suit when the state trial court granted summary judgment in her favor.

MacGregor sued Rutberg in a federal district court, complaining that his testimony defamed her and constituted a breach of contract. Rutberg failed to disclose in his deposition that he was offering a medical opinion at variance with the consensus of neurosurgeons, MacGregor alleged. Moreover, Rutberg failed to review the depositions of MacGregor or the patient, and had he done so, according to MacGregor, this would have demonstrated that the retractors had been positioned correctly. MacGregor also contended that Rutberg had breached a contract by violating the rules of the American Association of Neurological Surgeons (AANS) pertaining to expert testimony, which state that the neurosurgical expert witness “shall identify as such personal opinions that vary significantly from generally accepted neurological practice.”
The district court dismissed the suit for failure to state a claim. The Seventh Circuit affirmed. As to the defamation claim, the appeals court noted, “Illinois like other states recognizes an absolute privilege for statements in testimony or pleadings in a judicial proceeding,” and “however reckless or dishonest the testimony,” does not recognize an exception for expert witnesses. To create such an exception “would not only tend to turn one case into two or more cases (depending on the number of expert witnesses), but also drive up expert witnesses’ fees,” the appeals court continued.

Turning to MacGregor’s breach of contract claim, the appeals court observed that Rutberg had been expelled from the AANS for violating its rules pertaining to expert testimony. Rutberg agreed to abide by the AANS’ rules, including the rules governing members’ expert testimony, and to be subject to expulsion for violating these rules, the appeals court acknowledged. However, “it would not follow that [Rutberg] had consented to be sued for breach of contract,” the appeals court reasoned. “[T]here is no indication that in joining the AANS, neurosurgeons think they’re exposing themselves to damages suits by other members, or for that matter by the association, should they ever have the temerity to testify against another member.” *MacGregor v. Rutberg*, No. 06-2829 (7th Cir. Feb. 27, 2007).

**Texas High Court Upholds Jury’s Verdict Finding Psychiatrist Contributorily Negligent For Failing To Fully Report His Symptoms To His Physician**

A jury reasonably concluded that a psychiatrist, who sought treatment from his physician for abdominal pain but allegedly failed to disclose a critical symptom of his condition, was contributorily responsible for injuries he sustained after his condition was misdiagnosed, the Texas Supreme Court ruled April 20, 2007. The Texas high court reasoned that the jury in the medical malpractice action could reasonably hold the psychiatrist to a higher standard of disclosure concerning his symptoms when being questioned about his medical problems and history. The high court therefore overturned a state appeals court’s decision reversing the jury’s verdict, which found the psychiatrist 51% negligent and his physician 49% negligent. The high court also reinstated the trial court’s order for a take-nothing judgment. Under Texas law, Tex. Civ. Prac. & Rem. Code § 33.001, a claimant may not recover damages if his percentage of responsibility is greater than 50%, the high court explained.

Psychiatrist Dr. David Axelrad sought treatment from his physician, Dr. Richard Jackson, when the intermittent abdominal cramps he had been experiencing over a period of months worsened into acute abdominal pain. After asking questions in an effort to obtain an accurate medical history, Jackson ultimately misdiagnosed Axelrad’s problem as fecal impaction. Axelrad’s condition worsened and he ultimately underwent surgery that revealed diverticulitis and a perforated colon. The main issue before the high court was “whether Axelrad’s medical training should be taken into account in evaluating the history he gave [to Jackson],” which potentially caused him to misdiagnosis his condition. The high court concluded that the jury could consider Axelrad’s expertise, given that he designated himself as a testifying expert, and gave several expert opinions to the jury. *Jackson v. Axelrad*, No. 04-0923 (Tex. Apr. 20, 2007).
MEDICAL RECORDS

New Hampshire Supreme Court Says Claim For Pain and Suffering Does Not Necessarily Waive Psychotherapist-Patient Privilege

A patient suing a hospital for medical negligence does not necessarily waive the psychotherapist-patient privilege by seeking damages for pain and suffering and loss of enjoyment of life, the New Jersey Supreme Court ruled. After becoming a quadriplegic, Linda Desclos brought a medical negligence lawsuit against Southern New Hampshire Medical Center (SNHMC), claiming damages including pain and suffering, loss of earning capacity, and loss of enjoyment of life. SNHMC sought all of Desclos’ psychiatric and psychological records created prior to her injury.

The trial court allowed discovery of her pre-injury mental health records on the grounds they were relevant to the issue of damages for pain and suffering and loss of enjoyment of life. While other courts have held that a plaintiff impliedly waives the psychotherapist-patient privilege by putting his or her emotional or mental condition “at issue,” the New Hampshire Supreme Court noted that here Desclos was claiming primarily a physical injury. Remanding the case, the high court said if Desclos’ claims include a clinically diagnosed disorder or require expert testimony regarding her mental suffering, then her privilege would be waived. If the claims involve only generic mental suffering, however, then there is no privilege waiver, the high court said. Desclos v. Southern New Hampshire Med. Ctr., No. 2005-596 (N.H. June 9, 2006).

California Appeals Court Finds Health Plan May Disclose To Its Attorney Medical Records Of Potential Malpractice Complainants

A state trial court correctly dismissed a lawsuit brought by a California nonprofit healthcare advocacy organization seeking to enjoin the Kaiser Foundation Health Plan (Kaiser) from its practice of sharing with its attorneys complete medical records of patients who have filed (or intend to file) a medical malpractice claim against the plan, a California appeals court said July 25, 2006 in an unpublished opinion. The California Consumer Health Care Council (CHC Council) filed the lawsuit against Kaiser on behalf of the general public alleging violations of California’s Unfair Competition Law (UCL). According to the complaint, Kaiser’s practice of transmitting to its attorneys the complete medical records of patients who were in the process of filing a malpractice claim against Kaiser constituted an unlawful business practice because it violated California’s Confidentiality of Medical Information Act (Confidentiality Act) and affected patients’ privacy rights under the state constitution.

The California Court of Appeal first noted an exception to the Confidentiality Act that authorizes the disclosure of “medical information regarding a patient” to persons “responsible for, or defending professional liability that a provider may incur” when those persons are “engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.” The appeals court also declined to imply any intention to exclude potentially “irrelevant” medical information from the scope of the disclosure. “Once a patient signals his intention to bring a malpractice claim
against a health care provider, he or she simply cannot reasonably expect to keep the
details of his or her professional relationship with that health care provider a secret from
the attorney employed as an agent of the health care provider to defend that liability
claim,” the appeals court said. California Consumer Health Care Council v. Kaiser

**Mississippi Supreme Court Finds Health Insurer Did Not Owe Fiduciary Duty To
Maintain Confidentiality Of Insured’s Medical Records**

A state appeals court erred in holding that a health insurer owed a fiduciary duty to an
insured’s wife to maintain the confidentiality of her medical records, the Mississippi
Supreme Court ruled August 10, 2006. The high court therefore concluded that the
appeals court’s basis for remanding the case to the trial court—to have a jury determine
whether the health insurer met its fiduciary duty—was erroneous. The high court also
found that the trial court erred in granting a directed verdict in favor of the health insurer
on the issue of whether it was appropriate to disclose the plaintiff’s medical record under
the circumstances, and whether plaintiff was entitled to any damages against the health
insurer for negligent infliction of emotional distress.

Cheryl Robley and her daughter, Kelly, had dependent health coverage under a Blue
Cross Blue Shield (Blue Cross) group health insurance contract sponsored by her
husband’s employer. Blue Cross, as Robley’s insurer, was therefore privy to Robley’s
medical records, which included a history of severe migraine headaches for which she
was prescribed narcotic medication by her physicians. According to Robley, a case
manager assigned to her plan informed a nurse who was treating her daughter that Robley
was a “drug seeker.” Robley sued Blue Cross in state trial court, seeking damages for
negligent infliction of emotional distress, as well as a breach of confidentiality. In her
complaint, she asserted that Blue Cross owed her a fiduciary duty to maintain the
confidentiality of her medical records.

The Mississippi Supreme Court concluded that the group health insurance policy at issue
created an “arm’s length relationship” that obligated Blue Cross to keep Robley’s
medical records confidential except where, “in the discretion of the company,” medical
record information should be disclosed to the insured’s physicians. At the same time, the
high court ruled that the trial court should not have directed a verdict in favor of Blue
Cross on Robley’s claims for breach of confidentiality and negligent infliction of
emotional distress. Although the policy at issue seemed to give broad authority to Blue
Cross to release a patient’s medical records to the patient’s physicians, this authority was
not unfettered, the high court reasoned. On remand, a jury should decide remaining
factual issues, such as whether the case manager at Blue Cross “unreasonably” disclosed
Robley’s confidential medical information, the high court determined. Robley v. Blue
Cross Blue Shield, No. 2003-CT002209-SCT (Miss. Aug. 10, 2006).

**California Appeals Court Finds Patient May Bring Class Action Against Hospital
That Violated Cost Limits Of State Medical Records Law**

An individual patient may bring a class action against a hospital that allegedly violated a
provision of California law specifying cost limits on the charges that healthcare providers
may impose for the copying and delivery of requested medical records, an appeals court in that state ruled September 22, 2006. In reaching this conclusion, the California Court of Appeal, Fourth Appellate District, held that an individual patient has a private right of action to seek enforcement of the cost limitation set forth in Cal. Evid. Code § 1158. Patience Thornburg submitted a request to El Centro Medical Center (El Centro) for a copy of her medical records. She received a $60 bill for thirty photocopied pages, or $2 a page. Thornburg filed a class action against El Centro, alleging that the hospital “systematically” violated § 1158. El Centro moved for judgment on the pleadings, arguing that the cost limitation provision of § 1158 is not enforceable by way of a private civil action, but rather is enforceable exclusively by California’s Department of Health Services. After the trial court granted the hospital’s motion without leave to amend, Thornburg appealed.

The appeals court reversed, concluding that § 1158, by its terms, “plainly contemplates” private enforcement by patients. “Nothing in its legislative history or in the cases which have interpreted it suggest any narrower enforcement mechanism,” the appeals court said. “Without ability to enforce the statute privately, the cost limitations would, as a practical matter, be of little use to patients, who would have to pay the excessive fees and then wait for administrative action,” the appeals court reasoned. This would result in a “circuitous remedy [that] would seriously undermine the utility of a procedure designed to assist patients in the short period of time before the statute of limitations on any potential medical malpractice claims expired,” the appeals court said. *Thornburg v. El Centro Reg’l Med. Ctr.*, No. D047004 (Cal. Ct. App. Sept. 22, 2006).

**MEDICARE**

*Regulatory Developments*

(1) Proposed Actions

**CMS Proposes Changes To Work, Practice Expenses For Physician Fee Schedule**

The Centers for Medicare and Medicaid Services (CMS) proposed June 21, 2006 changes to the Medicare physician fee schedule intended to boost payments for “evaluation and management” services, which involve the time and effort physicians spend with patients in evaluating their conditions. The proposal, published in the June 29 *Federal Register*, also calls for changes to the methodology used to calculate practice expenses. According to CMS, the proposed rule would make sweeping revisions to the physician work relative value units (RVUs) for over 400 services to more accurately reflect the time needed to perform procedures and evaluate a patient’s condition. CMS estimated that the proposed work RVU changes would increase expenditures under the fee schedule by about $4 billion.

With respect to practice expenses, which include both direct costs like supplies and personnel and indirect costs like office rents, the proposed revisions are aimed at improving transparency and increasing consistency across procedures, CMS said.
The proposal would, among other things, involve adopting a “bottom-up” methodology for calculating direct costs using procedure-level data for staff times, supplies, and equipment that have been previously reviewed by the RUC; modifying the methodology used to calculate indirect practice expenses; and eliminating the so-called nonphysician work pool exception. Work RVUs account for over half, or about $35 billion, of Medicare payments made under the fee schedule while practice expenses represent about 45%, or $30 billion, of overall payments, CMS said. The RVU revisions if adopted would go into effect January 1, 2007, while the practice expense revisions would be phased in over a four-year period.

CMS Announces Payment Updates For Home Health Services
The Centers for Medicare and Medicaid Services (CMS) proposed August 3, 2006 a 3.1% increase in Medicare payment rates to home health agencies (HHAs) for calendar year 2007, which would to about $460 million more in payments to these providers than in 2006 (71 Fed. Reg. 44082). As required under the Deficit Reduction Act of 2005 (DRA), HHAs will be paid less than the full home health market basket update in 2007 unless they submit quality data. CMS is proposing ten Outcome and Assessment Information Set (OASIS) quality measures as the basis for evaluating home healthcare. Those HHAs that fail to submit data on the ten measures would see their market basket percentage increase reduced by 2% to 1.1% for 2007, CMS said. CMS also is proposing certain revisions to the payment methodology for oxygen equipment, oxygen contents, and capped rental durable medical equipment as required under the DRA. CMS asked for comments by September 25, 2006.

CMS Projects 5.1% Reduction In Medicare Physician Payment Rates For 2007
The Centers for Medicare and Medicaid Services (CMS) projected a negative 5.1% update in the Medicare physician fee schedule for 2007 under the Sustainable Growth Rate (SGR) formula, according to a proposed rule released August 8, 2006. Under the proposal, CMS expects payments of roughly $61.5 billion to 875,000 physicians and other healthcare professionals in 2007. CMS has been projecting negative updates in the physician fee schedule of approximately 5% for the near future under the much-criticized SGR formula, which sets spending targets and adjusts physician fees based on the extent to which spending aligns with the specified targets. A large gap between spending and the SGR target can result in fee reductions. “Expenditures for physicians’ services in 2005 increased 10 percent over 2004, even faster than had been previously projected,” CMS said in a press release. Growth of Part B services in 2006 is projected at 10.6%, CMS added. CMS attributed the increase to more frequent and intensive office visits and the rapid growth in the use of imaging techniques, laboratory services, and physician-administered drugs. Comments on the proposed rule, which was published in the August 22, 2006 Federal Register (71 Fed. Reg. 48982), were due October 10, 2006.

CMS Issues Proposed OPPS Rule Containing Significant Revisions To ASC Payment
Hospitals will receive an overall average increase in Medicare payments of 3% in calendar year (CY) 2007 for outpatient services under the proposed hospital outpatient prospective payment system (OPPS) rule issued August 8, 2006 by the Centers for
Medicare and Medicaid Services (CMS). This increase reflects a trend of rapid growth in hospital outpatient expenditures, CMS said, noting that OPPS expenditures in CY 2007 are projected to be about 9.2% higher than estimated CY 2006 expenditures. CMS proposed to tie payment rate increases to the reporting of quality measures beginning in 2007. Under the proposed system, hospitals that report quality measures for purposes of the update in the inpatient prospective payment system (IPPS) would receive a full update on outpatient payments as well, CMS explained. Those hospitals that fail to report quality measures would receive the OPPS update minus 2.0 percentage points, CMS said.

CMS also proposed a major revision of payments for ambulatory surgical centers (ASCs) that would better align payments for surgical procedures provided in ASCs and hospital outpatient departments, the agency said. According to CMS, its proposal would allow payment to an ASC for any surgical procedure that does not pose a significant safety risk, expanding by fourteen procedures the list of surgical procedures for which Medicare pays an ASC facility fee. CMS proposed to adopt relative payment weights established under the OPPS to define the relativity in resource costs among different surgical procedures payable in an ASC. Payments in the ASC setting would be lower than the payment for the corresponding procedure in the hospital outpatient department for the same procedure, CMS said, because of the lower costs associated with performing procedures in the ASC setting. CMS proposed a two-year transition from the current ASC payment rates to the new payment rates. Comments on the proposal, which was published August 23 in the Federal Register (71 Fed. Reg. 49506), were due October 10, 2006.

**CMS Proposes Prohibition On Midyear Benefit Enhancements By MA Plans**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule September 1, 2006 (71 Fed. Reg. 52014) that would prohibit Medicare Advantage (MA) plans from making midyear enhancements to non-drug benefits or reductions in premiums and cost-sharing set forth in their approved bids for a given contract year. The proposed prohibition on midyear benefit enhancements (MYBEs), which was subject to comment until October 31, 2006, would include organizations offering employer/union group health plans, but not programs of all-inclusive care for the elderly (PACE). These programs could continue to offer enhanced benefits per guidance specific to PACE plans, CMS said.

**CMS Proposes Limit On Recoupment Of Provider And Supplier Overpayments Until Second-Level Appeal Complete**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that would prohibit Medicare from recouping provider and supplier overpayments under appeal until a decision is rendered by a Qualified Independent Contractor (QIC). The proposal would implement a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that required certain changes to the recoupment process. Comments on the proposed rule, which appeared in the September 22, 2006 Federal Register (71 Fed. Reg. 55404), were due November 21, 2006. A QIC decision is at the second-level of the Medicare Part A and B appeal decision-making process. The fee-for-service appeal process consists of redetermination by a Medicare contractor; reconsideration by a QIC; a hearing before an administrative
law judge; followed by the Departmental Appeals Board; and finally judicial review. Under the proposed rule, Medicare would cease recoupment when a valid first level appeal is received. If a provider or supplier appeals to the QIC, recoupment would be precluded until the QIC issues a decision. The proposed rule also would change how interest is paid to providers or suppliers whose overpayment is reversed at the ALJ or subsequent levels. “At these higher levels of administrative appeal or judicial review, interest becomes payable by Medicare based on the period we recouped and retained the provider’s or supplier’s funds,” the proposal said. CMS added that it does not interpret the new statutory provision as amending its authority to recover overpayments from providers or suppliers that have been placed on payment suspension.

CMS Releases Expanded List Of Potential Quality Measures For 2007 Medicare Physician Voluntary Reporting Program
The Centers for Medicare and Medicaid Services (CMS) has posted on its website a list of eighty-six quality measures that it expects to be available in 2007 for its Medicare Physician Voluntary Reporting Program (PVRP), according to the agency's October 16, 2006 fact sheet. From the eighty-six measures, CMS plans to select a subset as the 2007 PVRP measures “in order to achieve an appropriate balance in measures to be reported by different specialties,” the agency explained. The list of selected quality measures for 2007 will be available before January 1, 2007 and may be updated throughout the year. The list of eighty-six measures currently covers thirty-two of thirty-nine Medicare physician specialty designations, the fact sheet said. The remaining seven medical specialties do not yet have measures that have been adopted by the Ambulatory Quality Care Alliance (AQA) or endorsed by the National Quality Forum (NQF). CMS plans to continue working on developing measures for these specialties, with the ultimate goal of having AQA-adopted and NQF-endorsed measures for all thirty-nine specialties.

CMS Proposes To Make Part D Claims Data Available To Researchers
The Centers for Medicare and Medicaid Services (CMS) issued proposed regulations in the October 18, 2006 Federal Register (71 Fed. Reg. 61445), which would make available Medicare Part D claims data for research and quality initiatives. Under the proposal, CMS will be able to use the claims data to report on and evaluate the impact of drugs used in the Medicare prescription drug program, including the interaction between prescription drug coverage and the services and utilization under traditional Medicare (Parts A & B) and the Medicare Advantage Program (Part C), the agency said. CMS also would use the data to conduct demonstration projects to evaluate the impact of drug coverage and make recommendations for improving the economy, efficiency, or effectiveness of the Medicare program. Under the proposed rule, the Food and Drug Administration, the National Institutes of Health, the Agency for Healthcare Research and Quality, and academic researchers would have access to the data. The information would be made available only with appropriate privacy protections in place, CMS noted. Comments on the proposal were due December 18, 2006.

CMS Issues Proposed Rule Requiring Sprinklers In All Long Term Care Facilities
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule in the October 27, 2006 Federal Register (71 Fed. Reg. 62957) that would require all long term
care facilities to be equipped with sprinkler systems. Under current rules, all newly constructed facilities and all facilities that undergo major renovations must install automatic sprinkler systems. Existing facilities are not required to install automatic sprinkler systems provided they meet certain construction standards. Also, renovated facilities are only required to install sprinklers in the renovated portion of the facility. The proposed rule also would require long term care facilities to test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with industry standards. Comments on an appropriate phase-in timeframe for the installation of an automatic sprinkler system were due December 26, 2006.

**CMS Proposes Changes To Repayment Plans For Overpayments Due To “Hardship”**

The Centers for Medicare and Medicaid Services (CMS) published in the November 27, 2006 *Federal Register* (71 Fed. Reg. 68520) a proposed rule establishing criteria and procedures for granting extended repayment schedules (ERSs) of Medicare overpayments to providers and suppliers based on “hardship” and “extreme hardship.” CMS’ current policy for granting an ERS focuses mostly on the debtor’s ability to repay the overpayment, which is determined by assessing the debtor’s financial status. The Medicare Modernization Act of 2003 (MMA) added certain statutory criteria for evaluating whether a provider or supplier should be granted a repayment schedule of at least six months and up to five years based on “hardship” or “extreme hardship.”

The MMA deems a provider or supplier to be in “hardship” when the total amount of all outstanding overpayments not included in an existing repayment schedule is 10% or more than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report (in the case of a provider) or the previous calendar year (in the case of a supplier). The statute requires that a provider or supplier meeting the “hardship” test be granted a repayment period of at least six months but not longer than three years.

CMS said that it proposes to interpret “outstanding overpayments” to include both principal and accrued interest and to exclude overpayments already subject to an approved ERS. In addition, CMS in the proposed rule said it believes the new “hardship” test does not supersede its existing extended repayment schedule regulations. Thus, under the proposed rule, requests for ERSs would first be evaluated under the new “hardship” test but the existing regulations used to grant repayment plans would remain in place.

Under the MMA, a provider or supplier found to be in “extreme hardship” is afforded thirty-six months or up to five years for repaying an overpayment. The MMA left to the agency’s discretion how to define “extreme hardship.” CMS said it opted not to propose a specific financial threshold because it could result in discriminating against providers and suppliers who may be similarly situated financially but may attribute more of their total revenue to Medicare income.

CMS also proposed changes to its existing regulations regarding the initial handling of ERS requests—namely, providers or suppliers that meet the “hardship” test could opt for
an automatic six-month repayment plan and avoid having to submit additional financial documentation. As for providers or suppliers who miss a scheduled payment, CMS proposed continuing to define a default of an ERS as missing two consecutive installment payments. Providers and suppliers that elect the automatic six-month repayment schedules, however, would be subject to immediate collection of the entire overpayment if they miss one installment. Comments on the proposal were due January 26, 2007.

**CMS Issues Proposed Rule Updating LTCH, Graduate Medical Education Payments**

The Centers for Medicare and Medicaid Services (CMS) January 25, 2007 issued a proposed rule updating the Long Term Care Hospital (LTCH) Prospective Payment System rate by 0.71% to $38,356.45 for rate year (RY) 2008. Under the rule, Medicare payments to LTCHs will be an estimated $4.4 billion for RY 2008. According to CMS, the “update reflects the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket of 3.2 percent adjusted for the difference between the reported case mix increase due to coding practices and the real case mix increase due to increases in patient severity.” The proposed update is larger than the zero percent update recommended by the Medicare Payment Advisory Commission.

The proposed rule also would set the outlier fixed-loss amount for RY 2008 at $18,477, up from $14,887 in RY 2007, but would make no changes to the Long Term Care Diagnosis Related Groups and relative weights. The rule proposes to extend the so-called “25% rule” to certain situations not currently covered under the existing regulations. Under the current policy, if a LTC hospital-within-a-hospital or a LTCH satellite’s percentage of discharges that were admitted from its co-located host hospital exceed a given percentage (generally 25%) for the cost reporting period, the payment to the LTCH would be adjusted downward, CMS explained. The proposed policy would extend this rule to virtually all LTCHs for which more than 25% (or the applicable percentage in certain special circumstances) of its discharged patients were admitted from an individual hospital, regardless of whether that hospital was located in the general vicinity of the LTCH.

The rule also contains a provision revising Medicare’s payment policies for graduate medical education payments. Currently, if residents are training in a nonhospital setting, a teaching hospital may count those residents in calculating their graduate medical education payments if, in part, the teaching hospital pays “all or substantially all of the costs for the training program in the nonhospital setting,” CMS explained. The proposed rule would define that requirement to mean that the teaching hospital pays at least 90% of the total costs of training residents in the nonhospital setting. The final rule was published February 1 at 72 Fed. Reg. 4776.

**CMS Projects MA Program Rate Increases For CY 2008**

The Centers for Medicare and Medicaid Services (CMS) proposed February 16, 2007 an inflation-related rate increase for the Medicare Advantage (MA) program of 4.1% in calendar year (CY) 2008. In its advance notice to MA organizations, CMS also discussed proposed changes in the MA capitation rate methodology and risk adjustment.
methodology applied under Part C of the Social Security Act for CY 2008. CMS said the preliminary estimates are subject to change before it announces the final MA capitation rates. Comments on the advanced notice were due March 2, 2007. MA capitation rates for years when CMS is not “rebasing” the amount representing the actuarial value of costs under original fee-for-service Medicare are based on the minimum percentage increases, which is the higher of 2% or the national per capita MA growth percentage.

CMS Announces Proposed Revisions To Medicare National Clinical Trial Policy
The Centers for Medicare and Medicaid Services (CMS) proposed revisions to the Medicare National Clinical Trial Policy, including changes to the requirements that clinical research studies must meet for Medicare to pay for certain items and services, according to an April 10, 2007 press release issued by the agency. Under CMS’ proposal to revise its Clinical Research Policy (CRP), Food and Drug Administration post-approved studies and coverage with evidence development (CED) would be added to studies qualifying under the policy. The CRP also would add a new definition for the term “research.”

The CRP would contain the existing seven “highly desirable characteristics” from the original Policy, the release said, but they would be renamed the “general standards for a scientifically and technically sound clinical research study” and include one additional standard: that the research study must have a written protocol. In addition, the CRP would revise the existing requirements that qualify a clinical study for Medicare coverage, and rename them “Medicare-specific standards.” The CRP would add other Medicare-specific requirements, including that all research studies must be registered on the ClinicalTrials.gov website prior to the enrollment of the first study subject, and must take into consideration relevant subpopulations (as defined by age, gender, race/ethnicity, socioeconomic, or other factors) in the study protocol. Further, the CRP would include Medicare-specific standards requiring the research study protocol to publish their results, and to contain a discussion of how the results will generalize to the Medicare population.

Another proposed revision would expand the “deeming” agencies to all agencies under the Department of Health and Human Services (DHHS), as well as the Veterans Administration, and the Department of Defense. “Deeming agencies are agencies that can ‘deem’ whether a trial has met the general standards outlined in the policy.” The April 10, 2007 release of the CRP marks the first day of a thirty-day comment period. After considering public comments, the agency will make a final determination and issue a decision memorandum no later than sixty days after the end of the comment period.

CMS Issues IPPS Proposed Rule, Revamps DRGs, Adds New Quality Measures
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule in the May 3, 2007 Federal Register (72 Fed. Reg. 24680) that would increase Medicare inpatient rates for hospitals reporting quality data by 3.3% in fiscal year (FY) 2008 and would further expand reforms aimed at improving payment accuracy. According to CMS, payments to more than 3,500 acute care hospitals are expected to increase by $3.3 billion under the proposed inpatient prospective payment system (IPPS) rule. Hospitals must report on specified quality measures to receive the full market basket update. The
proposed rule would add five new quality measures—for a total of thirty-two—including thirty-day mortality for Medicare patients with pneumonia and other measures related to surgical care improvement, CMS said.

Among the payment reforms, CMS is proposing to adopt the Medicare Severity diagnosis related groups (or MS-DRGs) payment system in FY 2008, an agency fact sheet said. Specifically, the proposed rule would create 745 new DRGs to replace the current 538. CMS said the proposed change would have little net effect on spending, but would mean hospitals treating more severely ill and costlier patients would see their payments go up, while those treating less severely ill patients would see their payments decline. The changes to the IPPS are aimed at better aligning payments with costs of care to, among other things, address concerns that the current system encourages investment in certain more profitable service areas and has spurred the growth of so-called specialty hospitals, CMS explained. The proposal also would put in place new disclosure requirements for specialty hospitals—requiring physician-owners to disclose their ownership interest to patients they refer to the hospital.

Continuing with reforms from last year, the proposed rule would phase-in assigning DRG weights using estimated hospital costs, rather than list charges. Under the proposed rule, hospitals would be paid during FY 2008 based on a blend of one-third list charge based weights and two-thirds cost-based weights for DRGs. The switch-over would be complete by FY 2009. CMS specifically asked for public comments on whether to expand from thirteen to nineteen the number of distinct hospital departments used in the calculation to improve payment accuracy. CMS also is proposing to set the “outlier” threshold for high-cost cases of $23,015, down from $24,475 in FY 2007. Comments on the proposed rule are due June 12, 2007.

CMS Issues Hospice Wage Index Proposed Rule For FY 2008
The Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the May 1, 2007 Federal Register (72 Fed. Reg. 24116) that would update the hospice wage index for fiscal year (FY) 2008. CMS estimates “that the total hospice payments will decrease $538,000 as a result of the proposed FY 2008 wage index values.” The hospice wage index is used to adjust Medicare payment rates to hospice providers to reflect local labor and wage levels. CMS said the proposed FY 2008 hospice wage index values were calculated using the FY 2007 hospital wage index as the most current data available. The proposed rule would make changes to the methodology for updating the wage index for rural areas without hospital wage data. The proposed rule also would clarify certain Medicare hospice regulations and policies, including those pertaining to certification of terminal illness. Comments on the proposed rule are due July 2, 2007.

CMS Releases IRF PPS Proposed Rule
The Centers for Medicare and Medicaid Services (CMS) issued proposed changes May 2, 2007 to the Inpatient Rehabilitation Facility (IRF) prospective payment system (PPS). The proposed rule increases by 3.3% the IRF Medicare payment, based on the rehabilitation, psychiatric, and long term care hospital market basket, amounting to additional payments of approximately $150 million in FY 2008. The rule carries over the
phase-in for the so-called “75% rule,” which, when fully implemented, will require that at least 75% of an IRF’s total inpatient population have one of the thirteen designated medical conditions for which intensive inpatient rehabilitation services are medically necessary. The rule also would increase the high cost outlier threshold from $5,534 to $7,522, based on an analysis of 2005 data indicating that this threshold would maintain estimated outlier payments at 3% of total payments under the IRF PPS, CMS said. In addition, the proposal would modify the wage index methodology as it applies to IRFs in certain rural areas where there are no hospitals from which to generate wage index data. Comments on the proposal are due July 2, 2007. The proposed rule was published May 8, 2007 at 72 Fed. Reg. 26230.

**CMS Issues Proposed Medicare Home Health Payment Rule**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule April 27, 2007 that amends the Medicare home health prospective payment system (HH PPS). The rule, published in the May 4, 2007 *Federal Register* (72 Fed. Reg. 25356). The rule would provide an additional $140 million in payments to home health agencies in CY 2008, increasing the home health market basket for CY 2008 by 2.9%. In addition, the rule includes a provision to continue to adjust payment for reporting of quality data. HHAs that submit the required quality data would receive the full market basket update of 2.9% while those that failed to do so would only see a market basket increase of 0.9%. Under the proposal, CMS also would increase the number of quality measures that HHAs are required to report on from ten to twelve. To account for the changes in case-mix that are not related to a home health patient’s actual clinical condition, CMS proposes to reduce the national standardized 60-day episode payment rate by 2.75% per year for three years beginning in CY 2008, the agency said.

**CMS Proposes 3.3% Update For Medicare Nursing Home Payments In FY 2008**
The Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the May 4, 2007 *Federal Register* (72 Fed. Reg. 25526) that would boost Medicare payments to nursing homes under the skilled nursing facility (SNF) prospective payment system (PPS) by 3.3%, or $690 million, in fiscal year (FY 2008). Comments on the proposal are due June 29, 2007. The President’s budget and the Medicare Payment Advisory Commission’s recommendations called for a 0% update in the SNF PPS. CMS said any legislation to enact those proposals would have to be reflected in the rule’s final provisions. In addition to the payment update, the proposed rule would “rebase” the market basket to reflect data from FY 2004. The SNF market basket measures changes in the prices of an appropriate mix of goods and services included in covered skilled nursing facility stays. CMS currently uses data from FY 1997 as the base year for annual adjustments to Medicare payments. According to CMS, FY 2004 is the most recent year for which relatively complete Medicare cost report data are available. The proposed rule also would implement various market basket revisions, including: using Medicare allowable total cost data instead of facility total cost data to derive the SNF market basket cost weights; using new wage and salary, benefits, and chemical price proxies; and using new data to estimate useful lives for fixed and moveable equipment. CMS said the proposed rebasing and revising of the market basket index resulted in twenty-three cost weights, two more than the 1997-based index.
(2) Final Actions

CMS Announces Payment Update For SNFs
The Centers for Medicare and Medicaid Services (CMS) published a notice July 31, 2006 updating Medicare payment rates for nursing homes, which in 2007 will increase by 3.1% (71 Fed. Reg. 43158). This rate hike translates to roughly $560 million in additional Medicare payments to nursing facilities that furnish certain skilled nursing and rehabilitation care next year, CMS said.

CMS Issues Final IPPS Rule That Phases-In Move To Cost-Based System
The Centers for Medicare and Medicaid Services (CMS) issued August 1, 2006 the much-anticipated inpatient prospective payment system (IPPS) final rule for fiscal year (FY) 2007 that seeks to improve the accuracy of hospital payments by moving from a charge to cost-based system and by accounting more fully for patient severity. Then CMS Administrator Mark McClellan said the final rule, which is effective October 1, 2006, was shaped by the “extensive” public comments that the agency received on the proposal issued in April. Under the final rule, hospitals that report quality data will see an increase in Medicare payments of about 3.5% in FY 2007, an overall estimated hike in payments to acute care hospitals of $3.4 billion, McClellan said. Due to refinements intended to improve payment accuracy, payments for cardiac specialty hospitals will increase less than the national average—only 1.2% in FY 2007, according to a CMS fact sheet.

The final rule assigns weights to Diagnosis Related Groups (DRGs) based on hospital costs rather than charges beginning in October 1, 2006. In response to public comments on the proposed rule, the final rule phases-in this change over a three-year period, expands the number of distinct hospital departments used in the calculation from ten to thirteen, and includes more hospital data in the final calculations, CMS said. The second aspect of the payment reforms—better accounting for the severity of a patient’s illness—will begin in 2007 by adding twenty new groups to the current DRG system. CMS plans more comprehensive changes in 2008 following further evaluation and public input on potential alternative systems. The final rule was published in the August 18 Federal Register (71 Fed. Reg. 47870).

CMS Issues Final Rule Updating Payment Rates For IRFs In FY 2007
The Centers for Medicare and Medicaid Services (CMS) issued August 1 a final rule that provides for a market basket update of 3.3% for Medicare payments to inpatient rehabilitation facilities (IRFs) in fiscal year (FY) 2007. The rule will result in an increase in Medicare payments in FY 2007 of approximately $50 million, CMS said.

The final rule, published in the August 18 Federal Register (71 Fed. Reg. 48354), also implements certain provisions in the Deficit Reduction Act of 2005 (DRA) affecting IRFs. Specifically, the rule amends existing regulations regarding the three-year phase-in to a compliance threshold that requires at least 75% of a facility’s patient admissions to be for one of thirteen qualifying medical conditions for the facility to be designated as an IRF. Under existing regulations, the compliance threshold was scheduled to gradually
increase from 50% to 75% by July 1, 2007. As required by the DRA, the final rule delays the full implementation of the 75% threshold for one year until July 1, 2008. Accordingly, for providers with cost reporting periods that start on or after July 1, 2006 and before July 1, 2007, the compliance threshold will be 60%. For cost reporting periods starting on or after July 1, 2007 and before July 1, 2008, the threshold will increase to 65%, with full implementation of the 75% threshold for cost periods beginning on or after July 1, 2008. The updated payment rates and policies will apply to discharges occurring on or after October 1, 2006 through September 30, 2007.

**CMS Issues Final Rule On Accreditation Of DME Suppliers**
The Centers for Medicare and Medicaid Services (CMS) issued August 1, 2006 a final rule that establishes requirements for accreditation of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and lays the foundation for implementation of the Medicare DMEPOS Competitive Bidding Program. The final rule outlines the application process for independent accrediting organizations that would apply quality standards for all DMEPOS suppliers, including suppliers that would participate in the Medicare DMEPOS Competitive Bidding Program.

Under the final rule, all suppliers that furnish DMEPOS under Medicare Part B will need to meet quality standards and accreditation requirements. CMS-approved independent accrediting organizations will survey DMEPOS suppliers to measure compliance with the new quality standards. In an effort to minimize the burden placed on suppliers by the new rule’s requirements, CMS said it included provisions directing accreditation organization to consider previous accreditation, Medicare certification, and licensure that would indicate the quality standards are being met.

**CMS Issues Final Quality Standards For DMEPOS Suppliers**
The Centers for Medicare and Medicaid Services (CMS) released August 14, 2006 its final quality standards for suppliers of durable medical equipment, prosthetics, orthotics, supplies, (DMEPOS) and other items and services under the Medicare program. The standards were scaled-back substantially from the draft version issued in September 2005, thereby reducing the standards document from 104 pages to fourteen pages. The agency said it significantly revised the draft version of the standards to reduce the burden on small DMEPOS suppliers, while also ensuring quality services for Medicare beneficiaries. By consolidating and incorporating certain product specific standards included in the draft version into the general product-specific service section of the final standards, CMS reduced the number of product specific standards from fifteen to three, the agency said. These remaining three product specific standards address respiratory equipment, supplies, and services; manual wheelchairs and power mobility devices; and custom-fabricated or fitted orthotics and prosthetic devices. In a notice published in the August 16 Federal Register (71 Fed. Reg. 47230), CMS invited independent accreditation organizations to submit applications to participate in the DMEPOS accreditation program. The notice provided a broad definition of eligible organizations and outlined the specific requirements an organization must meet to apply for the program. The deadline for submission of the application to CMS was October 2, 2006.
CMS Announces FY 2007 Update To Hospice Wage Index
The Centers for Medicare and Medicaid Services (CMS) announced September 1, 2006 a full market basket update for the hospice wage index effective October 1, 2006 through September 30, 2007. The hospice wage index is used to adjust Medicare payment rates to hospice providers to reflect local labor and wage levels. The fiscal year 2007 hospice wage index for the first time will be based entirely on the Office of Management and Budget’s Core-Based Statistical Areas (CBSAs) instead of the Metropolitan Statistical Areas (MSAs). In FY 2006, the index for each hospice provider consisted of a 50-50 blend of the MSAs and CBSAs, CMS said. The notice was published in the Federal Register at 71 Fed. Reg. 52080.

CMS Revises Wage Index For IPPS Rates
The Centers for Medicare and Medicaid Services (CMS) announced September 29, 2006 the final hospital inpatient prospective payment system (IPPS) rates for fiscal year (FY) 2007 that fully adjust the wage indices for occupational mix. The revised rule does not significantly change the diagnosis related groups relative weights previously published by CMS, the agency said in a fact sheet. In addition, the outlier threshold increased by only $10 using the revised wage data and the final IPPS standardized amounts will be approximately $4 less than those previously announced. According to the agency, less than half of urban Core Based Statistical Areas (CBSAs) (46.9%) will experience an increase in their wage index as a result of the occupational mix adjustment and “[c]lose to a third of rural CBSAs (29.8%) will experience a decrease in their wage indexes as a result of the occupational mix adjustment, although more rural CBSAs were experiencing a decrease using the old occupational mix data (36.2%), as compared to using the new data (29.8%).”

CMS Implements Pay For Performance For Small Physician Practices
The Centers for Medicare and Medicaid Services (CMS) announced October 13, 2006 a new initiative that will implement a pay-for-performance program aimed at physicians practicing in solo or small to medium-sized group practices. The Medicare Care Management Performance (MCMP) Demonstration will be implemented in four state—Arkansas, California, Massachusetts, and Utah. Under the three-year demonstration, physicians will continue to be paid on a fee-for-service basis, but will be required to submit data annually on up to twenty-six quality measures related to the care of patients with diabetes, congestive heart failure, and coronary artery disease, as well as the provision of preventive health services such as immunizations and cancer screenings to high risk patients with a range of chronic diseases, CMS said. In the first year, the program will act as a “pay for reporting” program to provide baseline information on quality and familiarize physicians with the process. In the next two years, practices will be eligible to earn an annual incentive of up to $10,000 per physician and up to $50,000 per practice year, according to CMS.

SSA Issues Final Rules On Part B Income-Related Monthly Adjustment Amount
The Social Security Administration (SSA) issued October 27, 2006 in the Federal Register (71 Fed. Reg. 62923) final rules used to determine when Medicare beneficiaries with higher incomes will have to pay more than the standard Part B premium. The federal
government currently subsidizes about 75% of the full cost of Medicare Part B. The Centers for Medicare and Medicaid Services (CMS) sets the standard monthly premium to cover the remaining 25% of Medicare Part B program costs. Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a Medicare Part P premium subsidy reduction, termed “the income-related monthly adjustment amount” in the final SSA rules, for those beneficiaries with certain income levels. Starting in January 2007, the Medicare Part B premium will be reduced roughly 4% to 5% for the approximately 40 million Medicare beneficiaries, the SSA said in the final rules. For 2007, the modified adjusted gross income threshold that triggers the adjustment is $80,000 for individuals and $160,000 for married couples. The final rules detail, among other things, how the income-related monthly amount will be determined, what will be considered a “major life-changing event” that results in a significant reduction in a beneficiary’s modified adjusted gross income, and how to appeal an SSA determination.

**CMS Issues Final Medicare Physician Fee Schedule For 2007, Includes Negative 5% Update**
The Centers for Medicare and Medicaid Services (CMS) issued November 1, 2006 the Medicare Physician Fee Schedule (MPFS) final rule, which includes a 5% cut in the annual MPFS update, boosts payments for the time and effort physicians spend with patients in evaluating their conditions, and caps payment rates for imaging services under the MPFS at the amount paid for the same services when performed in the hospital outpatient setting. Under the proposal, CMS expects payments of roughly $61.5 billion to over 900,000 physicians and other healthcare professionals in 2007. Significantly, the MPFS for 2007 does not finalize two controversial proposals to clarify that reassignments pursuant to the contractual arrangement exception are subject to program integrity safeguards for diagnostic tests and to restrict the types of space ownership or leasing arrangements that will qualify for the in-office ancillary services or physician services exceptions to the physician self-referral prohibition. CMS said it planned to issue regulations on these proposals after further consideration. The final rule was published December 1 at 71 Fed. Reg. 69624.

**CMS Issues Final OPPS Rule, Calls For Outpatient-Specific Quality Measures**
Hospitals will receive an overall average increase in Medicare payments of 3% in calendar year (CY) 2007 for outpatient services under the hospital outpatient prospective payment system (OPPS) final rule issued November 1, 2006 by the Centers for Medicare and Medicaid Services (CMS). The final rule includes a 3.4% market basket update to payment rates, with hospitals expected to receive about $32.5 billion under the OPPS in CY 2007. The final rule is effective January 1, 2007.

Under the final rule, CMS announced plans to develop quality reporting measures specific to hospital outpatient care. CMS previously had proposed tying hospital payment rate increases under the OPPS to reporting inpatient quality measures beginning in CY 2007. Instead, starting two years later in CY 2009, hospitals will have to report outpatient-specific quality measures to receive the full market basket update, CMS said. The final rule also includes certain new quality reporting requirements for inpatient
hospitals. Beginning in fiscal year 2008, hospitals must report consistent measures on patient satisfaction with hospital care to receive a full payment update under the inpatient prospective payment system (IPPS). In addition, the final rule requires reporting of three new surgical care improvement measures and mortality measures to receive full reimbursement under the IPPS. The final rule was published November 24 at 71 Fed. Reg. 67960.

CMS Issues Final Rule Requiring Medicare Payment System Changes For HHAs And Certain DME
The Centers for Medicare and Medicaid Services (CMS) released a final rule November 1, 2006 that includes a 3.3% market basket increase for Medicare payment rates for home health agencies for calendar year (CY) 2007, according to a press release issued by the agency. This annual update to the home health prospective payment system (HH PPS) will bring an estimated additional $410 million in wage-adjusted payments to home health agencies in CY 2007, the press release said. In addition, the final rule changes how Medicare will pay for certain durable medical equipment (DME), namely oxygen and oxygen equipment and capped rental items (e.g., wheelchairs and hospital beds), and establishes new protections for beneficiaries who need these items, the release explained. The final rule becomes effective January 1, 2007.

CMS Issues Final Rule Revising Certain Hospital Conditions Of Participation
The Centers for Medicare and Medicaid Services (CMS) issued November 27, 2006 a final rule revising certain requirements in the hospital conditions of participation (CoPs). The revisions focus on hospital CoPs for completion of history and physical examinations, authentication of verbal orders, securing medications, and completion of post anesthesia evaluations. The final rule is effective January 26, 2007. CMS said it decided to carve out the selected four CoPs rather than wait to revise all hospital CoPs at the same time because of overwhelming comments from stakeholders “that the existing regulations for these requirements no longer reflect current health care practice” and are overly burdensome. The final rule was published November 27 at 71 Fed. Reg. 68672.

CMS Finalizes New Hospital Discharge Requirements, Scraps Additional Notice Requirement But Strengthens Existing Form
The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the November 27, 2006 Federal Register (71 Fed. Reg. 68708) providing new requirements for hospital discharge notices under both Medicare and the Medicare Advantage program. The final rule on hospital discharge notification procedures, which is effective July 1, 2007, includes substantial changes from a proposal issued in April 2006 that CMS said drew strong objections from the vast majority of the roughly 500 comments it received.

Under the proposed rule, hospitals would have had to follow a two-step notice process. The rule would have required hospitals to deliver a standardized, largely generic notice of non-coverage on the day prior to discharge to each Medicare beneficiary whose physician concurred with the discharge decision. Hospitals or Medicare health plans also would deliver a more detailed discharge notice to beneficiaries who exercise their right to appeal the discharge. Given concerns about this approach, CMS in the final rule calls for
hospitals to use a revised version of the existing statutorily required Important Message from Medicare (IM) notice to explain discharge rights. The hospital must issue the IM within two days of admission and obtain the beneficiary’s signature. Hospitals also will deliver a copy of the signed notice prior to discharge but not more than two days before the discharge. For those beneficiaries requesting an appeal, the hospital must deliver a more detailed notice, CMS said.

CMS Posts Payment Data For Physicians, Outpatient Procedures
The Centers for Medicare and Medicaid Services (CMS) has posted payment information for certain common services provided by physicians or outpatient departments to further the administration’s goal of increasing healthcare price and quality transparency. According to the agency’s November 20, 2006 press release, the payment data will allow for consumer price comparisons on over seventy physician services rendered in non-office settings as well as nineteen services usually performed in a physician’s office. The outpatient hospital patient data also provides information for certain commonly performed procedures, the release said. President George W. Bush signed an executive order directing federal agencies that administer or sponsor a healthcare program to increase price and quality transparency by January 1, 2007. CMS already has posted such information for inpatient hospitals and ambulatory surgical centers.

CMS Drops Part D Late Fee In 2007 For Low-Income Medicare Beneficiaries
Medicare beneficiaries who are eligible for the low income subsidy as part of Medicare Part D will not have to pay a late fee this year even if they failed to sign up by the program’s initial deadline, Centers for Medicare and Medicaid Services (CMS) Acting Administrator Leslie V. Norwalk announced January 9, 2007. “These fees were intended to encourage Medicare beneficiaries to sign up for the drug coverage plan when they first become eligible, but may cause some low-income beneficiaries to avoid seeking coverage,” CMS said. As a result, low-income seniors who qualify for extra help paying for prescription drug coverage can enroll in a Medicare prescription drug plan with no penalty through December 31, 2007.

CMS Final Rule For Medicare Transplant Centers Stresses Outcomes
The Centers for Medicare and Medicaid Services (CMS) announced March 22, 2007 a final rule detailing the requirements that transplant centers must meet to participate in the Medicare program. “This final rule will move Medicare-covered transplant programs toward an outcome-focused system that reflects clinical experience, resources and commitment of the transplant program,” CMS said. The final rule consolidates all transplant center requirements into one regulation. CMS previously issued coverage decisions related to heart transplants in 1987, liver transplants in 1991, lung transplants in 1995, and intestine transplants in 2001 and 2006, the agency explained. All transplant centers must submit a request for initial approval to participate in Medicare. Those that obtain approval will be eligible for re-approval every three years, CMS said. Existing Medicare-covered transplant centers that apply for initial approval within 180 days of the rule’s effective date may continue to provide services and receive Medicare payments pending CMS’ decision. Senate Finance Committee Ranking Member Charles Grassley (R-IA) sought review of federal efforts to oversee the transplant system following reports
of “line jumping” and other violations of organ procurement policies at St. Vincent Medical Center in Los Angeles, California and of serious problems with the University of California Irvine Medical Center's liver transplant program.

**CMS Issues Final Rule On DMEPOS Competitive Bidding Program**
The Centers for Medicare and Medicaid Services (CMS) issued April 2, 2007 a final rule establishing a competitive bidding process to set Medicare payment amounts for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that the agency expects will save the program $1 billion annually when fully implemented in 2010. The final rule, which was published in the April 10, 2007 *Federal Register* (72 Fed. Reg. 17992), calls for phasing in the competitive bidding program over several years beginning in 2007. The program is intended to bring down costs to Medicare and beneficiaries while improving service delivery and quality of care, CMS said.

CMS said it anticipates accepting DMEPOS supplier bids for a period of sixty days in ten competitive bidding areas (CBAs) that qualify as one of the fifty largest metropolitan areas in the country and rank high in terms of total Medicare DMEPOS allowed charges and suppliers per beneficiary. The following ten CBAs have been selected for this initial phase of the competitive bidding program: Charlotte-Gastonia-Concord, North Carolina-South Carolina; Cincinnati-Middletown, Ohio-Kentucky-Indiana; Cleveland-Elyria-Mentor, Ohio; Dallas-Fort Worth-Arlington, Texas; Kansas City, Missouri-Kansas; Miami-Fort Lauderdale-Miami Beach, Florida; Orlando-Kissimmee, Florida; Pittsburgh, Pennsylvania; Riverside-San Bernardino-Ontario, California; and San Juan-Caguas-Guaynabo, Puerto Rico. The bidding will involve ten categories of DMEPOS that are high-price and high-use items such as standard power wheelchairs and scooters, oxygen supplies and equipment, and mail-order diabetic supplies.

According to CMS, the bidding will be expanded into seventy additional Metropolitan Statistical Areas in 2009, and to other areas thereafter. The bids will be used to set a single payment amount for each item in the particular CBA. Payments under the competitive bidding program, which was mandated by the Medicare Modernization Act of 2003 to replace the existing fee schedule for certain DMEPOS, will go into effect in April 2008. To participate in the bidding, suppliers must be accredited as meeting CMS quality standards by an approved accreditation organization. In the final rule, CMS outlines its approach for selecting winning bids, noting that while a supplier need not be physically located in a CBA, it generally will be required to service the entire CBA regardless of the beneficiary’s location.

Responding to comments on the proposed rule, CMS added new provisions exempting from the competitive bidding process physicians, physician assistants, clinical nurse specialists, nurse practitioners, occupational therapists, and physical therapists who provide DMEPOS to their patients as part of their professional service. These healthcare professionals could still provide DMEPOS to their patients and be paid the single payment amount established for the item of DMEPOS in the CBA, CMS said. The final rule also sets a 30% target number for small supplier participation. The rule defines small suppliers, which comprise about 85% of DMEPOS Medicare suppliers, as those having
gross revenue of $3.5 million or less in annual receipts. Under the final rule, if not enough small suppliers with winning bids meet the 30% target in each product category, then contracts will be offered to small suppliers, in order of their bids, that agree to accept the single payment amounts until the threshold is reached, or until no small suppliers remain. In addition, the final rule permits small suppliers to form networks to participate in the bidding process, so long as they comply with federal and state laws, and to submit bids for select product categories rather than the entire group as required for other suppliers. Skilled nursing facilities and nursing facilities also will be allowed to compete for a contract to provide DMEPOS only to their residents, instead of having to serve the entire CBA as generally required for participating in the competitive bid program.

**CMS Posts Specifications For Physician Quality Measures**

The Centers for Medicare and Medicaid Services (CMS) posted April 3, 2007 detailed specifications for the seventy-four measures physicians will use to participate in a voluntary quality reporting program that could earn them extra Medicare payments in 2007. Eligible physicians who report data for a designated set of quality measures may earn a bonus payment, subject to a cap, of 1.5% of total allowed charges for covered Medicare physician fee schedule services provided during the reporting period, which starts July 1, 2007 and goes through the end of the year. According to an agency press release, CMS posted the specifications well before the July 1, 2007 start date “to help eligible professionals to identify measures applicable to their practices and to prepare for submission of quality data.” CMS added that it expects a number of additional coding updates to the specifications, which could expand the measures’ application to additional eligible professionals. The evidence- and consensus-based measures were developed in conjunction with a number of national organizations including the American Medical Association Physician Consortium for Performance Improvement, the National Committee for Quality Assurance, and the National Quality Forum. Measures involve, for example, the percentage of patients with diabetes who have their blood pressure under control or those with coronary artery disease who have been prescribed beta blockers.

The Physician Quality Reporting Initiative was authorized by the Tax Relief and Health Care Act of 2006.

**2008 MA And Part D Payment Rates Posted By CMS**

The Centers for Medicare and Medicaid Services (CMS) announced April 2, 2007 the Calendar Year (CY) 2008 Medicare Advantage (MA) and Part D payment rates. According to the notice, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 5.71%. CMS also stated in the notice that it “has decided not to rebase the county fee-for-service (FFS) rates for 2008. Therefore, all 2008 non-ESRD capitation rates increase a uniform amount over 2007 rates, reflecting application of the National Per Capita MA Growth Percentage and the change in budget neutrality (BN) factor.” According to the Part D notice, key changes in payment methodology include: updated benefit parameters for the defined standard benefit and the Retiree Drug Subsidy; calculations of the national average monthly bid amount and the regional low-income benchmark premium amounts; normalization of the Part D risk adjustment model; and statutory changes in the risk corridors.
CMS Guidance Clarifies Medicare Emergency Services Requirements For Hospitals

Nearly all hospitals (including specialty hospitals) participating in Medicare must be capable of providing emergency care interventions at all times, regardless of whether they have an emergency department, according to new guidance issued April 26, 2007 by the Centers for Medicare and Medicaid Services (CMS). The guidance, sent as survey and certification letters to state surveyors, makes clear that, to comply with Medicare Conditions of Participation (CoPs), hospitals must be capable of appraising an emergency situation, providing initial treatment, and referring or transferring patients where appropriate. The guidance also stresses that a hospital “may not rely on 911 services to provide appraisal or initial treatment of individuals in lieu of its own capability to do so.” CMS adds that the guidance does not apply to critical access hospitals, which are small rural hospitals that are subject to separate regulation.

A hospital may call 911 to obtain transport of a patient to another hospital but this does not relieve the hospital of its obligation to arrange for the transfer and to ensure the necessary medical information is sent along with the patient. The guidance notes that while the Medicare CoPs do not define a medical emergency, the definition under the Emergency Medical Treatment and Labor Act “might be a helpful reference when considering a hospital’s compliance.” CMS notes that the guidance, although applicable to all hospitals, also implements one element of its strategic plan addressing specialty hospitals, which the agency reported to Congress in August 2006.

Medicare Trustees Issue Funding Warning

According to the Medicare Trustees report released April 23, 2007 Medicare’s Hospital Insurance (HI) Trust Fund is projected to be exhausted in 2019, one year later than was estimated last year. The report found Medicare’s financial outlook still dim, however, leading the Trustees to issue a “Medicare funding warning.” The warning is triggered by a finding of “excess general revenue Medicare funding” for two consecutive years. The Trustees made that determination because program costs financed by general revenues, rather than by “dedicated revenues,” are projected to exceed 45% in 2013. A Medicare funding warning requires President Bush to propose legislation to respond to the issue within fifteen days following the release of the Fiscal Year 2009 Budget. Congress is then required to consider the legislation on an expedited basis.

CMS Issues Final Rule On Medicare Payments To LTCHs For RY 2008

The Centers for Medicare and Medicaid Services (CMS) issued May 1, 2007 a final rule that updates the long term care hospital (LTCH) prospective payment system (PPS) for rate year (RY) 2008 and makes a number of controversial policy changes to how LTCHs are paid under Medicare. The final rule updates the LTCH PPS by 0.71% to $38,356.45 for RY 2008. The update reflects a market basket of 3.2% less a 2.9% adjustment to account for changes in coding practices and documentation rather than the treatment of more resource intensive patients, CMS said.

Despite the positive update, Medicare payments per discharge to LTCHs are projected to decrease 3.8% on average in RY 2008 as compared to RY 2007 due to changes in the
fixed-loss amount, the area wage adjustment, and the short stay outlier (SSO) policy. LTCHs are defined as those hospitals that generally have an average Medicare inpatient length of stay greater than twenty-five days and that typically provide care to clinically complex cases. Under the final rule, Medicare payments to LTCHs are expected to exceed $4 billion for RY 2008, which is effective for discharges on or after July 1, 2007 through June 30, 2008, CMS said.

The final rule raises the outlier fixed-loss amount, the threshold at which LTCHs treating high-cost cases are eligible for additional Medicare payments, to $22,954 from $14,887 in RY 2007. The proposed rule had set the threshold at $18,477. According to CMS, the change was necessary, based on more recent LTCH data, to keep aggregate outlier payments within the required 8% target of total LTCH PPS estimated payments for RY 2008. CMS projected the change to the fixed-loss amount would decrease estimated payments per discharge by 2.5% from RY 2007 to RY 2008. CMS also noted changes to the wage index based on the most recent available data will result in an estimated 1% drop in estimated payments per discharge in RY 2008. CMS attributed the rest of the decrease to revisions in its SSO policy, which the final rule adopted without change from the proposed rule. The revised policy will be applicable to discharges with a lengths of stay (LOS) that are less than or equal to an inpatient prospective payment system (IPPS) “comparable threshold.” Medicare will pay LTCHs for these charges a lesser amount comparable to the IPPS per diem rate. CMS said the policy change was designed to ensure Medicare pays at appropriate rates for cases admitted to LTCHs that have a LOS similar to those more typically treated in acute care hospitals under the IPPS.

The final rule also adopts a controversial proposal to extend the “25 percent rule” to virtually all LTCHs. Based on comments on the proposed rule, however, CMS opted to phase-in implementation of this change over three years. Under the current policy, if a LTC hospital-within-a-hospital’s or an LTCH satellite’s discharges that were admitted from its co-located host hospital exceed a given percentage (generally 25%) for the cost reporting period, the payment to the LTCH is adjusted downward. The new policy will extend this rule to freestanding LTCHs for which more than 25% (or the applicable percentage in certain special circumstances) of its discharged patients were admitted from an individual hospital, regardless of whether that hospital was located in the general vicinity of the LTCH. This aspect of the proposed rule drew criticism from a number of industry groups, including the Federation of American Hospitals and the American Hospital Association, and the Medicare Payment Advisory Commission (MedPAC), which has advocated developing facility and patient-level criteria to define long term hospital care. CMS said that during the three-year transition, it would continue to explore MedPAC’s recommendations on this issue.

The final rule also revises Medicare’s payment policies for graduate medical education (GME) payments. Under current regulations, teaching hospitals may count residents training in nonhospital settings for purposes of calculating their GME payments if the teaching hospital pays “all or substantially all of the costs for the training program in the nonhospital setting.” The final rule defines that requirement to mean that the teaching
hospital pays at least 90% of the total costs of training residents in the nonhospital setting. The final rule was published at 72 Fed. Reg. 26870.

**CMS Releases RY 2008 Update For Medicare Inpatient Psychiatric Facilities Payments**
The Centers for Medicare and Medicaid Services (CMS) published in the May 4 Federal Register (72 Fed. Reg. 25602) a notice announcing a market basket update that will increase Medicare payments to inpatient psychiatric facilities (IPFs) under the IPF prospective payment system (PPS) by 3.2%, or $130 million, in rate year (RY) 2008. The notice implements the second annual update to the IPF PPS, effective for discharges occurring during the rate year beginning July 1, 2007 through June 30, 2008. “The Federal per diem base rate for the implementation year (RY 2006) was $575.95, and for RY 2007, it was $595.09,” the notice said. “Applying the market basket increase of 3.2 percent . . . yields a Federal per diem base rate of $614.99 for RY 2008.” For the update for RY 2008, CMS concluded that it was “unnecessary to undertake notice and comment rulemaking because the update does not make any substantive changes in policy but merely reflects the application of previously established methodologies,” the notice said. Since this is the last year of the three-year transition period from cost-based reimbursement to full PPS, 75% of payment will be based on the federal per diem rate and 25% of payment will be based on a hospital-specific, cost-based reimbursement rate, CMS explained. CMS will continue to provide the same facility and patient-level adjustments to the PPS for RY 2008, according to the notice.

**Legislative Developments**

**House, Senate Pass Health Bill In Waning Days Of 109th Congress**
Before adjourning, Congress passed the Tax Relief and Health Care Act of 2006 (H.R. 6111), which President Bush signed into law December 20, 2006. The House passed the bill December 8 by a vote of 367 to 45 and the Senate followed suit on December 9, passing the measure 79 to 9. The legislation prevents the scheduled 5.5% cut in Medicare physician payments for 2007, instead providing for a one-year zero percent update to the Physician Fee Schedule. The bill also provides that physicians who submit data on applicable quality measures will receive bonus incentive payments of 1.5% for covered services, according to a summary of the bill. Other provisions of H.R. 6111 include increasing payments by 1.6% to end stage renal disease facilities for 2007; extending the Medicare Modernization Act’s geographic adjustment for physician services; addressing Medicare program beneficiary protections and Medicare program integrity efforts; and reducing the limit on provider taxes from 6.0% to 5.5% from January 1, 2008 through September 30, 2011.

**Litigation and Case Law Developments**

**Nurses Association Sues DHHS Over Staffing Requirements**
The American Nurses Association (ANA), the New York State Nurses Association (NYSNA), and the Washington State Nurses Association (WSNA) have sued the Department of Health and Human Services (DHHS) alleging the agency allows hospitals
that fail to meet federal nurse staffing requirements to participate in Medicare. The groups also claimed DHHS “unlawfully delegated its authority to [the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)]” by allowing it to use nurse staffing standards that are not equivalent to those set by DHHS for participating in the Medicare program.

The lawsuit, filed June 15, 2006 in the U.S. District Court for the District of Columbia, seeks declaratory and injunctive relief to prevent DHHS from delegating to JCAHO the authority to use its own nurse staffing requirements in accrediting hospitals. According to the lawsuit, JCAHO nurse staffing requirements are not equivalent to Medicare Conditions of Participation in that they do not require the “immediate availability of a registered nurse to render bedside care to patients.”

According to the suit, the public is harmed by DHHS’ failure to require adequate staffing on medical/surgical units where registered nurse-to-patient staffing ratios of one to eight result in patients being 31% more likely to die within thirty days than those in units with nurse-to-patient ratios of one to four. In addition, complications such as urinary tract infections, pneumonia, shock, and gastrointestinal bleeding are much more prevalent in the understaffed units, the lawsuit alleges.

Second Circuit Holds ALJ Lacked Jurisdiction Over Medicare Enrollee's Breach Of Contract Claim
An administrative law judge (ALJ) properly declined to hear an enrollee's claim for breach of contract damages against his Medicare+Choice provider, the Second Circuit ruled June 20, 2006. The appeals court found the ALJ lacked statutory authority to hear a state law contract claim for damages independent of the ALJ's determination of the enrollee's entitlement to benefits under the agreement. William F. Matthews, Sr., now deceased, was enrolled in Senior Choice, an M+C plan administered by Excellus Health Plan, Inc. The dispute arose after Senior Choice denied coverage of certain skilled nursing facility (SNF) care Matthews was receiving. Matthews contended that his premature release from the SNF caused him to fall and sustain another injury that required additional SNF care. The ALJ found that Senior Choice had satisfied the terms of the subscriber agreement by providing Matthews with a full 100 days of SNF coverage.

The Second Circuit found substantial evidence to support the ALJ's decision and agreed with the lower court that an ALJ has no statutory authority to entertain a state common law breach of contract claim for damages. In so holding, the appeals court rejected the estate's argument that because 42 U.S.C. § 1395w-22(g)(5) allows an ALJ to adjudicate an enrollee's claim of entitlement to any health service, an ALJ can hear a breach of contract claim for damages. “Although the statutory language . . . presumably empowers an ALJ to determine, as the ALJ did here, whether a Medicare Part C enrollee is entitled to particular supplemental benefits under the terms of his agreement with his provider—an undertaking that may involve the application of state contract law principles—it does not provide for the adjudication by the ALJ of a state law breach of contract action for damages that is independent of the ALJ's determination of the entitlement to benefits.
under the terms of the applicable agreement,” the appeals court said. *Matthews v. Leavitt*, No. 05-4853-cv (2d Cir. June 20, 2006).

**Eighth Circuit Says Hospital’s Classroom Costs Not Entitled To Pass-Through Treatment**

A hospital's classroom costs associated with an affiliated nursing school owned by its parent company did not qualify for pass-through treatment because the nursing home was not directly operated by the provider hospital, the Eighth Circuit ruled August 15, 2006. Baptist Memorial Medical Center—North Little Rock (Baptist Memorial) challenged the Department of Health and Human Services Secretary’s decision to deny for Medicare reimbursement purposes “approved educational activity” status for classroom costs incurred by the hospital in connection with its affiliated nursing school. “Approved education activities” are exempted from the prospective payment system (PPS) and therefore still reimbursed based on reasonable costs. Congress in the Omnibus Budget Reconciliation Act of 1990 (OBRA) provided pass-through treatment for educational activities that included costs of clinical nursing school programs conducted on the premises of, but not necessarily directly operated by, a provider hospital.

From 1991 to 1994, Baptist Memorial, which is owned and operated by Baptist Health, Inc., submitted its nursing school costs for pass-through payments, but the fiscal intermediary denied reasonable-cost reimbursement. Following various levels of administrative review, the Centers for Medicare and Medicaid Services Administrator determined that clinical costs were eligible for pass-through treatment under OBRA but the classroom costs were not because Baptist Memorial did not directly operate the nursing school.

Applying *Chevron*-level deference, the Eighth Circuit first noted Congress in OBRA did not clearly define the phrase “approved educational activities,” and that the “direct operation” requirement was a permissible interpretation of the statute. The Secretary explained in the final regulations that only those medical education programs operated directly by a hospital should be excluded from the PPS because “[w]hile the hospital may incur some costs associated with its provision of clinical training to students enrolled in a nearby institution, the hospital also gains in return.” Finally, the appeals court rejected Baptist Memorial’s common-ownership reimbursement theory—i.e. that the classroom costs should qualify for pass-through treatment because Baptist Memorial (as the provider hospital) and the nursing school were both operated by the same entity, Baptist Health. “[T]he Medicare reimbursement system is based on the costs incurred by individual provider hospitals, without regard to underlying ownership structures,” the appeals court said. *Baptist Health v. Thompson*, No. 05-4372 (8th Cir. Aug. 15, 2006).

**U.S. Court In Indiana Rejects Hospitals’ Bid For Retroactive Adjustment Of Their Outlier Payments**

The Department of Health and Human Services Secretary’s interpretation that the calculation of the total outlier payment percentage should be made prospectively is reasonable and consistent with the overall design of the prospective payment system, a federal district court in Indiana ruled September 15, 2006. In so holding, the court
rejected a group of hospitals’ attempt to have their outlier payments retroactively adjusted upward. Plaintiff medical providers sued the Secretary alleging Medicare underpaid them for inpatient care provided to patients unusually expensive to treat. At issue was the interpretation of a provision of Medicare law concerning outlier payments, which provides that “additional payments made . . . for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on [diagnosis related group (DRG)] prospective payment rates for discharges in that year.” See 42 U.S.C. § 1395ww(d)(5)(A)(iv).

Specifically, plaintiffs contended that actual outlier payments for 1991 through 1996 fell short of 5% of DRG prospective payments, ranging instead from 3.5% to 4.24%. But according to the Secretary’s interpretation of the statute, outlier thresholds must be set prospectively “at levels he estimates will result in outlier payments being between five and six percent of total payment.” The U.S. District Court for the Southern District of Indiana upheld the Secretary’s interpretation of § 1395ww(d)(5)(A) and granted summary judgment in his favor. The court noted the Secretary's interpretation “avoids the substantial administrative burden” of establishing outlier thresholds each fiscal year, processing claims based on those figures, and then redoing all those calculations again. Moreover, the idea of setting the outlier thresholds prospectively is in line with the overall goal of the PPS—determining reimbursement rates that remain constant throughout the year to motivate hospitals to keep costs down. Clarian Health Partners, Inc. v. Leavitt, No. 1:05-cv-00726-JDT-WTL (S.D. Ind. Sept. 15, 2006).

**U.S. Court In District Of Columbia Says DRA Retroactively Changed DSH Formula To Exclude Expansion Populations From Earlier Calculation**

A group of hospitals in Tennessee are no longer entitled to additional Medicare reimbursement under the disproportionate share hospital (DSH) formula for the TennCare patients they provided services to in the years before 2000 because of a retroactive change to the calculation made by the Deficit Reduction Act of 2005 (DRA), a federal judge in the District of Columbia ruled September 26, 2006. In his decision, Judge James Robertson of the U.S. District Court for the District of Columbia said as a result of the DRA change, he would grant the Department of Health and Human Services (DHHS) Secretary’s motion to alter the previous judgment in favor of the plaintiff hospitals should the case be remanded from the D.C. Circuit.

Judge Robertson issued a written decision on October 28, 2005, holding the DHHS Secretary improperly excluded those low-income patients who would not have otherwise been eligible for Medicaid absent a § 1115 waiver from the hospitals' DSH calculation. The fifteen Tennessee hospitals sued the DHHS Secretary alleging they had been wrongfully denied Medicare reimbursements under the agency’s interpretation of the DSH formula for services they provided to low-income patients in the years before 2000. At issue in the case was the Secretary's initial interpretation of Medicaid eligibility for purposes of the DSH calculation. Specifically, before 2000, the Secretary viewed the DSH statute as excluding so-called "expansion populations" from the Medicaid fraction on which DSH compensation levels are partially based. DHHS subsequently issued an interim final rule reversing this position to include all patients that received Medicaid
The judge in his initial decision found the relevant statutory language unambiguous and concluded that the Secretary's exclusion of expansion populations from the hospitals' DSH adjustments prior to 2000 "contravenes the clear language of the statute." In his latest decision, Judge Robertson concluded that the DRA amendment to the DSH formula amounted to a substantive change in the law, rather than a "clarification" as the Secretary contended. At the same time, Robertson found Congress clearly intended the change in the DRA to be applied retroactively, because it titled the provision a "clarification" and because it expressly ratified the Secretary's regulation. Cookeville Reg'l Med. Ctr. v. Leavitt, No. 04-1052 (D.D.C. Sept. 26, 2006).

U.S. Court in Connecticut Dismisses Class Action Challenging DHHS’ Denial Of Medicare Coverage For Post-Hospital SNF Stays

A federal district court in Connecticut upheld September 1, 2006 the Department of Health and Human Services Secretary’s interpretation of Medicare’s three-day hospitalization requirement for coverage of post-hospital skilled nursing facility (SNF) stays as requiring a patient be formally admitted to qualify as an inpatient. Under the statute at issue, 42 U.S.C. § 1395x(i), Medicare is required to cover post-hospital extended care services at SNFs for a beneficiary who was transferred to an SNF “from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer.” Marion Landers, Marion Dixon, and Muriel Grigley, the three named plaintiffs in the case representing the class of similarly situated Medicare beneficiaries, challenged the Secretary’s interpretation of the three-day hospitalization requirement as requiring formal admission. Although each of them received treatment from hospitals for at least three days before being transferred to SNFs, part of that time was spent in the emergency room or on “observation” status before being formally admitted to the hospital as inpatients. As a result, each of them was later denied Medicare coverage for their subsequent SNF stays.

The U.S. District Court for the District of Connecticut rejected the argument that the statute’s definition of “inpatient hospital services” shows that Congress intended the term “inpatient” to be defined with reference to the services that the hospital provides to a patient, rather than whether the hospital has formally admitted the patient. Plaintiffs also argued that hospitals have increased the practice of keeping patients in the emergency room or on “observation status” prior to admission. But the court was not persuaded, noting that “[i]f hospital admissions policies have changed drastically since Congress created the three-day inpatient requirement, such changes may persuade Congress to amend that requirement to include observation status and possibly emergency room care.” Congress has yet to pass such an amendment, the court pointed out.
Although the court said it did “not take lightly the plaintiffs’ concern that the Secretary’s current interpretation of ‘inpatient’ has created confusion among those trying to determine whether SNF care is covered or that changes in medical care have altered the circumstances under which that rule is applied,” it nonetheless found that plaintiffs’ arguments essentially amounted to asking “the court to make a policy judgment that [was] not within its purview.” *Landers v. Leavitt*, No. 3:04-cv-1988 (JCH) (D. Conn. Sept. 1, 2006).

**U.S. Court In Pennsylvania Finds Nonprofit Hospital Merger Was Not A Related-Party Transaction**

A nonprofit hospital’s merger with a health system was not a related-party transaction because cross-over board members did not exert “significant” control over the new combined entity, a federal trial court in Pennsylvania ruled September 29, 2006. Because of competitive pressure in the Philadelphia healthcare market, nonprofit Jeanes Hospital decided to affiliate with other hospitals and began discussions with several health systems. Jeanes Hospital eventually entered into a merger agreement with Temple University Health System, Inc. and various associated entities (Temple). The merger agreement called for members of Jeanes Hospital’s Board to be appointed to a foundation that would name twenty directors to the new entity’s board. The Jeanes Hospital Board members that transferred over to the surviving entity constituted 47% of the voting positions.

At the time of the merger, Jeanes Hospital’s net book value was $98,708,000 while the total value of Temple’s assumption of the hospital’s liabilities and additional consideration totaled $69,214,000. In its terminating cost report, Jeanes Hospital claimed reimbursement from Medicare for a “loss-on-sale” totaling $16,338,246 in depreciation payments. The fiscal intermediary determined the merger was a transaction among related parties, citing Jeanes Hospital’s continued participation in the surviving entity, and that therefore it was not a bona fide sale of assets.

The U.S. District Court for the Eastern District of Pennsylvania concluded that substantial evidence did not support the Centers for Medicare and Medicaid Services Administrator’s determination that the merger was a related-party transaction and was not a bona fide transaction because Jeanes Hospital board members did not have “significant” control of the new entity. The court stressed that the former Jeanes Hospital board members had only a minority of votes on the new board. In addition, Temple assumed day-to-day operational control, including approving all operating and capital budgets, negotiating managed care contracts, and conducting labor negotiations. The court also noted that Jeanes Hospital comprised only one subsidiary in the larger hospital system operated by Temple and that the cross-over board members' control must be evaluated in the context of the overarching parent corporation. *Jeanes Hosp. v. Leavitt*, No. 04-CV-395 (E.D. Pa. Sept. 29, 2006).

**U.S. Court In Massachusetts Defines “Average Wholesale Price” Under 1998 Medicare Part B Statute**
A federal trial court in Massachusetts issued a ruling November 2, 2006 in the ongoing class action concerning the average wholesale price (AWP) of drugs paid by Medicare beneficiaries and third-party payors, holding that under the 1998 Medicare statute, the AWP calculation should account for discounts and rebates. Three certified classes of plaintiffs sued forty-two pharmaceutical defendants, arguing they inflated the AWP in violation of state consumer protection laws. In the first phase of the litigation, involving four defendants, the parties filed cross motions for summary judgment asking the court to define AWP under the 1998 Medicare statute as a matter of law. A limited number of prescription drugs are covered under Medicare Part B. The government reimburses healthcare providers up to 80% of the allowable cost of these drugs, with the Medicare beneficiary paying the other 20% as a copayment.

According to the U.S. District Court for the District of Massachusetts, AWP should be interpreted in accordance with its plain language meaning. Consulting the dictionary, the court found that one problem is discerning whether the AWP accounts for discounts and rebates. Department of Health and Human Services regulations issued in 1991 indicated that the government intended to get the benefit of rebates and discounts by surveying actual invoice prices, the court noted. Thus, the meaning of AWP under the 1998 Medicare statute included discounts and rebates. Finally, the court cautioned that its ruling did not extend to the interpretation of AWP under the 2003 Medicare statute, by which time AWP had become a term of art as evidenced by Congress’ reduction of reimbursement to 85% of the AWP during the phase-in of a new pricing system. In re Pharmaceutical Industry Average Wholesale Price Litig., No. 01-12257-PBS (D. Mass. Nov. 2, 2006).

Eleventh Circuit Finds DHHS May Require Submission Of Evidence Beyond Certificate Of Medical Necessity To Show That DME Is Medically Necessary

In determining whether a submitted claim for durable medical equipment (DME) is covered by Medicare Part B, the Department of Health and Human Services (DHHS) Secretary may require a DME supplier to submit additional evidence beyond a certificate of medical necessity (CMN) to prove that the DME is medically reasonable and necessary, the Eleventh Circuit ruled November 3, 2006. An audit of the DME supplier in this case, Gulfcoast Medical Supply Inc., revealed that a number of the patients for whom Gulfcoast had submitted claims criteria for Medicare reimbursement did not meet the necessary criteria. A Medicare carrier audit revealed that a number of beneficiaries’ records did not support the services provided or did not need a power wheelchair. The carrier ultimately concluded Gulfcoast had been overpaid by $280,573.68.

Following administrative appeals, a federal district court upheld the overpayment assessment. The Eleventh Circuit affirmed, rejecting Gulfcoast’s argument that because it had submitted a CMN signed by a physician for each of the claims at issue, the carrier lacked the discretion to deny such claims on the basis of additional evidence. Noting that the question of law at issue was one of first impression, the appeals court found that the Medicare statute does not unambiguously preclude DHHS from requiring a supplier to submit information beyond a CMN to prove medical reasonableness and necessity. Further, Gulfcoast failed to refer to any other section of the Medicare Act “that states, or
even suggests, that the Secretary may not require that a supplier supplement a CMN with other documentation,” the appeals court noted. *Gulfcoast Med. Supply Inc. v. Department of Health and Human Servs.*, No. 05-16935 (11th Cir. Nov. 3, 2006).

**Second Circuit Vacates Ruling In Prolonged Investigational Device Coverage Litigation, Finds 1986 Medicare Policy Manual Provision Arbitrary And Capricious**

The Department of Health and Human Services (DHHS) cannot seek recoupment of Medicare payments made to a hospital for implantable cardiac devices used during a clinical trial because a subsequent policy manual provision that required premarket approval of investigational medical devices for coverage altered historical practice and therefore was arbitrary and capricious, the Second Circuit ruled November 16, 2006 in the long-running dispute. In 1986, Medicare reimbursement manuals issued to fiscal intermediaries announced that Medicare Part A would cover only those medical devices with Food and Drug Administration (FDA) premarket approval for commercial distribution. Prior to 1986, Medicare coverage guidelines for investigational medical services directed intermediaries to determine coverage based on whether the professional medical community generally accepted the device as an effective and proven treatment for the beneficiary’s condition. DHHS Secretary Michael O. Leavitt sought recoupment from Yale-New Haven Hospital (Yale) to recover $1.5 million paid on behalf of forty-eight Medicare beneficiaries who received implantable cardioverter-defibrillator devices (ICDs) in the course of clinical trials between 1994 and 1995. The FDA had granted Investigational Device Exemptions (IDEs) for the devices, but had not granted premarket approval.

The Second Circuit ruled that the Secretary adopted the 1986 Manual Provision in an arbitrary and capricious manner. Rejecting the Secretary’s contention that the Manual Provision did not constitute a new position, but merely expressed Medicare’s historical de facto practice, the appeals court emphasized the distinction between the discretion previously conferred on fiscal intermediaries and the per se rule under the Manual Provision. “[E]ven if the 1986 Manual Provision was merely interpretive in nature, and therefore lacked the force of law over the agency, it operated with nearly undiminished force on beneficiaries because it was binding on the fiscal intermediaries who paid for treatment.” The appeals court went on to determine that the Secretary failed to explain why the 1986 Manual Provision adopted the FDA premarket approval standard, emphasizing that “reasonable and necessary” services under the Medicare statute do not equate to “safe and effective” devices under FDA standards. The appeals court also highlighted legislative history suggesting that Congress wanted Medicare beneficiaries to have access to care suited to their individual needs, including innovative treatments. Noting a legislative preference to afford coverage in the absence of a substantial reason to the contrary, the appeals court ruled that the 1986 Manual Provision was the type of policy choice that the agency was required to explain. Thus, because the Secretary’s recoupment efforts relied on an invalid and unenforceable rule, the appeals court remanded the case to the district court, with instructions to adjudicate Yale’s claims under the rules in place when Yale submitted the claims, without reference to the 1986 Manual Provision. *Yale-New Haven Hosp. v. Leavitt*, Nos. 05-1224-cv-LEAD, 05-1434-cv-XAP (2d Cir. Nov. 16, 2006).
U.S. Court In California Allows Dual Eligibles’ Part D Dispute To Proceed

A group of dual eligibles who are suing the Bush Administration over the transition of their prescription drug coverage from Medicaid to Medicare Part D won a partial victory December 18 when a federal court in California ruled eight of the individual plaintiffs could go ahead with their claims. At the same time, the court dismissed the claims brought by four organizational plaintiffs, finding they lacked standing to sue on their own behalf or on behalf of their members.

The lawsuit stems from problems involved in switching dual eligibles, in many cases automatically, from Medicaid to Medicare Part D when the prescription drug program went live January 1, 2006. According to the complaint, the Department of Health and Human Services (DHHS) failed to implement “uniformly and properly” the auto-enrollment requirement; failed to inform Part D plans on a timely basis of auto-enrolled beneficiaries; and failed to process changes in plan enrollment adequately when dual eligibles switched drug plans. The DHHS Secretary, who was named in the suit, moved to dismiss on grounds of standing and mootness.

The U.S. District Court for the Northern District of California refused to dismiss the action as to eight plaintiffs at the current stage of the litigation, although it cautioned that its ruling did not mean these plaintiffs had necessarily established standing. The court first noted that plaintiffs’ allegations of stress and anxiety arising from the problems with their prescription drug coverage could potentially serve to satisfy the injury-in-fact requirement for standing. As to causation and redressability, the DHHS Secretary argued that plaintiffs’ alleged injuries, including being overcharged for medication or premiums and being unable to obtain medication, were attributable to others’ conduct such as private insurance plans and plaintiffs themselves. Rejecting this argument, the court noted that the Centers for Medicare and Medicaid Services (CMS) ultimately was responsible for the auto-enrollment process and other aspects of implementing Medicare Part D such as the Low Income Subsidy program. Plaintiffs’ injuries therefore may be traceable to actions CMS did or did not take, the court concluded. The court also rejected the DHHS Secretary’s mootness argument, finding it failed to meet the “stringent” burden of demonstrating that the “allegedly wrongful behavior could not reasonably be expected to recur.” Situ v. Leavitt, No. C06-2842TEH (N.D. Cal. Dec. 18, 2006).

In a subsequent decision on January 12, 2007 the federal district court granted in part a motion to certify the lawsuit as a class action. The court defined the class to include “full benefit dually eligible Medicare beneficiaries who have not received full benefits of Medicare Part D prescription drug coverage or the Low Income Subsidy program” because of the problems with inadequate enrollment processes enumerated in the complaint. To be considered part of the class, a beneficiary must have lodged a complaint about enrollment difficulties with the Centers for Medicare and Medicaid Services (CMS), a state, or a Part D plan. Situ v. Leavitt, No. C06-2841 THE (N.D. Cal. Jan. 12, 2007).
U.S. Court In Tennessee Rejects MSP Action By Individual Claiming Standing As Qui Tam Relator

The U.S. District Court for the Middle District of Tennessee dismissed January 17, 2007 an action against a health system under the Medicare Secondary Payer (MSP) statute by a private individual who sought to establish standing as a qui tam relator suing on behalf of the government. Rejecting the plaintiff’s claims, the court held that the MSP does not permit a private qui tam action on behalf of the government. The court also said the action warranted dismissal because it was based on the alleged negligence of the health system's hospitals in treating Medicare patients that had not yet been established.

Douglas B. Stalley sued Sumner Regional Health Systems, Inc. alleging it and ten “John Doe” defendants, which included some insurance companies, caused harm to Medicare beneficiaries who were patients at Sumner’s hospitals. Stalley, who purported to sue on behalf of the United States, contended that when Sumner negligently injured these Medicare patients, it triggered liability under the MSP statute on behalf of defendants as primary payors to pay or reimburse Medicare for any bills incurred or conditional payments made as a result. According to Stalley, Medicare advanced millions of dollars in payments for the cost of treating Medicare patients who were injured by Sumner’s negligent conduct. Stalley asserted that he came by this information through various incident reports and investigations, internal peer reviews, risk management programs, billing and diagnostic codes, and mandatory inspections and surveys.

The U.S. District Court for the Middle District of Tennessee granted Sumner’s motion to dismiss. The court noted that the MSP, which makes Medicare the secondary payor of medical services provided to Medicare beneficiaries when payment is available from another primary payor, creates a private right of action with double recovery for those who know of non-payment by primary plans to enforce Medicare’s rights. Stalley, who is not a Medicare beneficiary, argued he had standing to pursue the case on behalf of the federal government because the MSP is a qui tam statute that requires no personal injury. Rejecting this argument, the court held Stalley lacked standing to pursue the claims, concluding that the MSP does not allow for a private qui tam action but rather only a private cause of action for an individual who has been injured. In support of this conclusion, the court noted that the MSP’s private right of action provision does not have the substantive and procedural safeguards found in typical qui tam statutes like the False Claims Act. The court went on to say that Sumner was entitled to dismissal in any event for failure to state a claim on which relief could be granted because Stalley alleged “only an inchoate potential tort liability” not a “demonstrated obligation to pay.” Stalley v. Sumner Reg’l Health Sys., Inc., No. 2:06-0074 (M.D. Tenn. Jan. 18, 2007)

Other federal courts to consider similar claims brought in their jurisdiction likewise have rejected Stalley's standing under the MSP as a qui tam relator. See, e.g., Stalley v. Catholic Health East, No. 06-2491 (E.D. Pa. Jan. 30, 2007) and Stalley v. Delta Health Group, Inc., No. 8:06-cv-1436-T-23MAP (M.D. Fla. Jan. 26, 2007).
U.S. Court In Louisiana Finds Nursing Facility Was Properly Reimbursed Under PPS Methodology

The U.S. District Court for the Eastern District of Louisiana on February 27, 2007 affirmed a decision by the Centers for Medicare and Medicaid Services (CMS) that a skilled nursing facility (SNF) was properly reimbursed under the applicable Prospective Payment System (PPS) payment methodology, instead of under a cost-based system. The district court found that CMS’ decision, which was based on the conclusion that the SNF was a “separate provider” and not a subprovider of a hospital, was “supported by federal statutes and regulations, and thus, was not arbitrary and capricious.”

The plaintiff in the case, Community Care LLC, is a medical provider that includes a hospital with an SNF floor. Community Care opened the SNF floor in 1999, which was then certified by Medicare as an SNF with its own provider number on April 1, 1999. On April 10, 1999, the SNF admitted its first skilled nursing patient. Community Care later submitted to CMS’ fiscal intermediary its cost report for the reporting period April 1, 1998 through April 30, 1999. Federal regulations (42 C.F.R. § 413.1) provide that any SNF seeking reimbursement for services rendered after July 1, 1998 would be reimbursed under the PPS payment methodology. Under an exception, however, “existing entities whose cost reporting period began before the cut-off date, but extended beyond July 1, 1998, could receive [the higher] cost-based reimbursement for the entire period.”

The fiscal intermediary, with CMS’ approval, determined that, although Community Care’s cost reporting period began on April 1, 1998, the reporting period for its SNF (as a separate provider) began after July 1, 1998, and it should therefore be reimbursed under the PPS payment methodology. Community Care appealed this decision to the Provider Review Reimbursement Board (PRRB). The CMS Administrator subsequently reversed the PRRB’s decision, relying on a provision in the Medicare Provider Reimbursement Manual (PRM), Section 102, which explains that “a hospital-based SNF has the same cost reporting year end as the hospital . . . [but] the beginning of the [SNF’s] cost reporting period can be different in the case of a newly certified SNF provider.” The PRM also states that, in such instances, the start of the cost report period is necessarily controlled by when the SNF provider first rendered patient care services that could be covered by Medicare.

The court found the PRM provision on which CMS relied “does not, standing alone, support the conclusion that Community Care’s SNF is a separate provider.” Nonetheless, the court ultimately found that despite these flaws, “the statutory and regulatory background of the Medicare program provides sufficient basis for [CMS’] conclusion, such that the finding that Community Care’s SNF is a separate provider is not arbitrary or capricious under the Administrative Procedure Act.” Community Care LLC v. Leavitt, No. 05-3768 (E.D. La. Feb. 27, 2007).

U.S. Court In Arizona Finds Resident Research Time May Be Included In IME Reimbursement

A federal court in Arizona held March 21, 2007 that a hospital was entitled to Medicare reimbursement for resident time spent on research. The governing statute was
unambiguous and therefore the Centers for Medicare and Medicaid Services (CMS) Administrator’s impermissibly determined that time spent by a resident in research that was not associated with the treatment of a particular patient should be excluded, the court found. Plaintiff University Medical Center Corporation sought reimbursement from Medicare for indirect medical education (IME) for time spent by residents conducting research and other scholarly. Plaintiff’s fiscal intermediary excluded this time because the research rotations did not involve patient care. The negative reimbursement impact of this exclusion was approximately $428,626. Plaintiff appealed to the Provider Reimbursement Review Board (PRRB), which ruled in plaintiff’s favor. The CMS Administrator reversed.

According to the statute, a resident must be assigned to “the portion of the hospital subject to the prospective payment system” or to the outpatient department in order to be included in IME. See 42 C.F.R. § 412.105(f)(1)(A) (1999). Plaintiff contended that “portion” is a geographical term, and thus all residents assigned to the hospital are included, but defendant argued that “portion” is an ambiguous term which implies, or can be construed to imply, a direct patient care requirement, the court explained. The court agreed with the Ninth Circuit’s construction of a similar regulation, which found the limitation “unambiguously geographical.” Thus, the residents’ research time should be included in IME, the court concluded. University Med. Ctr. Corp. v. Leavitt, No. 05-CV-495 TUCJMR (D. Ariz. Mar. 21, 2007).

U.S. Court In Washington Says DHHS’ Methodology Used In Calculating Rural Residency Programs’ GME Expenses Was Unlawful
A federal trial court in Washington found the methodology the Department of Health and Human Services (DHHS) used in calculating Medicare reimbursements for graduate medical education (GME) expenses of certain hospitals’ rural residency programs was unlawful and had to be set aside. In 1986, Congress changed the methodology under which Medicare reimburses participating hospitals for GME expenses. Among the factors used in the new calculation is the hospital’s per resident amount (PRA), which is determined using 1984 cost reports as the “base year.” For hospitals that did not have a GME program in 1984, Congress instructed the DHHS to base its calculations on “comparable programs.”

The regulation DHHS finalized in 1989 provided that the Centers for Medicare and Medicaid Services (CMS) would assign PRAs to hospitals with GME programs established after 1984 using the lower of the hospital’s actual costs or the mean of the PRAs of all other hospitals in the same geographic area. See 42 C.F.R. § 413.86(e)(4)(i)(B). When a hospital was located in a geographic wage area with less than three teaching hospitals, the regulation provided that CMS’ Central Office would determine the hospital’s PRA. In these cases, the Central Office applied a “sequential geography methodology,” which involved looking to larger and larger geographic areas until it identified three or more hospitals with base year PRAs to average into a mean. The sequential geography methodology ultimately was not adopted in a subsequent final regulation DHHS issued in 1997. Five not-for-profit hospitals that operated residency
training programs in rural family medicine brought the action challenging the 1989 regulation and the sequential geography methodology.

The U.S. District Court for the Eastern District of Washington upheld the 1989 regulation, but found the sequential geography methodology was arbitrary and capricious and therefore unlawful. The court concluded that the methodology “lack[ed] the force of law” and therefore was “entitled to deference only to the extent” it had the power to persuade. See *Skidmore v. Swift & Co*, 323 U.S. 134 (1944). Applying *Skidmore*, the court found the sequential geography methodology unpersuasive. The court said the record failed to show DHHS, in formulating the methodology, thoroughly considered the facts and relevant law or the unique position of hospitals in rural areas with less than three teaching hospitals. Moreover, “[n]othing in the 1989 regulation suggests that contiguous wage areas are necessarily similar. . . . It seems that HHS was more concerned with mechanically applying a readily available formula than with ensuring that the PRAs of more isolated hospitals were based on those of truly ‘comparable’ facilities,” the court said. Finally, the court held the challenged methodology was inconsistent with the 1989 regulation “because it resulted in PRAs that bore no relationship to Plaintiffs’ actual costs” and failed to take into account that the residency programs at issue were “uniquely expensive to operate.” *Providence Yakima Med. Ctr. v. Leavitt*, No. CV-03-3096-FVS (E.D. Wash. Mar. 29, 2007).

**D.C. Circuit Vacates Injunction Ordering DHHS Secretary To Return Beneficiaries’ Repayments Of Erroneously Refunded Part D Premiums**

The D.C. Circuit held April 17, 2007 that the U.S. District Court for the District of Columbia lacked jurisdiction to consider a claim that Part D participants who received erroneous premium refunds were entitled to a waiver of repayment. Because the plaintiffs never presented that claim to any concerned government agency, judicial review was precluded, the appeals court said. In addition, the appeals court found that, although the district court did have jurisdiction to review a second claim under a different statute requiring written notice of the beneficiaries’ right to seek a waiver, that claim lacked merit.

In August 2006, the Social Security Administration (SSA) wrote a letter to 230,000 Medicare Part D beneficiaries telling them that it would no longer deduct Part D premiums from their monthly benefits and informing each recipient that they would be receiving a check for a specified amount. In early September, after realizing the payments were made in error, the Secretary of the Department of Health and Human Services (DHHS) requested repayment of the funds by the end of that month. The Action Alliance of Senior Citizens and the Gray Panthers (collectively Alliance), both advocacy organizations whose membership includes many Part D participants, filed suit in district court seeking injunctive, declaratory, and mandamus relief on statutory and constitutional grounds. The district court judge ordered the Secretary to give back the erroneous payments to Part D participants who had repaid them and to notify all recipients of a right to request a hardship waiver. On October 4, 2006, the District of Columbia Circuit granted DHHS’ emergency motion for stay pending appeal.
The D.C. Circuit found the district court lacked jurisdiction because the Alliance failed to exhaust administrative remedies by presenting its claim to the Commissioner of Social Security before seeking review. The appeals court also found Alliance’s claim under 42 U.S.C. § 1395gg, involving the provision of written notice of rights to seek waiver of repayments, did not apply to erroneous refunds of Medicare premiums. Action Alliance of Senior Citizens v. Leavitt, No. 06-5295 (D.C. Cir. Apr. 17, 2007).

U.S. Court In Minnesota Dismisses Claims Against Device Manufacturer
A federal court in Minnesota dismissed various claims against a device manufacturer that made and sold allegedly defective devices, finding plaintiffs lacked standing to bring some claims, and for others failed to state a valid claim. Guidant Corporation manufactured, marketed, and sold pacemakers and implantable cardioverter defibrillators (ICDs). Some of these items were eventually recalled. Plaintiffs alleged that Guidant was aware of a short-circuiting failure with one of its ICDs, the VENTAK PRIZM 2 DR, Model 1861, as early as February 2002, but did not inform the Food and Drug Administration (FDA), doctors, patients, or the public of the problem until May 2005. After the ICDs were recalled, Guidant told patients that it would pay for certain out-of-pocket costs and, if needed, a new Guidant ICD, but it did not offer to reimburse for expenses covered by Medicare or a patient's health insurance and incurred in connection with the recalled ICDs or the replacement ICDs. Three individual device recipients, one plaintiff under the Medicare Secondary Payer (MSP) statute, and third-party payors (TPP) (collectively plaintiffs), sued Guidant. Guidant moved to dismiss on the basis that the MSP and TPP plaintiffs did not have standing to pursue their claims and failed to state a claim upon which relief could be granted.

The U.S. District Court for the District of Minnesota granted the motion. The court first considered whether Tamela Ivens, a Medicare beneficiary, had standing under the MSP. Ivens argued that she had Article III standing to bring suit even though she lacked any injuries from her ICD because the MSP, like the False Claims Act (FCA), partially assigns the government's claims to relators. In rejecting that argument, the court found that “[u]nlike the FCA, the MSP does not unambiguously indicate that Congress, expressly or by implication, assigned any individual the right to bring suit on behalf of all Medicare beneficiaries.” Thus, the court dismissed the MSP claims.

The court next turned to the TPP claims, finding plaintiffs lacked standing to assert seven of their claims, specifically those involving state consumer protection statutes, warranties, and misrepresentation by omission. The court found no standing under Article III because the payors had no direct injury. The court rejected plaintiffs’ argument that they suffered an ecumenical injury by paying for the ICDs for their plan members, finding no evidence that plaintiffs “agreed to pay for the devices at issue and related costs based on their relationship with Guidant or representations Guidant made.” Instead, the court found the plaintiffs were contractually bound to pay for the devices. In re Guidant Corp. Implantable Defibrillators Prod. Liability Lit., MDL No. 05-1708 (DWF/AJB) (D. Minn. Apr. 16, 2007).
U.S. Court In Ohio Says DHHS’ Refusal To Reclassify Hospital In Different MSA Was Reasonable
A federal trial court in Ohio found April 23, 2007 that action taken by the Department of Health and Human Services (DHHS) Secretary resulting in a hospital being classified in a different Metropolitan Statistical Area (MSA) with lower Medicare reimbursement rates was not arbitrary or capricious. In 2003, plaintiff St. Vincent Mercy Medical Center, a tertiary-care hospital in Toledo, Ohio, sought and obtained a reclassification for purposes of its wage index to the Ann Arbor, Michigan MSA, which allowed it to receive a higher reimbursement rate for its Medicare patients. At that time, St. Vincent met the regulatory proximity and comparable-cost requirements for the reclassification. In a final rule issued August 4, 2004 (69 Fed. Reg. 48916), the DHHS Secretary adopted new MSA definitions, which were later challenged and upheld by the Second Circuit in Bellevue Hosp. Ctr. v. Leavitt, 443 F.3d 163 (2006). The final rule included transition periods to help some hospitals that were reclassified because of the changes adjust to lower reimbursement rates. For example, the rule provided a three-year transition period in fiscal years 2005, 2006, and 2007 for urban hospitals that became “rural” under the new MSA definitions for purposes of their wage index.

As a result of the MSA changes, St. Vincent no longer qualified for reclassification to the Ann Arbor MSA because Lenawee County, which was the reason St. Vincent’s met the proximity test, was re-designated to a rural geographic area. Because of this “newly rural” designation, all the hospitals located in Lenawee County were entitled to the three-year transition period under the final rule. St. Vincent challenged the implementation of the new hospital labor market classification rules, arguing that the Secretary acted arbitrarily and capriciously by precluding St. Vincent from being reclassified to the Ann Arbor MSA.

After rejecting the Secretary’s procedural arguments, the U.S. District Court for the Northern District of Ohio held “it was reasonable for the Secretary to provide newly-rural hospitals with a transition period,” but not to do so for other hospitals. The court therefore rejected St. Vincent’s argument that it was arbitrary and capricious to provide Lenawee County hospitals with a three-year transition period but not allow plaintiff use of the geographic boundary of Lenawee County for its proximity determination during that same period. The court did not view the longer transition period granted newly rural hospitals as favoritism, noting these hospitals would see the most drastic cuts to their wage indices. According to the court, St. Vincent was essentially seeking individualized treatment, but asking the agency to take into account the specific fiscal impact on every hospital in the United States would be impractical. St. Vincent Mercy Med. Ctr. v. Leavitt, No. 3:05 CV 7485 (N.D. Ohio Apr. 23, 2007).

PATIENT SAFETY

JCAHO Announces 2007 Patient Safety Goals
On June 12, 2006, The Joint Commission (TJC) announced its 2007 National Patient Safety Goals for each of its accreditation programs and its disease-specific care certification program. One significant change is the extension of a requirement that
accredited organizations define and communicate the means by which patients and their families can report safety concerns across all TCJ accreditation and certification programs, according to the news release. The requirement, which was first applied in 2006 in the home care, laboratory, assisted living, and disease-specific care programs, is the “central expectation” of a specific goal—“to encourage patients’ active involvement in their own care as a patient safety strategy,” TJC explained. In addition, a new requirement specifies that behavioral healthcare organizations, including psychiatric hospitals and general acute-care hospitals treating patients for behavioral disorders, must now identify patients at risk for suicide, according to TJC. A corresponding new requirement for home healthcare organizations specifies that these organizations must now identify the risks associated with long term oxygen therapy, such as home fires. There is also new language in one of two requirements under the existing goal pertaining to medication reconciliation that certain accredited organizations must now provide a complete list of current medications to each patient upon discharge.

Compliance with the requirements is a condition of continuing accreditation or certification for Joint Commission-accredited or certified organizations and programs. TJC released goals for ambulatory care and office-based surgery, assisted living, behavioral healthcare, home care, hospitals and critical access hospitals, laboratories, long term care, home health, and its disease-specific care certification program.

**JCAHO Announces New Patient Safety Initiatives**
The World Health Organization (WHO) Collaborating Centre on Patient Safety (led by The Joint Commission (TJC), the World Alliance for Patient Safety, and the Commonwealth Fund announced December 4, 2006 a seven-country initiative implementing five standardized patient safety solutions to prevent avoidable catastrophic events in hospitals. The project—dubbed “high 5s”—aims to “achieve significant, sustained, and measurable reduction or elimination of five highly prevalent patient safety problems in selected hospitals in each country over a five-year period,” TJC said. The five protocols are: prevention of patient care hand-over errors; prevention of wrong site/wrong procedure/wrong person surgical error; prevention of continuity of medication errors; prevention of high concentration drug errors; and promotion of effective hand hygiene practices.

**PHYSICIANS**

_Credentialing and Peer Review_

**Rhode Island Supreme Court Says Hospital Must Produce Records That Did Not “Originate” With Peer Review Committee**
Documents that did not “originate” with a peer review committee are not protected from discovery by the statutory peer review privilege, the Rhode Island Supreme Court ruled June 16, 2006. Fred Pastore died after receiving care at Kent County Memorial Hospital. Pastore’s daughter, Margaret Pastore (plaintiff), in her capacity as administrator of his estate, sued her father’s treating physicians and the hospital for medical malpractice. Plaintiff also asserted a negligent credentialing claim against the hospital. During
discovery, plaintiff sought documents relating to the credentialing or privileges of the physicians, documents sent to the physicians by any committee investigating or reviewing their request for or renewal of privileges, and all items limiting the physicians' privileges.

With respect to the peer review privilege, the Rhode Island Supreme Court said the documents at issue were not shielded from discovery except for one report summarizing a hospital committee meeting on whether the physician deviated from the standard of care. The high court at the outset reaffirmed its previous decisions holding that the statutory peer review privilege protects “only the records and the proceedings which originate with the peer-review board,” despite the hospital’s urging to “revisit” these rulings. (Emphasis added.) The report in question, which summarized a hospital meeting involving whether the physician responded in a timely manner to a patient who needed care, qualified as a “record” of a peer-review board protected from discovery by the peer-review privilege. The high court noted, however, that portions of the document, such as any that placed restrictions on the physician’s emergency room privileges, were discoverable so long as the record was redacted to “cloak the summary of key items discussed in the meeting.”

The high court also noted that the peer review privilege is not incompatible with a negligent credentialing cause of action, as one of the defendant physicians contended. Specifically, the high court said that a plaintiff asserting a negligent credentialing claim is entitled to discover patient complaints, even when those complaints lead to peer review proceedings, as well as any information regarding restrictions on a physician’s license. This type of information can then form the basis of a negligent credentialing claim. Pastore v. Samson, No. 2004-110-M.P. (R.I. June 16, 2006).

California Supreme Court Holds Hospital Could File Anti-SLAPP Motion To Strike Complaint Arising From Peer Review Proceedings

A hospital being sued by a staff physician who its peer review committee summarily suspended was entitled to file a motion to strike the complaint under the state’s anti-SLAPP (strategic lawsuit against public participation) statute, the California Supreme Court held July 20, 2006. In so holding, the high court found that a hospital’s peer review proceeding was an “official proceeding authorized by law” and therefore qualified for the special motion to strike applicable to harassing lawsuits brought to challenge the exercise of constitutionally protected free speech rights. A peer review committee at Northern Inyo Hospital in California summarily suspended the staff privileges of Dr. George Kibler for “unprofessional conduct of extremely hostile and threatening verbal assaults, threats of physical violence, including assault with a gun, and related erratic actions . . .” Kibler sued the hospital and various physicians and nurses for defamation, abuse of process, and interference with his medical practice. The hospital moved to strike Kibler’s complaint as a SLAPP suit, i.e. one brought solely to harass them.

The high court found the hospital peer review proceeding was an “official proceeding authorized by law” as contemplated in the anti-SLAPP statute, noting that under California law hospitals must include in their bylaws a provision for conducting peer review and sets forth other obligations on granting and renewing a physician’s staff
privileges—all of which “[p]lay a significant role in protecting the public against incompetent, impaired, or negligent physicians.” Moreover, the high court said, the legislature has accorded a hospital’s peer review decisions a status comparable to that of quasi-judicial public agencies whose decisions are reviewable by administrative mandate. *Kibler v. Northern Inyo County Local Hosp. Dist.*, No. S131641 (Cal. July 20, 2006).

**U.S. Court In Pennsylvania Finds Hospital Has HCQIA Immunity From Suspected Physician’s Antitrust And Breach Of Contract Claims**

A Pennsylvania hospital and its peer review committee are immune under the Health Care Quality Improvement Act (HCQIA) from antitrust and breach of contract claims brought against them by a physician whose privileges were suspended based on the committee’s recommendations, a federal district court in that state ruled August 24, 2006. The U.S. District Court for the Middle District of Pennsylvania granted the motion for summary judgment filed by the hospital and individual peer review committee members on grounds of HCQIA immunity. The court also granted defendants’ motion for summary judgment based on its finding that the physician failed to establish his other claims alleging antitrust violations, tortious interference with contract, and breach of contract.

The physician, Ayodeji O. Bakare, is a board certified obstetrician-gynecologist (OB/GYN) licensed by the state of Pennsylvania. Bakare had unrestricted staff privileges at Pinnacle Health Hospitals Inc., a subsidiary of Pinnacle Health System (PHS), and/or its predecessors from 1987 through August 2002. In December 1999, the Quality Assurance (QA) Committee of Pinnacle’s OB/GYN Department began reviewing the charts for a number of Bakare’s patients, and ultimately identified him as “falling outside the standard of care” for the Department. Subsequently, in April 2002, Pinnacle’s medical executive committee (MEC) formally initiated an investigation into the quality of care issues involving Bakare, and eventually voted to suspend his clinical privileges. At the time of his suspension, PHS and Hamilton Health Center (HHC) were engaged in preliminary merger discussions.

The district court held defendants were entitled to immunity, finding that Bakare “failed to adduce any evidence from which a jury could reasonably conclude that MEC’s corrective action against him was not taken ‘in reasonable belief that the action was in the furtherance of quality health care’” as required by the HCQIA. Finding that Pinnacle and its MEC met all other requirements specified in the HCQIA, the district court therefore concluded Bakare failed to overcome the presumption that immunity was conferred by that Act on the hospital and its peer review committee, as well as on individual peer review committee members.

The district court also found Bakare failed to establish his antitrust claims against PHS, Pinnacle, and individual members of the MEC. “In an attempt to demonstrate antitrust injury, . . . Bakare suggests that he was suspended to facilitate the proposed combination between PHS’s and HHC’s OB/GYN services . . . [a] suggestion [that] is pure speculation . . . [and] unsupported by evidence of record,” the court said. Moreover, “[o]ther than the temporal proximity of his suspension to the preliminary merger discussions between [the other hospital] and Pinnacle, . . . Bakare has not produced any
evidence to link these two events. That Pinnacle and Hamilton were negotiating a potential combination at the time of his precautionary suspension does not automatically convert the suspension into a deliberate act in furtherance of the combination,” the court said. *Bakare v. Pinnacle Health Hosps. Inc.*, No. 1:03-CV-1098 (M.D. Pa. Aug. 24, 2006).

**U.S. Court In Texas Says Physician Must Accept Reduced Damages Or Face New Trial In Credentialing Case Against Hospital**

A federal district court in Texas ruled September 18, 2006 that a physician who won a landmark $366 million jury verdict against a hospital that suspended his privileges could agree to a reduced damages award of $22 million or face a new trial. The court said while the jury’s punitive and actual damages awards were excessive and therefore required a remittitur, they were not the “product of passion or prejudice” such that the only option was to order a new trial. Dr. Lawrence R. Poliner and his professional association sued Presbyterian Hospital of Dallas and several other physicians, including cardiologists that served on various hospital peer review committees, (collectively defendants) after his privileges were summarily suspended. Poliner claimed defendants improperly and maliciously used the peer review process to interfere with his interventional cardiology practice. A jury found in favor of Poliner and awarded him compensatory and exemplary damages of over $366 million.

In March 2006, the U.S. District Court for the Northern District of Texas denied defendants' motion for a new trial, finding defendants were not entitled to peer review immunity and that sufficient evidence supported the jury verdict. The court did find that, while the jury awarded separate amounts for his contract and tort claims, Poliner’s recovery was limited under the one-satisfaction rule because he suffered the same injuries for all his causes of action—namely loss of earnings, mental anguish, and damage to his reputation. Thus, the court said it would only award judgment on the defamation claim, which afforded the greatest recovery. The court at that time decided not to address the question of whether the damages award was appropriate and instead ordered the parties to further mediate the issue.

In its latest decision on defendants’ motion for remittitur, the court upheld the jury’s $10,526.55 award for lost earnings against each defendant, but found the other damages awarded were excessive. The court went on to identify the maximum verdict supported by the evidence as $21 million in actual damages and $1.54 million in punitive damages. *Poliner v. Texas Health Sys.*, No. 3:00-CV-1007-P (N.D. Tex. Sept. 18, 2006).

**U.S. Court In Kansas Rejects Physician's Discrimination, Antitrust Claims Against Hospital Following Denial Of Medical Staff Reappointment**

A Kansas federal trial court granted summary judgment against a physician who argued that his dismissal from a hospital medical staff constituted race discrimination under Title VI of the Civil Rights Act of 1964 and 42 U.S.C. § 1981; conspiracy to discriminate under 42 U.S.C. § 1985; an antitrust violation under § 1 of the Sherman Act; and retaliatory discharge under state whistleblower protections. After the hospital governing board (Board) denied his application for reappointment to the medical staff, the
physician, Pitt Vesom, M.D., sued Atchison Hospital Association (AHA), along with three physicians who served on the Medical Executive Committee (MEC).

Finding no Kansas authority on whether hospital bylaws create an enforceable contract between a hospital and its medical staff, the U.S. District Court for the District of Kansas reviewed the split of authority in other jurisdictions and elected to follow the "better-reasoned" line of cases holding that hospital bylaws do not create a contract. In doing so, the court emphasized language in the AHA medical staff bylaws, which stated both that medical staff privileges are not a right and that staff members are not entitled to continued staff privileges. Without a contract, Vesom could not prove a prima facie case under Title VI and § 1981.

Even if Vesom had stated a valid claim, the court continued, defendants offered a legitimate nondiscriminatory reason for refusing reappointment—that he had a history of disruptive behavior. Vesom countered that that the stated reason was merely a pretext for discrimination, but the court found he did not prove a pretext because the evidence did not link any racial discrimination to the reappointment decision. Similarly, the court continued, because Vesom did not raise a genuine issue of material fact that would lead a reasonable factfinder to conclude that defendants based the decision to deny reappointment on "invidiously discriminatory animus," the physician's § 1985 claim also failed.

As to his claims under the Sherman Act, with no evidence that the Board failed to act independently, Vesom did not create an issue of fact as to whether concerted action occurred. Further, without evidence that the decision not to reappoint him affected prices or quality of goods and services, the court decided that Vesom did not establish the existence of an antitrust injury under the Sherman Act.

Under Kansas law, retaliation against whistleblowers is an actionable tort, the court acknowledged. Vesom, however, was an employee neither of AHA nor of defendants. Finding that the state law exception to the at-will employee doctrine does not apply to independent contractors such as Vesom, the court ruled against the physician on his whistleblowing claim as well. *Vesom v. Atchison Hosp. Ass'n*, No. 04-2218-JAR (D. Kan. Sept. 22, 2006).

**U.S. Court In West Virginia Says Hospital Entitled To HCQIA Immunity From Physicians’ Claims**

A hospital was entitled to statutory immunity under federal law from civil liabilities alleged by a physician whose privileges had been suspended, a federal trial court in West Virginia ruled September 29, 2006. The court also rejected the physician’s contract and civil rights claims, to which immunity under the Health Care Quality Improvement Act (HCQIA) did not apply, finding no contract existed between the parties and that the hospital offered a legitimate, non-discriminatory reason—health and safety concerns—for its actions.
Rakesh Wahi, M.D., a licensed physician in West Virginia who specializes in cardiovascular, thoracic, and general surgical procedures, sued Charleston Area Medical Center (CAMC) after it suspended him from its medical staff. According to Wahi, CAMC’s chief of staff appointed an "investigative" committee to evaluate his performance that included five members who were in direct competition with him at the time the committee was formed. Wahi sued CAMC and several other healthcare providers (defendants) alleging, among other things, antitrust violations, breach of contract, and various civil rights claims.

In an earlier decision, the U.S. District Court for the Southern District of West Virginia dismissed some of Wahi’s claims but allowed him to amend the complaint. The court here first concluded that CAMC was entitled to immunity under HCQIA from civil liability for all counts except Wahi’s contract and civil rights claims. As a threshold issue, the court held the hospital’s activities giving rise to the lawsuit qualified as a professional peer review action regardless of how they were conducted because they involved Wahi’s competence and whether he would be allowed to maintain his privileges. According to the court, Wahi failed to rebut the presumption of HCQIA immunity under the four-prong “objective reasonableness” test, noting “overwhelming” evidence that CAMC’s actions were taken in the reasonable belief of furthering quality healthcare; that CAMC made a reasonable effort to obtain the facts given its extensive investigations of the matter; that CAMC provided Wahi with adequate process; and that the hospital had a reasonable belief that the action was warranted.

The court also granted CAMC summary judgment on Wahi’s breach of contract claim, finding the medical staff bylaws did not constitute a contract between CAMC and Wahi under West Virginia law, and his discrimination claims, holding Wahi failed to show the hospital’s legitimate, non-discriminatory justifications for its actions were pretextual. Wahi v. Charleston Area Med. Ctr., No. 2:04-cv-00019 (S.D. W.Va. Sept. 29, 2006).

U.S. Court In New York Dismisses Physician's HCQIA And RICO Claims Against Hospital That Terminated His Privileges
A federal trial court recently dismissed a physician's claims that a hospital violated the Health Care Quality Improvement Act of 1986 (HCQIA) and the Racketeer Influenced and Corrupt Organizations Act (RICO) when it summarily suspended and later terminated his privileges. Jay Mitchell Bauman, M.D. a solo practitioner, board certified in obstetrics and gynecology, sued Mount Sinai Hospital after it terminated his labor and delivery privileges citing patient care concerns. Bauman had held privileges at the hospital over his entire career and had been disciplined several times and required to comply with corrective action and additional monitoring. The lawsuit alleged violations of HCQIA and RICO, among other state law fraud and defamation claims. Defendants moved to dismiss, arguing that the court lacked jurisdiction because New York law requires any physician challenging the termination of hospital privileges to file a complaint with the state Public Health Council (PHC) before seeking redress in the courts.
The U.S. District Court for the Southern District of New York agreed. "[A] federal
district court must refrain from hearing a damages claim by a physician where the
legitimacy of the termination of the physician's privileges is dispositive and the claim has
not first been filed before the PHC," the court stated. Although Bauman's HCQIA and
RICO claims did not directly challenge the termination of his privileges, these claims
disputed the basis for his suspension. Further, the HCQIA and RICO claims did not
constitute an exception to the PHC requirement because the inherent patient care
concerns invoked the PHC's expertise, and because the presence or absence of medical
reasons for the action against Bauman's privileges was dispositive. Finding no evidence
that the investigation lacked good faith, and that the statements made in the challenged
documents were "undeniably true," the federal court granted defendants' motion to
dismiss. Bauman v. Mount Sinai Hosp., No. 05 Civ. 7126(D.C.) (S.D.N.Y. Sept. 29,
2006).

**Pennsylvania Appeals Court Finds Billing Manager's Presence At Peer Review
Meetings Does Not Affect Applicability Of State's Peer Review Law**

A state trial court erred in concluding that Pennsylvania’s peer review law did not protect
from discovery certain peer review documents used by an ambulatory surgery center’s
peer review committee because a billing manager—a non-"health care provider"—was
present during the review process, an appeals court in that state ruled October 12, 2006.
David Piroli was administrator of the estate of Cathy Piroli, who died after undergoing a
surgical procedure performed by Dr. Mark R. LoDico at Three Rivers Endoscopy Center
(TRE). In the subsequent wrongful death action, Piroli alleged that LoDico punctured
Cathy Piroli’s left vertebral artery while injecting an epidural steroid, and that this error
caused her death. During the course of discovery in the wrongful death action, Piroli filed
a notice of his intention to serve a subpoena on TRE that would request a “complete
copy” of any documents about the investigation of the quality of care for Cathy Piroli,
“including but not limited to letters, medical report . . . [and] medical records.” LoDico
objected to the subpoena, arguing that some of the requested materials were protected
from discovery under Pennsylvania’s Peer Review Protection Act (PRPA), 63 Pa. Cons.
Stat. §§ 425.1-425.4. The trial court subsequently overruled LoDico’s objections,
concluding the peer review proceedings at issue were not protected by the PRPA because
TRE’s billing manager—an individual other than “professional health care providers” as
defined by the PRPA—was present at the relevant peer review committee meetings.

On appeal, the Superior Court of Pennsylvania rejected this argument, concluding that the
“trial court’s decision conflicts with the legislative intent underlying the [PRPA].”
The appeals court highlighted testimony from TRE’s executive director confirming that
TRE formed an ad hoc peer review committee to review the care LoDico rendered to
Piroli. The committee consisted of several physicians, nurses, TRE’s executive director,
and TRE’s billing manager. “[T]he review process that [TRE’s executive director]
described fits within the statute’s definition of peer review . . . [i]n deed, the documents
generated by the committee . . . were used solely by the . . . committee to evaluate the
quality of care rendered by Dr. LoDico,” the appeals court said.
The appeals court rejected the lower court’s conclusion that the PRPA’s definition of peer review as a “procedure for evaluation by professional health care providers” means that only healthcare providers could be included on the peer review committee. “The mere fact that the billing manager was present, in addition to the health care professionals, on the ad hoc committee should not serve to eviscerate the protections that the legislature intended the PRPA to provide,” the appeals court said. *Piroli v. LoDico*, No. 1695 WDA 2005 (Pa. Super. Ct. Oct. 12, 2006).

**Missouri Appeals Court Upholds Finding Of HCQIA Immunity For Physician Who Prompted Hospital To Review Another Physician’s “Medical Necessity” Decisions**

A Missouri trial court properly concluded that the physician-director of a hospital’s cardiac catheterization laboratory (cath lab) was entitled to immunity under the Health Care Quality Improvement Act (HCQIA) after he accused a cardiologist of performing medically unnecessary procedures, a Missouri appeals court ruled October 31, 2006. The Missouri Court of Appeals therefore upheld the trial court’s grant of summary judgment, on HCQIA immunity grounds, in favor of the physician-director in a case brought by the cardiologist (and his group practice) who alleged the director’s actions in writing letters to hospital executives and other staff resulted impaired the group’s business relationships.

Dr. William Wright, who became the cath lab director at St. Anthony’s Medical Center in 1998, sent a letter in January 2004 to St. Anthony’s President and CEO objecting to the director proposed to succeed him at the end of his term—Dr. Bassam Al-Joundi, who worked in a group practice, Gateway Cardiology P.C. In his letter to St. Anthony’s CEO, as well as to other members of the hospital staff, Wright expressed his concerns regarding the medical necessity of certain procedures performed by one of the other cardiologists at Gateway, Dr. Nazir Assi. These members of the hospital staff then formed an ad hoc committee to consider Wright’s claims, concluding that none of the identified procedures performed on specified patients were medically unnecessary. Following further proceedings, Assi, Al-Joundi, and Gateway sued Wright, alleging that his claims amounted to an accusation of billing fraud that impaired plaintiffs’ relationships with St. Anthony’s.

The appeals court rejected plaintiffs’ contention that Wright’s accusations of billing fraud fell within the meaning of HCQIA § 11151(9), otherwise known as the “physician’s fees exception,” and therefore did not constitute a protected “professional review action” based on the competence or professional conduct of a physician as provided by the statute. According to the appeals court, “the record very clearly convinces us that the activities in questions were concerned primarily with the ‘competence or professional conduct of a physician.’” The appeals court also rejected plaintiffs’ argument that the ad hoc committee was not a “professional review body” within the meaning of HCQIA, finding ample support that it met the HCQIA definition. Finally, the trial court did not err because it failed to analyze whether Wright personally satisfied requirements set forth in § 11112(a) of HCQIA by holding a “reasonable belief” that his conduct was in “furtherance of quality health care” and engaging in a “reasonable effort to obtain the facts of the matter.” Plaintiffs “improperly focus on Dr. Wright’s conduct alone,” rather

**Florida Appeals Court Holds State Agency May Subpoena Peer Review Records During Physician Investigation**

The Florida Department of Health can issue a subpoena for otherwise privileged peer review records to further a disciplinary investigation of a physician who surrendered his hospital privileges, a Florida appeals court ruled December 27, 2006. A physician, referred to as John Doe in the appeals court’s opinion, resigned his staff privileges at a Florida hospital in May 2005. As required by Florida law, the hospital notified the Department of Health that Doe had surrendered his privileges during an ongoing investigation concerning his professional competence. The Department began investigating Doe and sought through a subpoena certain peer review records from the hospital. Doe sought to quash the subpoena, arguing the records were privileged under the state’s peer review statute. The Department refused to quash the subpoena and Doe appealed in court.

The Florida District Court of Appeal, Second District, refused to quash the subpoena. The appeals court recognized an apparent conflict between Florida statutes contemplating the Department’s access to certain peer review records for purposes of a physician disciplinary investigation and those shielding peer review documents from public disclosure. Under Florida’s peer review statutes, “investigations, proceedings, and records” of a peer review committee “shall not be subject to discovery or introduction into evidence in any civil or administrative action against a provider . . .” The appeals court noted, however, that applying the literal meaning of the peer review statute would lead to the unreasonable result of substantially impeding the Department’s statutorily authorized disciplinary process. Thus, the appeals court said the peer review protection must be read to exclude the Department’s physician disciplinary proceedings. *Doe v. Department of Health*, No. 2D06-1273 (Fla. Dist. Ct. App. Dec. 27, 2006).

**North Dakota Supreme Court Upholds Medical Board’s Revocation Of Physician’s License, Refusal To Allow Monitoring**

The North Dakota State Board of Medical Examiners (Board) did not abuse its discretion in revoking the license of a physician and refusing to implement a supervision plan as alternatively recommended by an Administrative Law Judge (ALJ), the state’s high court ruled January 23, 2007. Reversing a lower court’s ruling, the high court declined to second guess the Board’s decision where the evidence did not suggest that it acted inappropriately.

The Board revoked Dr. George S. Hsu’s medical license after concluding that he had engaged in a continuing pattern of inappropriate patient care. The Board in its final decision rejected an ALJ’s recommendation for monitoring, citing the seriousness of the departure from the standard of care based on the cumulative evidence presented at two separate hearings; Hsu’s prior behavior, including chronic substandard record keeping; and that Hsu’s attitude and other factors made monitoring unworkable.
The North Dakota Supreme Court concluded that the Board did not abuse its discretion in revoking Hsu’s license and therefore reversed the trial court’s decision in this respect. The high court first found that the preponderance of the evidence standard of proof for physician disciplinary proceedings did not offend due process or equal protection as Hsu argued. While acknowledging that a physician’s property interest in a medical license was not “insubstantial,” the high court nonetheless found the state’s interest in protecting its citizens’ health and welfare was paramount.

Hsu also argued that the use of the preponderance of the evidence standard violated equal protection, noting North Dakota imposes a more rigorous clear and convincing standard of proof for attorney disciplinary proceedings. But the high court found the adversarial role in which attorneys are often placed justified the higher standard of proof to "weed out unwarranted complaints by unhappy litigants."

The high court also determined that the Board adequately explained its reasons for departing from the ALJ’s recommendation to allow for ongoing monitor instead of immediately revoking Hsu’s license. According to the high court, the Board was entitled to rely on the cumulative effect of the two disciplinary proceedings and its own expertise in concluding Hsu’s conduct reflected a serious departure from the standard of care. 


U.S. Court In Louisiana Says Physician’s Summary Suspension Did Not Violate Due Process Where Patient Safety At Issue
A post-suspension hearing satisfied due process where a hospital district summarily suspended a physician’s privileges based on patient safety concerns, a federal trial court in Louisiana ruled January 21, 2007. Dr. Charles Reed sued Franklin Parish Hospital Service District d/b/a Franklin Medical Center, a political subdivision of Louisiana, under 42 U.S.C. § 1983 alleging his procedural due process rights were violated when the hospital suspended his privileges without providing a pre-suspension hearing. The hospital, which moved for summary judgment, argued a pre-suspension hearing was not required because it believed he posed a risk to patient safety.

The U.S. District Court for the Western District of Louisiana granted summary judgment to the hospital. The court noted that a post-suspension remedy satisfies due process where a physician’s privileges are summarily suspended under exigent circumstances, making the relevant inquiry whether the hospital had reasonable grounds for suspending him as a danger to patient safety. The court concluded that the hospital’s decision was objectively reasonable given the serious nature and number of patient complaints against Reed, noting also that the hospital sought to substantiate these concerns by consulting two independent physicians. Reed v. Franklin Parish Hosp. Serve. Dist., No. 04-1481 (W.D. La. Jan. 29, 2007).

Massachusetts High Court Finds Physician Suspended For Disruptive Behavior Not Entitled To Discovery Of Peer Review Documents
A physician whose surgical privileges at a Massachusetts hospital were summarily suspended after he engaged in disruptive behavior at a meeting was not entitled to
discovery of documents that were generated as part of the peer review process triggered by his suspension, the highest court in that state ruled February 27, 2007. Dr. William Vranos, a partner in an orthopedic group practice and also chief of the Department of Surgery at Franklin Medical Center (FMC), engaged in a heated argument with FMC’s director of surgical and material services, Kenneth Gaspard, over a new policy that would restrict the availability of surgical services. The argument took place during a regularly scheduled meeting of the surgical support services committee. After the meeting, Gaspard reported to FMC’s president, Michael D. Skinner, that he had been physically threatened and verbally abused by Vranos at the meeting, and that he had been afraid that Vranos might hit him. Prior to this incident, Skinner had been engaged in a series of conversations with Vranos in an attempt to persuade him to leave his group practice and establish a competing orthopedic practice at FMC. However, Vranos ultimately accepted a similar recruitment offer from a hospital that was less than twenty miles from FMC.

The day after the meeting at issue, Skinner gave Vranos a notice of summary suspension, effective immediately. The notice charged him with engaging in threatening behavior and indicated that he had a “history of disruptive behavior . . . [and] unprofessional conduct . . . at FMC.” FMC subsequently convened a peer review committee to consider the terms of Vranos’ suspension. Skinner was a member of the committee, along with other FMC officers and staff members. After conducting its review of the incident, the committee recommended (and the FMC Board approved) reinstating Vranos subject to three conditions: that he resign as chief of surgery, that he apologize to Gaspard, and that he seek anger management counseling. Although Vranos accepted these terms and returned to work, he later sued FMC, Skinner, and Gaspard for defamation. In the course of discovery, Vranos requested material prepared for the peer review committee considering his suspension (e.g., incident reports, committee minutes, narrative statements, and other documents). Defendants objected to the majority of Vranos’ document requests on the basis of the peer review privilege. The state trial judge, however, ultimately granted in part Vranos’ motion to compel discovery.

Under Mass. Gen. L. ch. 111, §§ 204(a) and 205(b), “weighty protection” is provided to a medical peer review committee’s work product and materials, the Massachusetts Supreme Judicial Court said. The high court acknowledged that, under Mass. Gen. L. ch. 231, § 85N, the subject of a medical peer review is permitted to pierce the statutory privilege “to establish a cause of action against the member of a peer review committee for the member’s failure to act in good faith.” This exception, however, “must be construed narrowly,” the high court said. Quoting from Pardo v. General Hosp. Corp., 446 Mass. 1 (2006), the high court explained that the exception “operates to invade the peer review privilege only ‘on some threshold showing that a member of the committee did not act in good faith in connection with his activities as a member of the committee,’” such as not fully or honestly disclosing the facts of a case to a committee so as “to mislead the committee in some manner.”

In applying this exception to the facts of the case, the high court found that Vranos failed to submit any verified evidence supporting his claims that Skinner, a member of the peer review committee, acted in bad faith. “Vranos has failed to point to any evidence of
misconduct within the peer review process (which, in fact, resulted in the lifting of Vranos’s summary suspension),” the high court continued. Instead, Vranos presented only unverified claims of Skinner’s prior animus toward him, the high court concluded, noting that “such suspicions . . . are insufficient to pierce the thick armor of . . . [peer review] privilege.” Vranos v. Franklin Med. Ctr., No. SJC-09797 (Mass. Feb. 27, 2007).

Illinois Appeals Court Finds Hospital’s Staffing Decisions Not Reviewable
The doctrine of nonreview bars a court from hearing an orthopedic surgeon’s claims against a private hospital and its orthopedic surgical staff based on allegations that the hospital denied him emergency room trauma cases and access to residents to assist him in surgery, an Illinois appeals court ruled February 20, 2007. The appeals court explained that “as a matter of public policy internal staffing decisions of private hospitals are not subject to judicial review,” with the exception of cases in which the physician’s staff privileges have been revoked, suspended, or reduced. In this case, the appeals court noted, the surgeon conceded that his privileges were never adversely affected.

Robert S. Goldberg, an orthopedic surgeon and member of the medical staff at Rush University Medical Center (Rush), repeatedly complained to the chairman of Rush’s orthopedic surgery department and other staff members about his assignments and treatment as a member of the medical staff. Goldberg initiated a formal grievance under Rush’s bylaws. A five-member grievance committee dismissed several of Goldberg’s complaints because he did not allege they affected his practice or had not been grieved within thirty days as required by the bylaws. Goldberg then filed an action in state court, seeking damages for tortious interference with contractual relations and prospective economic advantages and for breach of contract. Goldberg alternatively sought injunctive relief. Rush and the individual co-defendants moved to dismiss the action, asserting, among other things, that under the doctrine of nonreview, the conduct underlying Goldberg’s claims was not subject to judicial review. The circuit court ultimately agreed and granted defendants’ motion to dismiss.

The Appellate Court of Illinois, First District, explained that the doctrine of nonreview in cases involving hospital staffing decisions “reflects the unwillingness of the courts to substitute their judgment for that of hospital officials with superior qualifications to consider and decided such issues.” The appeals court rejected Goldberg’s argument that the nonreview doctrine only applied to staffing decisions involving hospital appointments and privileging. “The power to manage the affairs of a private hospital necessarily must include the discretion to make routine clinical staffing assignments and allocation of resources and personnel,” the appeals court said, and under the doctrine of nonreview, such decisions “are entitled to deference from the courts.” Goldberg v. Rush Univ. Med. Ctr., No. 04 L 12403 (Ill. App. Ct. Feb. 20, 2007).

Tennessee Appeals Court Holds Physician May Not Shield Patient Records From Medical Board’s Review
Physicians in Tennessee have no reasonable expectation that they can shield their patients’ records from the regulatory oversight of the state’s medical board, a Tennessee appeals court ruled March 13, 2007. Accordingly, a physician who refused to comply
with the board’s lawful request for his patient records was properly subject to discipline, the appeals court found.

As part of an investigation, the Tennessee Board of Medical Examiners (Board) issued written requests to Frank McNiel, a family practitioner specializing in pain management, for thirty of his patient records (only four of which included signed patient releases). Under state law, the Board has the authority to obtain patient records through a written request from healthcare providers being investigated for potential wrong doing. *See* Tenn. Code Ann. § 63-1-117. Signed patient releases must accompany the request unless certain specific conditions are met—namely, that the request identifies the patients by name; is made in good faith; and contains a signed certification by an “independent reviewer” that the request is being made in response to a verified complaint. McNiel refused to hand over the records and initiated a court challenge, arguing the statute was unconstitutional because it amounted to an unreasonable search and seizure and did not provide a pre-enforcement judicial review of reasonableness. The trial court struck down § 63-1-117, concluding that the statute unconstitutionally coerced physicians into complying with requests for records by forcing them to run the risk of discipline if they refused.

The Tennessee Appeals Court reversed, upholding the statute. The appeals court recognized that patients’ interests in the privacy of their medical records and physicians’ legitimate interests in practicing free from unreasonable government interference must be balanced against the state’s compelling interest in protecting the public’s health and safety and establishing appropriate professional licensing standards. The appeals court concluded that the statutory scheme, which requires good cause to examine the records and that the records sought are necessary to investigate a complaint, provided sufficient safeguards to protect patients’ privacy interests. The appeals court also held the statute was not unconstitutionally coercive. “[W]e find no constitutional infirmity in a statute that permits a licensing board to discipline a licensee who willfully refuses to comply with a lawful request for records.” According to the appeals court, without disciplinary sanctions, “a licensing board’s investigation could easily be thwarted by a licensee” to the detriment of the Board’s ability to protect the health and welfare of Tennessee’s citizens. *McNiel v. Cooper*, No. M2005-01206-COA-R3-CV (Tenn. Ct. App. Mar. 13, 2007).

**California Appeals Court Says Physicians Must Exhaust Administrative Remedies Before Seeking Review Of Procedural Ruling**

A group of physicians must exhaust their administrative remedies before challenging in court a hospital Medical Executive Committee’s (MEC’s) refusal to consolidate eight individual disciplinary hearings involving the same matter, a California appeals court ruled May 2, 2007. The dispute involved eight unidentified physicians whose medical group provided nearly all anesthesia services at the Washington Township Hospital (Hospital). The physicians gave the Hospital only two days notice that they were moving their practices to another hospital.

The MEC sought to discipline the physicians for their “precipitous withdrawal,” citing patient safety concerns. The MEC recommended that the Hospital Board terminate the physicians’ privileges and the physicians, per the medical staff bylaws, each requested a
Judicial Review Committee (JRC) hearing to dispute the recommendation. The physicians then asked that the hearings be consolidated. The MEC denied the request and appointed eight JRC panels and eight hearing officers. The physicians again moved to consolidate the hearings—seven of the hearing officers essentially refused, while one granted the motion. Because of the conflicting rulings, the hearings were not consolidated and the physicians sought a writ of mandate in court. The MEC argued that the physicians could not seek judicial relief because they had failed to exhaust their administrative remedies. The trial court granted the physicians’ petition.

The California Court of Appeal, First District, reversed, noting the exhaustion requirement applies in medical disciplinary hearings unless no administrative remedy is available or if pursuit of that remedy would result in “irreparable harm.” Here, the physicians had an administrative remedy—per the bylaws, a JRC decision was appealable to the Board, the appeals court noted. To the extent the trial court found the physicians had no administrative remedy because the bylaws did not provide for review of the JRC decisions on the threshold consolidation issue, this position was “untenable” in light of applicable case law, the appeals court said. According to the appeals court, the common law did not require such “interim review procedures.” The physicians could appeal the final JRC decisions and this was an adequate available remedy. The court must not “intervene in the incomplete administrative proceedings and micromanage a process entrusted in the first instance to hospitals and their self-governing medical staffs,” the opinion said. Under the bylaws, the physicians clearly could challenge on appeal any procedural rulings such as the consolidation issue if they were somehow prejudiced as a result.

The appeals court also found requiring exhaustion would not subject the physicians to irreparable harm. The physicians argued that, because they lacked subpoena power, they may be unable to marshal necessary witnesses for all the hearings. But this potential problem would be faced equally by parties on both sides, the appeals court said. The appeals court also was not persuaded by the physicians’ argument that the cost of defending themselves in all eight hearings was prohibitive and would total over $1 million, while a consolidated hearing would only cost $150,000 to $200,000. “The expenses the physicians seek to avoid are ‘normal incidents’ of the administrative process, and they are not excepted from the exhaustion requirement by their failure to receive a group discount,” the appeals court held. *Eight Unnamed Physicians v. Medical Executive Committee of the Med. Staff of Wash. Township Hosp.*, No. A113456 (Cal. Ct. App. May 2, 2007).

*Practice Issues*

**Hawaii Supreme Court Allows Action Alleging Insurer Systematically Reduced, Denied Network Physicians’ Claims**

A physician association could proceed with an action on behalf of itself and its members alleging an insurer systematically reduced and denied claims for medically necessary healthcare services provided by network physicians, the Hawaii Supreme Court ruled September 8, 2006. The case arose as two separate actions against Hawaii Medical
Service Association (HMSA), one brought by the Hawaii Medical Association (HMA) on its behalf and on behalf of its 1,600 physician members who participate in HMSA’s network, and the other filed by two individual physicians. Both actions asserted HMSA state law claims of unfair methods of competition and tortious interference with economic advantage. According to plaintiffs, HMSA delayed, impeded, denied, or reduced reimbursement owed to HMA’s physician members for medically necessary healthcare services thereby causing them substantial injury.

Consolidating the actions on appeal, the Hawaii Supreme Court ruled that plaintiffs’ claims did not fall within the scope of the dispute resolution provision contained in the provider agreement and thus the lower court erred in compelling arbitration. The arbitration clause at issue specified that it covered “any and all claims, disputes or causes of action arising out of . . . or in any way related to this Agreement or its performance.” While at first blush this would seem to encompass all disputes, the high court said the clause in the context of the whole contract did not control here because plaintiffs brought their claims as a collective group rather than as individuals. “Indeed, as the plaintiffs argue—and we agree—the necessary system-wide relief could never be granted in an individual proceeding where the specific issue being addressed is one isolated decision or a series of decisions relating to one physician,” the high court noted.

The high court also found that HMA had standing at this stage of the litigation to sue on behalf of its members for declaratory and injunctive relief because its member physicians had standing to sue in their own right; the interests at stake were germane to HMA’s purpose; and HMA’s request for declaratory and injunctive relief would not require an inappropriate level of individual participation as it focused on systemic practices and methods used to make reimbursement decisions. The high court did agree that HMA lacked standing to sue for monetary damages as this would require an inappropriate level of individual participation. The high court also concluded that HMA had standing at this stage to sue on its own behalf, citing as a cognizable injury the HMA’s claims that it had devoted substantial resources to dealing with the fallout of HMSA’s allegedly unfair and deceptive practices.

The high court agreed with the lower court that plaintiffs were barred from asserting claims of unfair competition methods before June 28, 2002, when the relevant Hawaii statute was amended to create a private claim for relief that did not previously exist. But the high court said the circuit court erred in dismissing plaintiffs’ post-June 28, 2002 claims on the ground they were not competitors of, or in competition with, HMSA. The high court further held that plaintiffs sufficiently alleged claims of unfair methods of competition based on conduct that could otherwise support claims of unfair or deceptive acts or practices. The high court also concluded that plaintiffs’ tortious interference claim should not have been dismissed. Hawaii Med. Ass’n v. Hawaii Med. Serv. Ass’n, Inc., Nos. 25923, 25924 (Hawaii Sept. 8, 2006).
California Appeals Court Rules Fraud Indictments Do Not Preclude Enforcement Of Hospital's Relocation Agreement Against Physician
A physician who breached a relocation agreement with a Tenet Healthsystem hospital was liable for damages, despite criminal prosecutions alleging that other similar relocation agreements violated the federal Anti-Kickback Statute, a California appeals court ruled in an unpublished decision. Dr. Soodabeh Abravesh, M.D. entered into an employment contract with an obstetrics and gynecology practice. The practice would pay Abravesh a salary and he would assign all professional fees to the practice, including any monies received from Lakewood Regional Medical Center, a Tenet hospital (hospital). The employment contract also required Abravesh to sign a relocation agreement with the hospital. Under the relocation agreement, the hospital paid Abravesh’s relocation and marketing expenses and she agreed to maintain a full-time practice within the hospital's service area for three years. The relocation agreement also included a liquidated damages provision, requiring Abravesh to pay back all funds distributed under the relocation agreement if she breached that agreement.

The practice terminated the employment contract. Abravesh sought, but did not find a new job in the hospital's service area. After Abravesh moved and established a new practice, the hospital sued her for breach of the relocation agreement. The trial court issued summary judgment in the hospital's favor. On appeal, Abravesh argued that the relocation agreement was invalid because it violated the Anti-Kickback Statute. Abravesh cited criminal prosecutions against Tenet Healthsystem for entering into other similar relocation agreements. In one indictment, prosecutors alleged that Tenet used relocation agreements to obtain referrals for Tenet hospitals by passing relocation funds through the relocating doctors to their practices, which then referred patients to the hospitals.

The California Court of Appeal held that Abravesh did not create a triable issue of fact. "A federal indictment involving other doctors and relocation agreements, with nothing more, does not establish that the Relocation Agreement at issue here was illegal because it violated the federal anti-kickback statute," the appeals court explained. Specifically, Abravesh did not produce evidence that the hospital and the practice entered into a conspiracy for referrals, or that the relocation agreement was in furtherance of that conspiracy. Abravesh also argued that the legal doctrine of impossibility excused her from complying with the relocation agreement, emphasizing that she diligently tried to find another job in the area. The appeals court acknowledged that performance of a contract is excused not only where it is impossible, but also where it is impracticable because of extreme expense. Nonetheless, the appeals court ruled that, "the mere fact that a third person will not cooperate in a party's attempt to perform a contract will not excuse performance." Tenet Healthsystem Hosps. v. Abravesh, B184561(Cal. Ct. App. Sept. 27, 2006).

Ninth Circuit Allows Physician To Proceed With Retaliatory Termination, Unfair Competition Claims Against IPA
A primary care physician could proceed with state law claims of retaliatory termination and unfair competition after an independent practice association that had filed for bankruptcy refused to extend his contract because it thought he ordered unnecessary treatments.
cardiac tests for patients, the Ninth Circuit ruled in a 2-1 decision. Chandrahas Agarwal, a primary care physician and certified cardiologist, entered into a provider agreement with Pomona Valley Medical Group, Inc., d/b/a ProMed Health Network (ProMed), an independent practice association in Southern California. The twelve-month agreement was extended automatically for an unlimited number of additional twelve-month periods unless ProMed provided written notice of non-renewal. Shortly after the first automatic renewal, ProMed voluntarily filed for bankruptcy under Chapter 11.

According to the opinion, ProMed began routinely denying authorizations for cardiology tests Agarwal requested, although it later authorized most of the procedures after he protested. ProMed then notified Agarwal that it was not renewing the agreement when it expired, citing his frequent ordering of “unnecessary tests” to increase his compensation. Agarwal brought adversary proceedings in bankruptcy court and ProMed moved to reject its executory contract with Agarwal and to dismiss his complaint. The bankruptcy court granted ProMed’s motions and Agarwal appealed in district court, which affirmed the bankruptcy court's decision.

The Ninth Circuit first held that the bankruptcy court did not err in finding ProMed properly rejected its executory contract with Agarwal. Under 11 U.S.C. § 365(a), a Chapter 11 debtor-in-possession may, subject to court approval based on the business judgment rule, reject any executory contract. Here, ProMed justified its business decision that, as part of its Chapter 11 reorganization, it was trying to reduce costs by eliminating those physicians from its network that it believed ordered unnecessary tests.

Turning to his state law claims, the appeals court concluded the bankruptcy court erred in dismissing Agarwal’s claim for retaliatory discharge in violation of Cal. Bus. & Prof. Code § 2056, which provides that physicians cannot suffer retaliation for advocating medically appropriate care for their patients, and his claim for unfair competition. For purposes of surviving a motion to dismiss, the complaint sufficiently alleged that Agarwal was terminated for ordering medically appropriate healthcare that made him “too expensive” and that he protested or appealed ProMed’s denials. In re Pomona Valley Med. Group, Inc., No. 04-56334 (9th Cir. Jan. 17, 2007).

**Eighth Circuit Says Surgery Practice Not Required To Indemnify Physician For Recruitment Loan**

A surgery practice in Arkansas was not required to indemnify a physician for a loan repayment obligation to a hospital that arose when he failed to meet the terms of a recruitment agreement, the Eighth Circuit ruled February 9, 2007. Baptist Health and Central Arkansas Vascular Surgery (CAVS) jointly hired Dr. Todd Smith to offer medical services with both institutions. Baptist Health agreed to provide Smith a loan to start his practice, which it would forgive if Smith practiced in Arkansas for six years. Smith expressed some concern about the agreement and Dr. Robert Casali, CAVS’ sole shareholder, sent Smith a letter stating that he would “not be responsible for repayment of any loan to Baptist Health Center in any form or fashion.”
After entering into the agreement, Smith practiced in Arkansas for two years and then left. Baptist Health sued Smith to recover the roughly $154,000 loaned to him. Smith filed a third-party complaint against CAVS and Casali, alleging Casali’s letter was an agreement to indemnify Smith against any obligations owed to Baptist Health. The district court entered judgment in favor of Baptist Health. The court also concluded the letter was an indemnity agreement, granted Smith summary judgment on his third-party complaint, and ordered Casali to indemnify Smith. Casali appealed.

The Eighth Circuit held that the three-sentence letter was not an indemnity agreement, finding no clearly expressed intent by Casali in the language to indemnify Smith. “Conspicuously absent is any reference to Dr. Casali assuming responsibility for Dr. Smith’s obligation,” the appeals court noted. Rather, the appeals court viewed the letter more as a “mere articulation” of Casali’s understanding of the Baptist Health agreement’s terms. *Baptist Health v. Smith*, No. 06-1601 (8th Cir. Feb. 9, 2007).

**Kansas Supreme Court Allows Patient's Consumer Protection Claim Against Physician Alleging Back Surgery Failed To Achieve Promised Results**

The Kansas Consumer Protection Act (KCPA) applies to a patient’s claim that her surgeon willfully misrepresented or concealed information about the success rate of back surgery he performed, the Kansas Supreme Court ruled February 9, 2007. The high court added that expert testimony would be needed to determine whether a reasonable medical practitioner under the same circumstances would have affirmatively disclosed his level of experience or success rate.

Tracy Williamson sued Dr. Jacob Amrani, an orthopedic surgeon, alleging he engaged in deceptive acts and practices in violation of Kan. Stat. Ann. § 50-626 and unconscionable acts and practices in violation of Kan. Stat. Ann. § 50-627 by representing that the back surgery he planned to perform on her had benefits that, in fact, it did not have. According to Williamson, Amrani represented the surgery he recommended was highly likely to relieve her back pain but in reality the surgery had been unsuccessful in most cases. Amrani moved for summary judgment, arguing the KCPA did not apply to a physician’s professional conduct in treating patients. A judge hearing the case concluded that summary judgment was appropriate, agreeing with Amrani that the KCPA did not apply.

On appeal, the Kansas Supreme Court reversed, finding the KCPA’s language broad enough to encompass the provision of medical care within the physician-patient relationship and noting that the statute did not specifically exclude certain persons or transactions from its scope. A physician is a “seller” or “supplier” of services; a patient is a “consumer” of those services; and the sale of those services is a “consumer transaction” as contemplated under the KCPA, the high court explained. The high court also rejected Amrani’s argument that Williamson was attempting to creatively plead what in fact was a medical malpractice claim and a physician’s duty of informed consent. According to the high court, nothing prohibited the legislature from creating a statutory remedy even where a common-law remedy also may be available. Finally, the high court concluded that expert testimony would be necessary to establish whether Amrani’s failure to affirmatively disclose his level of experience or success rate constituted a deceptive or
unconscionable act or practice under the KCPA. *Williamson v. Amrani*, No. 95,154 (Kan. Feb. 9, 2007).

**QUALITY OF CARE**

**Bush Signs Executive Order Requiring Federal Agencies To Increase Price And Quality Transparency**

President George W. Bush signed August 22, 2006 an executive order directing federal agencies that administer or sponsor a healthcare program to increase price and quality transparency by January 1, 2007. The order requires the agencies to collect and share with the public information about prices paid to healthcare providers and about the quality of services provided by doctors, hospitals, and other healthcare providers. The order specifies that the agencies must make available the prices paid for procedures by the agency, its health insurance issuers, or its health insurance plans. The agencies also must develop information regarding the overall costs of services for common episodes of care and the treatment of common chronic diseases. In addition, the order requires agencies and their healthcare contractors to promote the use of interoperable health information technology products, so that data can be easily shared and requires agencies to offer insurance options that reward consumers who exercise choice among health providers based on value and quality of care.

**Local Organizations Will Join Nationwide Quality Reporting System Under Leavitt Plan**

Department of Health and Human Services (DHHS) Secretary Michael Leavitt announced February 28, 2007 a plan to bring local quality improvement organizations into a nationwide system that would use nationally recognized standards to measure and improve quality of care in local areas. Under the plan, the agency would select qualified regional collaboratives to be chartered as “Value Exchanges” that would continue to focus on quality improvement and would provide public reports on the performance of providers in their area, according to DHHS’ press release. Leavitt’s plan is part of his Value-Driven Health Care Initiative, a public-private effort launched last year to improve quality and lower costs in healthcare delivery. The Value Exchanges would be independent, non-profit organizations. “Existing local and regional collaboratives that have developed independently in recent years would be expected to form the initial core of Value Exchanges” receiving DHHS charters, the release said.

**Joint Commission Releases Hospital Quality Report**

Although hospitals in the United States have significantly improved the quality of care for heart attack, heart failure, and pneumonia patients over the four-year period 2002-2005, more progress needs to be made on certain quality measures in these areas, according to a report released March 20, 2007 by the Joint Commission. For example, the report, *Improving America’s Hospitals: A Report on Quality and Safety* found overall hospitals achieved 90% performance or higher for about half the measures tracked from 2002-2005, but achieved less than 65% performance on two other measures tracked over the same time period (providing pneumococcal screening and vaccination to pneumonia patients and providing discharge instructions to heart failure patients).
The data in the report, which is based on the performance of the more than 3,000 hospitals accredited by the Joint Commission, also showed how hospitals have improved on fifteen individual measures of quality that have been tracked from 2002-2005. Seven of these fifteen measures applied to heart attack, four to heart failure, and four to pneumonia care. The report found that generally hospitals’ performance results, with few exceptions, improved consistently from year to year on all fifteen measures tracked from 2002-2005. The report noted that the largest and fastest improvement occurred in providing smoking cessation advice to pneumonia patients, rising to 80% performance in 2005 from only 37.2% in 2002.

The data revealed, however, “considerable variability” in the performance of hospitals by state on most quality measures. For example, the report found hospitals’ statewide performance on the measure of providing discharge instructions to heart failure patients ranged from 33.5% to 89% in 2005. The report also noted variability in hospital-by-hospital performance in treating particular conditions (i.e., some hospitals performed better than other for certain surgeries or medical treatments). Nonetheless, the data confirmed overall quality improvement among accredited hospitals, which “strongly supports continual measurement of hospital performance against standard measures, as well as the reporting of the performance results back to hospitals and the public,” the report said.

TAX

Ohio Attorney General Proposes New Rules For Charities
Ohio Attorney General Jim Petro has proposed new rules aimed at improving oversight and transparency of charitable organizations’ business practices in the state. According to Petro, the new charitable trust rules would clarify, with fewer exceptions, the registration requirements imposed on charitable organizations in Ohio. Exemptions from registration would be limited to governmental entities, organizations operated in schools, churches, certain financial trusts, some 501(c)(4) organizations, and non-Ohio entities. Charitable hospitals and 501(c)(4) healthcare organizations are not exempt from charitable trust registration, thus mandating that they file the initial charitable registration form, a summary of the proposal notes.

The rules also include suggested provisions prohibiting excessive compensation and mandate special procedures for compensation above thirty times minimum wages or above 10% of the charity’s gross annual revenues, according to the summary. The rules provide a standard format for charitable hospitals, nursing homes, health insurers, health maintenance organizations, health sharing organizations, and large charitable organizations to disclose annual community benefit information for comparison purposes, the summary indicates. The proposed rules further provide a recommended “Fair Billing and Debt Collection Practices Policy” for charitable hospitals and nursing homes to limit charges to moderate income uninsured patients above the rate charged to insurers, mandate humane collection practices, and require board oversight of collection practices.
Fifth Circuit Reverses Tax Court Decision Upholding Excise Taxes Imposed By IRS, Finding Numerous Errors In Tax Court’s Valuation Of Entity’s Assets

The Fifth Circuit reversed July 11, 2006 a decision of the U.S. Tax Court upholding an assessment of excise taxes made by the Internal Revenue Service (IRS). Citing numerous errors that required reversal, the appeals court found the IRS failed to meet its burden of proving that the taxes were correctly assessed. In addition, the appeals court said the Tax Court erred as a matter of law in selecting the method to value the assets and liabilities transferred and made clearly erroneous fact findings in applying that valuation method.

In 1995, the Caracci family transferred the assets of their tax-exempt home health businesses—known as the Sta-Home Health Agency, Inc. (Sta-Home)—to various nonexempt corporations they owned for a zero cash payment. In exchange for the transfers, the buyers assumed the liabilities that went with the assets. Contemporaneous appraisals performed in support of the conversion showed that the consideration for the assets—the agreement to assume the debts and liabilities—exceeded the value of the assets, which had been unprofitable for the previous five years.

The Commissioner of the IRS challenged the transfer of the home health businesses as an excess benefit of approximately $18.5 million. Based solely on that valuation analysis, the Commissioner concluded that the transfer provided an “excess benefit” to the newly created nonexempt corporations and the Caracci family, in violation of Internal Revenue Code (Code) § 4958. According to the IRS, the sale was inconsistent with the fair market value of the assets. The IRS issued deficiency notices, which asserted that the taxpayers owed excise taxes totaling $256,114,435.

Sta-Home and the Caraccis filed petitions in the Tax Court challenging the notices. In a seventy-one page opinion—the first applying the intermediate sanctions provisions of § 4958—the Tax Court upheld the IRS’ assessment of penalty excise taxes, but rejected the revocation of the Sta-Home entities’ tax-exempt status. See Caracci v. Commissioner, 118 T.C. No. 25 (May 22, 2002). The Tax Court found that the total excess benefit to the disqualified persons was approximately $5 million. In reaching this conclusion, the Tax Court performed a detailed review of the competing valuations, largely discounting the conclusions of the Caraccis’ expert due to inconsistencies, unrealistic assumptions or multiples, and ignoring or undervaluing significant intangible assets. Despite the prolonged loss history, the Tax Court found that the home health agencies had a net fair market value in excess of $5 million and ordered the taxpayers to pay $69,702,390 in excise taxes. The taxpayers appealed.

The Fifth Circuit reversed, finding “so many legal and factual errors—many of which the Commissioner acknowledges—infecting this case from the outset that reversal must result.” The appeals court first noted that the IRS issued the deficiency notices prematurely on an incomplete analysis of the transaction. It was not until opening statements in front of the Tax Court that the Commissioner acknowledged that the deficiency notices were excessive and erroneous, the appeals court said. “In a Tax Court deficiency proceeding, once the taxpayer has established that the assessment is arbitrary and erroneous, the burden shifts to the government to prove the correct amount of any
taxes owed,” the appeals court said. Portillo v. Comm’r, 932 F.2d 1128, 1133 (5th Cir. 1991). The Tax Court in this case did not shift the burden to the government, the Fifth Circuit found. Instead, the Tax Court rejected the testimony of the Commissioner’s valuation expert. Thus, the appeals court said, the Commissioner failed to meet his burden of proof. “At that point, the Tax Court should have found in the taxpayers’ favor. Its failure to do so was error, as a matter of law,” the appeals court held.

The appeals court also held that the Tax Court made various errors in the valuation method it selected and in the facts it found in selecting and applying that method. For instance, despite undisputed facts that Sta-Home had millions in debts and liabilities and operated at a loss for years, “the Tax Court’s valuation method used an invested-capital valuation method that compared the Sta-Home entities with solvent, publicly traded companies with significant equity and a present ability to generate profits,” the appeals court observed. The appeals court further concluded the Tax Court’s finding that Sta-Home had the ability to make a profit was clearly erroneous and not harmless error as the Commissioner argued. Sta-Home Health Agency v. Commissioner, No. 02-60912 (5th Cir. July 11, 2006).

Exempt Organization Reform Legislation Passes Senate
On August 3, 2006, the Senate passed the Pension Protection Act of 2006, which includes certain provisions applicable to tax-exempt organizations. The Senate did not make any changes to the bill passed by the House of Representatives on July 28, 2006. The provisions applicable to tax-exempt healthcare providers include: (1) an increase in the maximum penalty excise tax (intermediate sanctions) applicable to organization managers, (2) permitted disclosures from the Internal Revenue Service to state officials regarding charities, (3) public disclosure of Form 990-T (the unrelated business income tax return of exempt organizations), and (4) certain changes to the rules applicable to supporting organizations. President Bush signed the legislation into law on August 17, 2006 (Pub. L. No. 109-280).

Grassley Continues To Examine Nonprofit Hospitals’ Provision Of Charity Care
Senate Finance Committee Chairman Charles Grassley (R-IA) took the next step in his effort to examine the nonprofit hospital sector by convening a hearing September 13, 2006, Taking the Pulse of Charitable Care and Community Benefits at Nonprofit Hospitals, as well as releasing responses from ten nonprofit hospitals on Grassley’s 2005 query about their charitable activities. Grassley sent a letter May 25, 2005 to ten hospitals and health systems asking them to account for the charitable activities in which they engage. In the letter, Grassley asked the hospitals to provide specific information on charity care and community benefit, patient charges and debt collection, and ventures with for-profit organizations.

Expressing disappointment in the answers he received, Grassley said “[n]on-profit doesn’t necessarily mean pro-poor patient.” Grassley also noted major differences among hospitals in how charity care is determined and valued, who is eligible for charity care, and what constitutes community benefit and how it is measured. “Not only is there often very little difference between for-profit and non-profit hospitals when it comes to serving
the community, but also the release of the answers today shows that there appears to be very little difference on executive compensation,” Grassley commented.

During the hearing, Grassley commended the Catholic Health Association (CHA) for its guidelines on planning, measuring, and documenting community benefits. According to Grassley, CHA has provided “real leadership in establishing best practices for measurements and reporting for community benefits.” Following the hearing, Grassley directed his staff to develop proposals on ways to make sure nonprofit hospitals deliver their fair share of care to the poor. “Federal, state and local governments give nonprofit hospitals tens of billions of dollars each year in tax breaks,” Grassley said. “It’s our responsibility as the Senate committee in charge of taxes to understand what benefits these hospitals provide to the public in exchange for this special tax treatment.”

**Illinois Department Of Revenue Denies Nonprofit Hospital’s Property Tax Exemption Renewal**

The nonprofit hospital, Provena Covenant Medical Center (Provena), does not qualify for the charitable institution property tax exemption because the hospital failed to demonstrate it met the statutory requirement to use its property primarily for charitable purposes, according to a final administrative decision issued September 29, 2006 by the Illinois Department of Revenue (IDOR). The decision overturned a prior recommendation by an IDOR administrative law judge (ALJ) to grant Provena’s renewal application for tax-exempt status. The underlying dispute in this case arose in 2002 when Provena applied to the Champaign County Board of Review (Board) for renewal of its property tax exemption for the 2002 tax year. Provena, a nonprofit general acute care hospital, uses several parcels of real estate located in Urbana, Illinois for its facilities.

“The primary basis of my conclusion is simple: [Provena] Covenant admitted that its 2002 revenues exceeded $113,000,000 and that its charitable activities cost it only $831,724, or about .7% of total revenue,” the IDOR director wrote in his decision. Also noting that the property tax exemption Provena requested was worth over $1,100,000, the IDOR found that all of the financial figures taken together “fall far short” of showing that Provena met the requirement of using its property primarily for the purpose of charitable care. The IDOR director highlighted several other facts in support of his decision, including Provena’s referral of patients with unpaid charges to collection agencies, a practice “lacking in the warmth and spontaneity indicative of charitable impulse,” and “Provena’s failure to meaningfully publicize its charity care policies.” *Illinois Dep’t of Revenue v. Provena Covenant Med. Ctr.*, No. 04-PT-0014 (Final Administrative Decision, Illinois Dep’t of Revenue, Office of Admin. Hearings, Sept. 29, 2006).

**Illinois Appeals Court Says Community-Based Clinic Not Entitled To Property Tax Exemption**

In an October 19, 2006 decision, the Illinois Appellate Court, Third District, agreed with the Illinois Department of Revenue (Department) that a community-based primary care clinic in Rock Island, Illinois was not entitled to a property tax exemption. After the Department denied Community Health Care, Inc.’s (CHC’s) request for a property tax exemption in October 2003, CHC appealed to an administrative law judge (ALJ).
Upholding the Department’s decision, the ALJ concluded that CHC failed to demonstrate that “it qualified as a charitable organization” or that it used the property “exclusively” for charitable purposes. An Illinois trial court disagreed, and reversed the ALJ’s order.

Reversing the trial court’s ruling, the appeals court concluded that CHC’s primary use of its facility was not for its stated “charitable purpose” of providing discounted or free medical services to a medically under-served community. “By its own admission it uses the property for that purpose only 27 percent of the time. The remaining 73 percent of the time, CHC uses the property as a not-for-profit medical clinic,” the opinion said. The appeals court also found CHC’s evidence as to the level of its charitable operations at the clinic “speculative,” because it relied on “organization-wide financial data to extrapolate the patient and payor mix” at the Rock Island facility. “As the question of how much CHC uses the Rock Island facility for its ‘charitable purpose’ is, at best, ‘debatable,’ we must resolve the issue in favor of taxation,” the appeals court concluded. Community Health Care, Inc. v. Illinois Dep’t of Revenue, No. 3-06-0001 (Ill. App. Ct. Oct. 19, 2006).

Illinois Department Of Revenue ALJ Recommends Denying Property Tax Exemption For Nonprofit Provider Of Hospice Services

For the 2004 tax year, a nonprofit provider of hospice services does not qualify for the charitable exemption under Illinois’ property tax exemption statutes because it failed to demonstrate that it uses the property primarily for charitable purposes, an administrative law judge (ALJ) for that state’s Department of Revenue said October 16, 2006. In his recommended decision, the ALJ concluded that Palliative Care Center and Hospice of the North Shore (Palliative), a provider with facilities in Evanston and Glenview, Illinois, should not receive a property tax exemption for tax year 2004 for its Glenview facility. Because this facility was in the process of being constructed in 2004 and was operational beginning in 2005, Galvin used evidence primarily related to Palliative’s already existing facility in Evanston.

“Palliative’s primary purpose is providing hospice care for paying patients and Palliative earned almost $22 million in revenue from providing this service in 2004,” the ALJ said in his recommended decision. “No charitable hospice care was provided by Palliative during this period,” the ALJ found The ALJ also noted that “Palliative places several obstacles in the way of those seeking charitable benefits,” the most significant of which is Palliative’s failure to advertise its charitable policy. Palliative Care Ctr. and Hospice of the North Shore v. Illinois Dep’t of Revenue, No. 05-PT-0054 (IDOR Oct. 16, 2006).

CHA Form 990 Community Benefit Template

As tax-exempt hospitals continue to experience intense scrutiny from Congress and others, the concept of community benefit has taken center stage. The Catholic Health Association (CHA) has led the nonprofit hospital sector in exploring the contours of community benefit, including not only charity care, but the various other activities and measures undertaken by nonprofit hospitals to meet the needs of their communities. CHA recently published a comprehensive guidebook on developing, implementing, and reporting on community benefit programs. As a follow-up measure, CHA issued a new
resource to assist tax-exempt hospitals in identifying, describing, and quantifying community benefit. This new tool is a template by which hospitals can supplement their reporting in response to IRS Form 990, Part III. CHA is encouraging its members (almost all of which have committed to follow CHA’s community benefit reporting guidelines) to use this template in preparing and submitting their Internal Revenue Service information returns. However, the design and content of the template are by no means unique to Catholic hospitals; as such, all tax-exempt hospitals may find the template to be a helpful resource as they undertake future reporting of their community benefit activities.

CBO Finds Nonprofit Hospitals Average More Uncompensated Care Than For-Profits
Nonprofit hospitals on average provided higher levels of uncompensated than similar for-profit hospitals, although the provision of uncompensated care varied widely among individual hospitals, according to a new report issued by the Congressional Budget Office (CBO). The report, Nonprofit Hospitals and the Provision of Community Benefits, compares community benefits provided by nonprofit, for-profit, and nonfederal government hospitals in five states—California, Florida, Georgia, Indiana, and Texas—based on 2003 data. Because of data limitations, CBO examined uncompensated care in terms of both charity care and bad debt.

In its five-state analysis, CBO found that nonprofit hospitals provided a total of roughly $3 billion in uncompensated care, government hospitals provided more than $3 billion, while for-profit hospitals provided about $1 billion. The difference between uncompensated care provided by nonprofits and for-profits “is largely attributable to the fact that nonprofit hospitals accounted for a much larger share of the hospital market than did for profits,” the report said. With respect to other community benefits, the CBO analysis revealed that nonprofit hospitals provided care to fewer Medicaid-covered patients as a share of their total patient populations than for-profit hospitals. In terms of providing certain specialized services (intensive care for burn victims, emergency room care, high-level trauma care, and labor and delivery services) not typically considered financially profitable, CBO found nonprofit hospitals were more likely to provide these services than for-profit hospitals.

HFMA Releases New Accounting Guidelines For Reporting Charity Care And Bad Debt
The Healthcare Financial Management Association (HFMA) released December 4, 2006 revised accounting guidelines for healthcare providers to follow in measuring and reporting bad debt and charity care. HFMA’s Board of Directors approved the guidelines in the form of revised Statement 15: Valuation and Financial Statement Presentation of Charity Care and Bad Debt by Institutional Healthcare Providers, at its November 7, 2006 board meeting. Similar guidance, but with significant variation in level of detail and content, has been issued by the Catholic Healthcare Association (June 2006) and more recently by the American Hospital Association (November 2006).

In the introductory section of its revised Statement 15, HFMA concedes that “[a]ppropriate classification of charity care and bad debts is often difficult.” This is
because the urgency and complexity of some treatments, as well as certain federal regulations, often requires the provision of service without consideration of a patient’s ability to pay, according to the Statement. Further difficulties may arise, the Statement says, because of “complex billing and payment arrangements.” The introduction to revised Statement 15 clearly distinguishes between bad debt and charity care: “Bad debts result when a patient who has been determined to have the financial capacity to pay for healthcare services is unwilling to settle the claim, whereas charity care is provided to a patient with demonstrated inability to pay.”

The Statement also addresses the timing of charity care eligibility determinations, recommending that “providers make every practical effort to make charity care determinations before or at the time of service.” With regard to valuation of charity care, the Statement indicates that “costs, not charges” should be the primary unit for valuing charity care. “[R]eporting based on costs is more reliably measured and will provide more consistency when comparing amounts of charity care from different providers,” the Statement explains. Other sections of the Statement provide specific and detailed recommendations with respect to the tracking, recordkeeping, and disclosure of bad debt. The new Statement 15 concludes with a section that specifically addresses Medicaid and Medicare shortfalls, i.e. when the government program pays less than the provider’s cost of rendering services. Medicaid (or similar government programs) shortfalls “should be disclosed as a community benefit, but should not be identified as charity care,” and Medicare shortfalls, if disclosed, should be treated separately, the Statement recommends.

**New York Court Says Retirement Community Not Entitled To Property Tax "Charitable Use" Exemption**

A continuing care retirement community (CCRC) that provides residents independent living, assisted living, and skilled nursing was no longer entitled to a charitable use exemption from property taxes, a New York court held December 30, 2006. “Although [the CCRC] is organized for charitable purposes . . . it is, clearly, not exclusively used for tax exempt purposes,” the court said in affirming the revocation of its charitable use exemption by the City of Rye and its assessor. At the same time, the court found that the CCRC was entitled to a partial hospital use exemption for the portion of its property devoted to providing skilled nursing care.

The case arose when Miriam Osborn Memorial Home Association (Osborn) challenged its real property tax assessments for the years 1997-2003. The city’s assessor had revoked its 100% tax exemption in 1996, although it was partially restored by the Board of Assessment Review to 20.8% in 1997-2001 and 18.04% in 2002-2003.

On an issue of first impression, the New York Supreme Court concluded that, despite Osborn’s contention that it operated as an “unassailable paragon of charity care,” it no longer deserved a charitable use exemption. Osborn has “dramatically changed from being a nursing home caring for indigent residents to a continuing care retirement community catering to the needs of wealthy and healthy seniors,” the court observed after a lengthy discussion documenting this transformation. The court pointed out that the
percentage of “charity beneficiaries” served by Osborn fell from roughly half of total residents in 1989 to only 6% in 2003. The court did find that Osborn was entitled to a partial hospital use exemption since a portion of the property was still used as a state-licensed skilled nursing facility. The court refused, however, to base the partial hospital use exemption on Osborn’s revenues, as it urged, and instead said the determination depended on square footage “as the most objective measure.” *Miriam Osborn Mem’l Home Ass’n v. The Assessor of the City of Rye*, No. 17175/97 (Dec. 30, 2006).

**Indiana Tax Court Says Primary Care Physicians’ Offices Affiliated With Nonprofit Hospitals Not Entitled To Charitable Purposes Tax Exemption**

Indiana’s Board of Tax Review correctly determined that two primary care physicians’ offices affiliated with two nonprofit acute care hospitals did not qualify for a charitable purposes property tax exemption for the 2000 tax year, an Indiana tax court ruled January 10. In reaching this conclusion, the Indiana Tax Court determined the evidence presented by the petitioner, Methodist Hospitals, Inc. (Methodist), failed to establish a prima facie case that the physicians’ offices are “substantially related to or supportive of the inpatient facility” at the two nonprofit hospitals.

Methodist is an Indiana nonprofit 501(c)(3) corporation that owns and operates two acute care hospitals. Methodist also owns and operates two Primary Care Associates offices (PCAs) located near each of the hospitals. These PCAs provide primary care services to the general public, and the physicians and other staff members who work there are Methodist employees. Methodist does not send patients to the PCAs, but rather they draw their patients from the general public. In addition, Methodist performs all PCA billing and collections, and ultimately deposits payments for services rendered at the PCAs in the same bank account that it uses for its acute care hospitals.

In May 2000, Methodist sought a charitable purposes exemption for both PCA offices. Seven months later, at the end of December 2000, the Lake County Property Tax Assessment Board of Appeals (PTABOA) declined that request, finding that the PCA offices and “all personal property therein” were taxable. Methodist filed an appeal in Indiana Tax Court, which upheld the PTABOA’s decision.

The tax court first highlighted language from the relevant statute, Ind. Code § 6-1.1-10-16(a), which provides that “all or part of a building is exempt from property taxation if it is owned, occupied, and used . . . for . . . charitable purposes.” The court noted that “the charitable purposes exemption will not apply to other property owned by an exempt hospital unless the other property is ‘substantially related to or supportive of’ the inpatient facility of the hospital.” Concluding that the PCAs did not meet the “substantially related to or supportive of” requirement, the tax court noted evidence only that Methodist provided administrative support (billing, banking, and other services) to the PCAs. Although acknowledging that the PCAs provide services that may support Methodist’s overall continuum of care, the court concluded that “merely demonstrating that such services are offered, without more, does not clarify how the PCAs are ‘substantially related to or supportive of’ Methodist’s inpatient facilities.” *Methodist*
New Hampshire High Court Finds Nonprofit Company Entitled To Charitable Purposes Tax Exemption On Nursing Home And Assisted Living Facility

A nonprofit corporation that owns two healthcare facilities—a nursing home and an assisted living facility—is entitled to a charitable tax exemption on these properties for tax year 2002, despite the fact that the corporation paid a substantial amount of its earnings to two for-profit corporations, the New Hampshire Supreme Court ruled January 18, 2007. One of the for-profit corporations in the case was National Health Investors (NHI), a real estate investment trust that held mortgages on both healthcare facilities—Epsom Manor (nursing home) and Heartland Place (assisted living facility). In 1999, after NHI foreclosed on the mortgages and temporarily managed the facilities, it contracted with the other for-profit corporation, National Healthcare Corporation (NHC), to take over management of the facilities. In 2001, the Tennessee nonprofit corporation ElderTrust of Florida Inc. (ElderTrust) purchased the facilities through a mortgage financed by NHI, and then executed its own contract with NHC to continue its management of the facilities for a fixed fee.

Subsequently, ElderTrust sought under N.H. Rev. Stat. Ann. § 72:23, V, a property tax exemption on its Epsom Manor and Heartland Place properties for tax year 2002. The Town of Epsom (Town) denied ElderTrust’s exemption application. ElderTrust paid the tax on both facilities totaling $104,774.90 and then appealed in state court, which held that ElderTrust’s request for tax exemption on both properties should have been granted.

Affirming, the New Hampshire Supreme Court summarily rejected the Town’s argument that because ElderTrust’s articles of incorporation did not expressly reference elderly persons with “low and moderate income,” ElderTrust “did not operate under an enforceable obligation to fulfill a charitable purpose.” According to the high court, an “organization does not necessarily have to serve the poor or the needy in order to qualify for the charitable exemption.” The record demonstrates that “Epsom Manor, as a skilled nursing facility, and Heartland Place, as an assisted living facility, provided more services than would be provided at a mere aggregate living facility and were occupied and used directly to advance ElderTrust’s charitable purpose,” the high court said. According to the court, “fees charged to live in [these facilities were] reasonably necessary for ElderTrust to carry out its mission of providing hospitals, nursing homes . . . and related . . . facilities for the elderly in southern New Hampshire.” ElderTrust of Fla. Inc. v. Epsom, No. 2005-706 (N.H. Jan. 18, 2007).

Revised Form 990 For 2006 Continues, But Clarifies Disclosure Requirements

On January 23, 2007, the Internal Revenue Service (IRS) issued revised instructions for Form 990 to be filed for the 2006 taxable year. The revisions reflect changes made by the Pension Protection Act of 2006 and other federal legislation. Moreover, the revisions address certain aspects of the 2005 instructions that met substantial criticism in the past year.
IRS Issues Draft Governance Guidelines For Charitable Organizations

The Internal Revenue Service (IRS) issued a set of draft good governance practices for 501(c)(3) charitable organizations. According to the guidance, the agency “believes that governing boards should be composed of persons who are informed and active in overseeing a charity’s operations and finances.” The draft guidance also notes that organizations with very small or very large governing boards “may be problematic.” Nine good governance practices are suggested in the guidance. The guidance reiterates that directors of a charity must use due diligence and owe the organization a duty of loyalty. In addition, directors “must be good stewards of a charity's financial resources.” The guidance additionally notes that charitable organizations should pay reasonable compensation to their employees and “should generally not compensate persons for service on the board of directors.” Lastly, the draft guidance advises that charities should adopt a written policy establishing standards for document integrity, retention, and destruction.

IRS Issues Report On Exempt Organizations Executive Compensation, Finds “Mixed Results”

The Internal Revenue Service (IRS) issued March 1, 2007 its much-anticipated report on the findings thus far of its Executive Compensation Compliance Initiative for tax-exempt organizations. While compliance checks uncovered “significant reporting errors and omissions,” particularly with respect to excess benefit transactions, transactions with disqualified persons, and loans to officers, the IRS examinations completed so far showed general compliance with section 4958 and private foundation self-dealing rules, the report said. “Where breaches of the rules were uncovered, however, the examinations led to proposed excise taxes in excess of $21 million,” of which over $4 million involved individuals associated with public charities and over $16 million was related to individuals associated with private foundations, the report noted.

The first phase of the Executive Compensation Compliance Initiative began in February 2004 with the IRS sending compliance check letters to over 1,200 organizations (1,023 public charities and 200 private foundations). In the second phase of the initiative, the agency performed 782 single-issue examinations, with about 10% of these still open, the IRS said. Of these examinations, 179 stemmed from unsatisfactory responses to the compliance checks. According to the IRS’ findings, 31% of the organizations amended their Forms 990 as a result of the compliance check contact and 15% of the compliance check recipients were selected for examination because of their responses. The IRS said examinations completed to date did not raise “widespread concerns other than reporting,” but cautioned that its findings “merely reflect the organizations selected and are not representative of the entire regulated community.”

Fifty-one percent of the public charities examined tried to satisfy all three-prongs of the section 4958 rebuttable presumption (independent governing body, use of comparable data, and adequate documentation) for establishing appropriate compensation for a disqualified person, according to the report. The agency acknowledged that it needed to better educate public charities about the section 4958 rebuttable presumption and how to satisfy its requirements. The IRS said it would report on the third part of the initiative,
which includes 200 compliance checks and fifty additional single-issue examinations focusing on loans to executives, at a later date.

**Illinois Department Of Revenue Denies Another Nonprofit Hospital Property Tax Exemption**

The Illinois Department of Revenue (IDOR) has denied Carle Foundation a property tax exemption on the majority of its properties, including its hospital and Carle Auxiliary Guest House, according to a February 26, 2007 statement issued by the foundation. Last year, the IDOR held nonprofit hospital Provena Covenant Medical Center did not qualify for a charitable institution property tax exemption because it failed to show it used the property primarily for charitable purposes.

Previously, the Champaign County Board of Review (BOR) had recommended that the IDOR deny Carle Foundation’s application for a property tax exemption on its various properties, finding the foundation failed to provide sufficient charity care and pointing out the hospital’s relationship with a for-profit clinic as particularly problematic. According to the BOR, in 2003, the hospital provided roughly $1.3 million in no-cost or discounted care, which amounted to “less than one half of one percent” of its assets or revenues. The BOR also found significant that uninsured patients at the hospital were charged “much higher rates than insured patients.” In addition, critical to the BOR’s ultimate recommendation to deny the property tax exemption was the hospital’s relationship with the for-profit Carle Clinic Association. “There is a glaring juxtaposition of a ‘charitable’ hospital allowing doctors complete access and use of their ‘exempt’ facilities to pursue private gain while this same ‘charitable’ hospital continues an unfair policy of overpricing and suing the uninsured,” the BOR concluded.

In its statement, the Carle Foundation said it provided more than $4.9 million in free and discounted care in fiscal year 2006 and nearly $43.7 million overall in community benefit. The Carle Foundation said it would “vigorously appeal this decision on behalf of our community.”

**Illinois Department Of Revenue Denies Richland Memorial Hospital Property Tax Exemption**

The Illinois Department of Revenue (IDOR) denied nonprofit hospital, Richland Memorial, a property tax exemption, according to a statement issued by the hospital. The hospital called the decision “deeply disappointing,” adding that it contradicted the Richland County Board of Review’s recommendation that Richland Memorial be exempted from property taxes. In its press release, Richland said the IDOR’s February 23, 2007 decision denying its request for an exemption from property taxes “ignores nearly 100 years of Supreme Court precedents” recognizing that “a hospital which treats patients regardless of their ability to pay and which does not provide profits to individuals is charitable and merits an exemption from property taxes, without regard to the specific amount of free care it provides.” According to Richland, in fiscal year 2005, over 75% of its patients were Medicare, Medicaid, or charity eligible, with uncompensated care costs totaling 14% of its operating budget (including unpaid costs and community programs and hospital subsidized health services). Richland said it planned to appeal the decision.
Pennsylvania Appeals Court Finds SNFs In Retirement Communities Were Not Entitled To “Public Charity” Property Tax Exemption

The skilled nursing facilities (SNFs) affiliated with two Pennsylvania continuing care retirement communities (CCRCs) do not qualify as “purely public charities” as defined by state supreme court precedent; therefore, they were not entitled to an exemption from state property taxes, a Pennsylvania appeals court ruled March 7, 2007. The Pennsylvania Commonwealth Court affirmed a state trial court’s dismissal of the CCRCs’ appeal from a county board’s decision finding the SNFs taxable.

The CCRCs—Menno Haven, Inc. and Menno Haven Penn Hall, Inc. (collectively, Menno Haven)—offer three levels of care: independent living, assisted living, and skilled nursing. The SNFs at both CCRCs have enjoyed tax exemption since the time of their construction in 1967. In 2002, county and township taxing authorities initiated proceedings to request that the SNFs tax-exempt status be revoked. A hearing was held in October 2004 before the Franklin County Board of Assessment and Revision of Taxes (Board), which ultimately found the SNFs taxable. In affirming the Board’s decision, the trial court found that Menno Haven did not qualify as a “purely public charity” as defined by the Pennsylvania Supreme Court in Hospital Utilization Project (HUP) v. Commonwealth, 487 A.2d 1306 (Pa. 1985). The trial court also found that Menno Haven did not satisfy the requirements for property tax exemption specified in relevant state statutes, namely the Institutions of Purely Public Charity Act (otherwise known as Act 55, codified at 10 Pa. Stat. §375).

The state appeals court agreed with the lower court’s conclusion in relation to the HUP decision and therefore found it unnecessary to address the lower court’s decision with respect to Act 55. In HUP, the appeals court explained, the state supreme court outlined a five-part test for determining whether an entity qualifies as a “purely public charity” within the meaning of Article 8, Section 2(a)(v) of the Pennsylvania Constitution, which provides that the General Assembly may by law exempt from taxation institutions of purely public charity. An entity is a “purely public charity” under the HUP test if it possesses the following five characteristics: “1) [a]dvances a charitable purpose; 2) [d]onates or renders gratuitously a substantial portion of its services; 3) [b]enefits a substantial and indefinite class of persons who are legitimate objects of charity; 4) [r]elieves government of some of its burden; and 5) [o]perates entirely free from private profit motive,” the appeals court said.

The appeals court found the trial court’s determination that Menno Haven did not satisfy the second or third prongs of the HUP test was based on substantial evidence. First, the appeals court emphasized the finding that Menno Haven reserved a portion of a CCRC applicant’s entrance fee and subsequent service charges upon entering into the independent living or assisted living components of the CCRCs for later care at the SNF. The appeals court also upheld the trial court’s finding that, based on figures showing 25% to 28% of Menno Haven’s residents were eligible for Medicaid between 2000 and 2004, Menno Haven failed to satisfy the requirement to donate or render gratuitously a substantial portion of its services. “The trial court found . . . after reviewing the statistics

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**Grassley Asks GAO To Study How Nonprofit Hospitals Fulfill Community Benefit Requirement**

Senate Finance Committee Ranking Member Charles Grassley (R-IA) sent a letter April 5, 2007 requesting that the Government Accountability Office (GAO) conduct further study of how nonprofit hospitals are fulfilling the community benefits requirement for their tax-exempt status and related tax breaks. In the letter to Comptroller General David M. Walker, Grassley expressed concern “about the extent to which nonprofit hospitals are providing services and benefit to the public commensurate with their favored federal tax status.”

The letter asked GAO to study several issues, including:

- the community benefit standards that states have established, in addition to those from the Internal Revenue Service, and any guidelines the hospital industry uses to interpret the community benefit standard;
- the standards and policies nonprofit hospitals use to define the components of uncompensated care, charity care, and bad debt, and how nonprofit hospitals interpret and report them in practice;
- how nonprofit hospitals interpret the community benefit standard for community benefits other than uncompensated care; and
- the level of nonprofit hospital executive and board compensation and the extent to which these individuals are involved with for-profit business ventures with the nonprofit hospital.

The letter also noted that GAO’s study should encompass “a broad range of nonprofit hospitals by size, geographic location, teaching status and the level of state legislative and regulatory requirements on charity care and other community benefits.”

**New Jersey Appeals Court Upholds Denial Of Property Tax Exemption To Hospital’s Off-Campus Facilities**

A tax court properly denied property tax exemptions to a hospital’s off-campus wellness center, physical therapy service, and pediatric practice, a New Jersey appeals court ruled March 28, 2007. *New Jersey Stat. Ann. 54:4-36* provides a property tax exemption for all buildings “used . . . exclusively for hospital purposes.” Hunterdon Medical Center (HMC) argued that the services provided at its off-campus facilities were part of the hospital’s “continuum of care” and were integral to its mission, thus meeting the hospital use requirement.

But the tax court judge found that HMC defined “hospital purposes” too broadly. According to the tax court, the previous standard established by case law was no longer
adequate in light of the expanding “continuum of care” functions, including wellness and lifestyle programs, adopted by most hospitals. Instead, the tax court set forth the following analytical framework to determine whether hospitals’ off-campus facilities qualify for property tax exemption: (1) the nature and extent of the integration between the hospital and the subject facility; (2) the extent to which the hospital’s medical staff controls or supervises the activity conducted in the facility; and (3) whether the facility serves primarily hospital patients or primarily members of the public. Applying this framework, the tax court concluded none of the three services qualified for the property tax exemption.

The New Jersey Superior Court, Appellate Division, affirmed, upholding the analytical framework used by the tax court. The appeals court first noted that the “continuum of care” concept now embraced by most hospitals was too open-ended and essentially allowed them to “self-define” what was “reasonably necessary” to fulfill their mission. Thus, while not abandoning the “reasonably necessary” standard, the appeals court endorsed the tax court’s more defined analytical framework. Hunterdon Med. Ctr. v. Township of Readington, 2007 WL 909544 (N.J. Super. Ct. App. Div. Mar. 28, 2007).

IRS Bifurcates "Patient" Status Among Affiliates in Integrated Healthcare System PLR

On April 20, 2007, the Internal Revenue Service (IRS) released a new Private Letter Ruling (PLR 200716034, Jan. 26, 2007), that likely will come as a surprise to those in the exempt healthcare sector who closely followed the integrated delivery system rulings issued in the mid-1990s and since. The new PLR involves an integrated healthcare delivery system, which includes a parent entity (Parent), a hospital (Hospital), and a number of controlled taxable professional corporations (PCs). The stock of the PCs is held by licensed physicians employed by the Hospital. This structure was necessitated by state law, which provides that only licensed physicians may hold the stock of professional corporations engaged in the practice of medicine. As with typical "captive PC" models, the Hospital, the PCs, and the physician-shareholders had entered into employment agreements, shareholder agreements, and affiliation agreements, that collectively resulted in the Hospital having effective control over, and beneficial interest in, the PCs.

The ruling focuses on the characterization of payments of interest by the PCs to the Hospital and the Parent under Internal Revenue Code § 512(b)(13) and, specifically, whether such amounts should be deemed to constitute unrelated business income (UBI) to the Hospital or Parent. Ultimately, the IRS concludes that such amounts should be treated as UBI. Specifically, the IRS concludes that patients of the PCs are not patients of the Hospital, such that the PCs' provision of professional medical services through employed physicians does not have a substantial causal relationship to the achievement of the Hospital's exempt purposes. This approach seems difficult to reconcile with innumerable prior IRS rulings holding that patients of one entity within an integrated system are to be treated as patients of all entities within that system. Moreover, there can be little doubt that the PCs here are "related" to the Hospital and the Parent for income tax purposes—the IRS in fact reaches that conclusion in the ruling by determining that the Hospital holds the beneficial interest in the PCs and thus is a controlling organization in relation to the PCs for purposes of Section 512(b)(13)(A).
IRS Issues Guidance on Hospital-Physician Electronic Health Record Arrangements

The Internal Revenue Service (IRS) released May 11, 2007 an internal memorandum from the Director of the Exempt Organizations Division addressing the provision of financial assistance by tax-exempt hospitals to staff physicians in the context of electronic health record (EHR) arrangements. The memorandum acknowledges the August 2006 U.S. Department of Health and Human Services (DHHS) final regulations allowing hospitals to provide certain items of EHR software and related services on a discounted basis (i.e., below fair market value) under specified conditions without violating the Stark Law and Anti-Kickback Statute.

The IRS memorandum essentially provides that, if hospitals structure EHR arrangements on a subsidized basis consistent with the DHHS final regulations, such arrangements will not result in impermissible private benefit or inurement, provided that: the arrangements require both the hospital and the participating physicians to comply with the DHHS final regulations on an ongoing basis; the hospital is able to access medical records created by physicians pursuant to the subsidized EHR arrangement to the extent permitted by law; the hospital makes the subsidized EHR software and services available to all physicians on its medical staff; and the hospital provides the same level of subsidy to all medical staff physicians, or the hospital varies the subsidy level by applying criteria related to meeting community healthcare needs.

The foregoing conditions establish some subtle distinctions from the standards set forth under the HHS final regulations, and thus will require careful review by hospitals in evaluating EHR arrangements currently in the planning stages or in the early phases of implementation. The memorandum does not address the treatment of ancillary items of software or services that are not integrated with the EHR, such as practice management systems. The memorandum also does not address the question of whether the subsidized amount constitutes taxable income to participating physicians.

Michigan Appeals Court Finds Medical Center And Practice Group That Jointly Occupied Building Both Entitled To Property Tax Exemptions

A medical center and an affiliated practice group that jointly occupied different portions of a building on property located in Owosso, Michigan qualified under state law as charitable institutions, and therefore, for the tax years in question, were eligible for property tax exemptions on the property they shared, a Michigan appeals court ruled May 3, 2007 in an unpublished opinion. The hospital, McLaren Regional Medical Center (MRMC), and the practice group, McLaren Medical Management Inc. (MMM), challenged the state tax tribunal’s decision to deny their requests for exemption from taxes imposed for tax years 1999 and 2000.

The Michigan Court of Appeals first rendered an opinion in the case in August 2004 in a consolidated appeal that also reviewed a case involving the city of Cadillac’s denial of a property tax exemption requested by Wexford Medical Group. In that opinion, the appeals court ruled against Wexford, as well as MRMC and MMM. Subsequently, in Wexford Medical Group v. City of Cadillac, 713 N.W.2d 734 (Mich. 2006), the Michigan
Supreme Court overturned the appeals court’s decision affirming the tax tribunal’s conclusion that Wexford Medical Group was not a charitable institution entitled to a tax exemption. In addition, the state supreme court vacated the appeals court’s judgment as it related to the McLaren petitioners, and remanded the case for reconsideration in light of its decision. The supreme court specifically instructed the appeals court to reconsider petitioners’ claims that they are entitled to an exemption under Mich. Comp. Laws § 211.7o, which defines the charitable institution exemption.

The McLaren property at issue was separated operationally into three areas for the tax years at issue, the appeals court explained on remand, with MMM using the east portion to operate a family medical practice and MRMC using the west and center portions as a laboratory draw station and for weight management and physical therapy programs. The appeals court ultimately agreed with the tax tribunal’s determination that MRMC, rather than MMM, owned the property during the tax years at issue.

Applying the Wexford three-prong standard for meeting the statutory exemption defined under Mich. Comp. Laws § 211.7o, the appeals court concluded that both MRMC and MMM were entitled to a property tax exemption. During tax years 1999 and 2000, both entities were “organized chiefly, if not solely, for charity,” the appeals court concluded, highlighting consistent statements (in articles of incorporation, etc.) from MMM and MRMC regarding their organizational purpose to provide medical services and “operating exclusively for charitable, scientific, and educational purposes.” The appeals court also found that both MMM and MRMC provided community health services on a non-discriminatory basis. Further, the city of Owosso presented no evidence suggesting the MMM or MRMC did not adhere to their stated nondiscrimination policies in providing medical services, the appeals court noted. The appeals court also found evidence showing that MMM devoted substantial resources to charitable activities during the 1999 and 2000 tax years. For example, as described by MMM’s president during the tax years at issue, MMM placed no limitation on the number of Medicaid and Medicare patients it treated in the building and MMM did not try to balance bill these patients for the difference between government reimbursement levels and MMM's standard charges. This, and other evidence, demonstrated that MMM constitutes “an institution of overall charitable nature,” the appeals court said. While the evidence regarding MRMC's charitable activities was less extensive," the record supports that MRMC services the MMM patients as a lab drawing station, and in providing weight management and physical therapy, and that MRMC accepted patients on the same basis as MMM.”

The appeals court therefore concluded that, under Wexford, the portions of property at issue for tax years 1999 and 2000 “were owned by MRMC, a nonprofit charitable institution, and were either occupied by MRMC solely for the purposes for which MRMC was organized, or made available to MMM, also a nonprofit charitable institution, and occupied by MMM solely for the purposes for which MMM was organized.” McLaren Reg’l Med. Ctr. v. Owosso, No. 244386 (Mich. Ct. App. May 3, 2007).