Year in Review
2007-2008
# American Health Lawyers Association
## Year in Review 2007-2008

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Executive Summary

Identifying the most significant developments in health law over the past twelve months presents new and different challenges every year for AHLA’s legal editorial staff. Sometimes, the task is made easy by the federal government or courts, and a major piece of legislation, administrative guidance, or a ruling becomes the centerpiece of the Year in Review (YIR). In other years, the sheer volume of activity around a particular topic dictates the focus of this article and constitutes the major portion of its content.

This year, in the absence of any single defining event and the proliferation of multiple, important developments in health law, AHLA has re-focused this introduction to the YIR to analyze the most significant developments in the areas identified in a survey by our members earlier this year in the Top Ten Health Law Issues for 2008 [See Health Lawyers News, January 2008, pp. 7-10]. The cases, regulations, and agency actions summarized over the past year in the HL Weekly and Digest that relate to these topics are compiled below so as to marry current events with the “Top Ten” list. You will find that AHLA’s members were indeed prescient as they prognosticated on 2008’s top ten health law issues. The result, we hope, is a forward-looking, trend-identifying report that will serve to connect actual developments with the topics members perceive to be significant areas of ongoing focus.

In addition, for your reference, is the entire collection of summaries taken from the Weekly and the Digest for the period since the 2007 Annual Meeting. These summaries are classified by topic area and many of the cases will be discussed in greater detail by Beth Schermer and Jack Schroder in their YIR session. With all of this material, we hope that members have in hand an organized and comprehensive picture of the past year in health law.
Physician-Hospital Relations and Stark

Always a keen area of interest for health lawyers, AHLA members predicted that the level of interest in this topic would intensify over the last twelve months. Below are the highlights of developments in this area.

The Centers for Medicare and Medicaid Services (CMS) posted August 27, 2007 the long-awaited Phase III final rule on the physician self-referral prohibition [the regulations were published in the Federal Register on September 5, 2007 (72 Fed. Reg. 51012)]. With respect to indirect compensation arrangements, CMS explained in the final rule that the relationship between the physician and his or her physician organization is disregarded and the physician “stands in the shoes” of his or her physician organization. As a result, “many arrangements that would have constituted indirect compensation arrangements if analyzed under Phase I and Phase II are now deemed to be direct compensation arrangements, and the indirect compensation arrangements exception cannot be used,” the final rule said. Moreover, under the Phase III final rule, “many arrangements that may not have met the definition of an ‘indirect compensation arrangement’ under the Phase I and Phase II analysis will constitute direct compensation arrangements that must satisfy the requirements of an exception in order for the physician to make DHS referrals to the entity furnishing DHS.”

However, on November 15, 2007, CMS issued a final rule (72 Fed. Reg. 64161) delaying for one-year the application of the so-called “stand-in-the-shoes” provision of the Stark Phase III final rule to academic medical centers (AMCs) and nonprofit integrated health systems. The “stand-in-the-shoes” provision in the final Phase III rule therefore does not apply to certain compensation arrangements between AMCs or nonprofit integrated health systems until December 4, 2008. CMS further signaled its intent to revisit the “stand-in-the-shoes” provisions in recent proposed rulemaking. In the fiscal year 2009 inpatient prospective payment system proposed rule [73 Fed. Reg. 23528 (April 30, 2008)], CMS requested comments on two specific alternative methods to address the issues raised by the “stand-in-the-shoes” provisions, as well as on other potential approaches.

In a decision in a qui tam case under the False Claims Act (FCA) challenging whether a hospital and various faculty physicians qualified for the AMC exception under
the Stark regulations, the U.S. District Court for the Western District of Kentucky found that the indirect flow of funds from the AMC (a Children’s hospital) to faculty members was protected by the AMC exception. This case serves as yet another example that AMCs (including Children’s hospitals) are indeed vulnerable to Stark Law charges and that appropriately and carefully structuring arrangements to fit within the AMC exception is an essential part of any AMC’s compliance program. *United States ex rel. Villafane v. Solinger*, No. 3:03-cv-519 (W.D. Ky. Apr. 8, 2008).

**Quality of Care**

By selecting quality of care as the second most important topic, health lawyers are reflecting the priorities of the government, private sector, and patient—all of whom have increased their focus on this issue over the past year. The topic of quality of care spills over into multiple areas of practice for health lawyers, including fraud and abuse, reimbursement, insurance coverage, liability, and physician representation. Not surprisingly therefore, a wide variety of cases and developments in health law over the past year relate to this subject area. Below are the highlights of this plethora of activity in this area.

CMS published in the February 12, 2008 *Federal Register* [73 Fed. Reg 8112] the much-anticipated proposed rule to implement patient safety legislation enacted in 2005 to promote medical error reporting. The Patient Safety and Quality Improvement Act of 2005 [Pub. L. No. 109-41], sets forth privilege and confidentiality protections in civil and criminal proceedings to “patient safety work product” reported by providers to new patient safety organizations (PSOs). The PSOs will then collect, aggregate, and analyze the data to identify ways to prevent medical errors.

The Food and Drug Administration Amendments Act of 2007 [Pub. L. No. 110-85], signed into law on September 27, 2007, contains an additional $225 million in user fees that will be collected over five years to help fund the agency’s drug safety activities. The legislation enhances the FDA’s authority over post-market drug safety, including allowing the agency to require labeling changes and to impose civil monetary penalties for certain violations of the federal Food, Drug, and Cosmetic Act with respect to drugs. The legislation also reauthorizes the Pediatric Research Equity Act of 2007 and the Best

The Joint Commission rolled out its 2008 National Patient Safety Goals and related requirements for each of its accreditation programs and its disease-specific care certification program. Compliance with the requirements set out in the Goals is a condition for continuing accreditation or certification for Joint Commission-accredited or certified organizations. One significant change in the Goals for 2008 is the addition of a new requirement to take specific actions to reduce the risks of patient harm associated with the use of anticoagulant therapy. Another new Goal is directed at improving the recognition of, and response to, unexpected deterioration in a patient’s condition. Both of these new requirements will be phased in over a one-year period that includes “defined milestones,” with full implementation slated for January 2009.

The Joint Commission also announced a revised accreditation participation requirement that explicitly prohibits retaliatory action by a hospital against physicians and medical staff who report quality of care concerns. Although the previous requirement referred to general hospital staff, it was always intended that physicians and medical staff be included as part of “Good Faith Participation” in the accreditation policy, according to the Joint Commission. Under the revised requirement, accredited hospitals must educate staff and medical staff that they can report quality concerns to the Joint Commission and inform them that no retaliatory disciplinary action will be taken by the hospital as a result.

A California appeals court upheld a $200,000 damages award to a physician who claimed his employment was terminated in retaliation for “advocating medically appropriate care.” The California Court of Appeal, Second District, found the physician was entitled to sue a medical group and a health plan in tort for their retaliatory conduct in violation of “public policy” as defined in state law. *Woods v. Southern Cal. Permanente Med. Group*, No. B193021 (Cal. Ct. App. filed Nov. 20, 2007 and posted Dec. 20, 2007).

In the area of long term care, Senate Finance Committee Ranking Member Charles Grassley (R-IA) called on CMS to develop a public “watch list” to identify nursing homes that “yo-yo” out of compliance with federal quality standards. According
to Grassley, while consumers have access to nursing home information through Medicare’s “Nursing Home Compare” website, they often are not privy to information about “repeat offenders” because sanctions are not publicly reported or are rescinded based on short-term fixes that “mask permanent problems.” On November 29, 2007, CMS released the first ever list of the nation’s 54 poorest performing nursing homes, followed in February 2008 by an expanded list that included information to enable consumers to distinguish between those nursing homes that are improving and those that are not.

The Department of Health and Human Services Office (HHS) of Inspector General (OIG) issued April 14, 2008 a draft of supplemental compliance program guidance for nursing facilities. The OIG said the draft is intended to supplement, rather than replace, nursing facility compliance guidance issued in 2000. The draft supplemental guidance includes sections on fraud and abuse risk areas that are particularly relevant to nursing facilities, recommendations for establishing an ethical culture and for assessing and improving an existing compliance program, and actions nursing facilities should take if they discover potential misconduct.

As part of its annual update to the inpatient prospective payment system [72 Fed. Reg. 47129 (Aug. 22, 2007)], CMS announced that Medicare would no longer pay hospitals for the additional costs associated with certain preventable infections and injuries (so-called “never events) that were not present on admission. Several private payors are considering a similar tack. For example, Aetna announced January 15, 2008 that it is incorporating language in its template for hospital contracts endorsing the Leapfrog Group’s approach to “never events.” The language, which will be used in negotiations or renegotiations that involve a new contract, calls on hospitals to report the medical error to either the Joint Commission, state reporting programs for medical errors, or patient safety organizations within ten days of becoming aware of the occurrence. The language also asks hospitals to take action to prevent future events, waive all costs related to the “never event,” and apologize to the affected patient and family.

denials for psychiatric hospitalizations where the patients were not seen by a psychiatrist on a daily basis. The state agency denied Medicaid reimbursement based on its conclusion that this failure fell below the regulatory requirement that care be rendered in accordance with “accepted medical treatment standards.” Both sides had experts—the hospital’s testifying to the fact that daily visits were not medically necessary, the agency’s that daily visits were the standard of care. While the standard of judicial review for administrative purposes was whether the determination below was supported by substantial evidence, the court held that even though the standard was general, it was not improperly vague and did put providers on notice of what was expected of them.

**False Claims Litigation & Fraud and Abuse**

AHLA members voiced their opinion that fraud and abuse enforcement would be a significant issue in 2008. The Civil False Claims Act (FCA) continues to be a popular enforcement tool for the federal government, and the indictment of Tenet’s former General Counsel this year will keep this statute at the forefront of concern for health lawyers. On September 18, 2007, the Department of Justice filed a lawsuit against Tenet Healthcare Corporation’s former General Counsel under the FCA, alleging she submitted false certifications about Tenet’s compliance with federal program legal requirements. Before making the certifications, the complaint alleges, counsel had received an internal memorandum raising concerns about the employment contracts at issue as well as confirmation from outside counsel that the arrangements were illegal.

According to the complaint, a Tenet-owned hospital was illegally billing Medicare for referrals from certain physicians whose employment contracts violated the Stark Law. The government contends that the former General Counsel submitted declarations in June 1997 and June 1998 to HHS stating that, to the best of her knowledge and belief, Tenet was in material compliance with all federal program legal requirements. Before making the certifications, the complaint alleges, counsel had received an internal memorandum raising concerns about the employment contracts at issue as well as confirmation from outside counsel that the arrangements were illegal.

Convictions under the FCA continued to generate larger monetary penalties over the past year, and not surprisingly, the amounts involved have been challenged on constitutional grounds. The Seventh Circuit found February 20, 2008 that a FCA defendant’s fine of over $64 million was not excessive, though the appeals court did not reach the defendant’s claim that the fine violated the Excessive Fines clause of the Eighth
Amendment. The defendant in this case argued that the Excessive Fines Clause prohibited the award because it was grossly disproportionate to the wrong. The appeals court disagreed, noting it was “far from clear that the Excessive Fines Clause applies to civil actions under the False Claims Act.” However, the court ultimately did not reach defendant’s constitutional argument for several reasons, including that he did not raise the issue below. According to the appeals court, it is “impossible to know whether the penalty was constitutionally ‘excessive’ without knowing what conduct the fine penalizes.” Because defendant persuaded the district court to exclude evidence that medical services were unnecessary, or never performed, he “has made the record unsuitable to resolution of his constitutional argument.” In addition, the appeals court found the total award here was less than four times actual damages, which is “well within the single-digit level” that the U.S. Supreme Court in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), held was not “grossly excessive” for punitive damages. Noting that no data was presented showing what multiplier would be appropriate for deterrence, the appeals court mused “for all we can tell, [defendant’s] penalty may be too low.” *United States v. Rogan*, No. 06-4144 (7th Cir. Feb. 20, 2008).

Many of the monetary penalties recovered under the FCA involved pharmaceutical manufacturers. Jazz Pharmaceuticals agreed to pay $20 million to settle criminal and civil allegations that its wholly-owned subsidiary Orphan Medical, Inc. illegally marketed the prescription drug Xyrem, also known as a “date rape” drug, for off-label uses. Orphan admitted that through sales representatives and at least one medical professional it promoted the drug to physicians for uses including fatigue, insomnia, chronic pain, weight loss, and depression. Orphan also paid a psychiatrist “tens of thousands of dollars” for speaking engagements to promote off-label uses of Xyrem, according to the government’s allegations. A federal grand jury indicted the psychiatrist last year on criminal charges for his involvement in promoting Xyrem.

Aventis Pharmaceuticals Inc. paid the United States and a number of states, as well as the District of Columbia, over $190 million to resolve allegations that the company caused false claims to be filed with Medicare and other federal healthcare programs as a result of its alleged fraudulent pricing and marketing of Anzemet, an anti-
emetic drug used primarily in conjunction with oncology and radiation treatment to prevent nausea and vomiting.

**SCHIP**

Many AHLA members identified the State Children’s Health Insurance Program (SCHIP) and more expansive healthcare reform initiatives that may follow the elections in November 2008 as an important area of focus for them in the year ahead. In some regards, the congressional debate about SCHIP over the past year can be seen as a dress rehearsal for broader reforms that Congress may undertake in the near future.

Over the last year, Congress passed two versions of legislation to reauthorize SCHIP, which expired October 1, 2007 under existing law, but was unable to muster enough votes to override President Bush’s vetoes. On October 3, 2007, Bush vetoed the first SCHIP reauthorization bill (H.R. 976), which supporters argued would preserve coverage for all 6.6 million children currently enrolled in the program and add about 3.8 million children to SCHIP’s rolls. While the Senate cleared the measure by an overwhelming 67-29 vote, the 265-159 approval margin in the House was short of a veto-proof majority. A subsequent override vote (273-156) failed to garner a two-thirds majority.

The House and Senate passed a revised bill (H.R. 3963) in late October 2007 that Democrats hoped would address what they said were unfounded concerns about the earlier measure. To this end, H.R. 3963 specified that states could only receive federal funding for children covered in SCHIP with family incomes up to 300% of the federal poverty level for a family of three; phased out coverage of childless adults after one year; and clarified that the program is for U.S. citizens only. The bill’s backers, however, refused to budge on the extent of additional funding, leaving intact the $35 billion over five years included in the original legislation. Like the earlier version, the bill also included a 61-cent hike in the federal tobacco tax. Bush vetoed H.R. 3963 on December 12, 2007, and the House’s override vote again failed. In their attempt to reauthorize the popular program, Bush and lawmakers wrangled over funding levels and the administration’s concern that the measure would result in government coverage displacing private health insurance (so-called “crowd out”) for many children.
During the debate, the program continued under various stop-gap measures that maintained funding at existing levels. Unable to reach a final agreement, Congress extended the program until March 31, 2009 in end of the year legislation [Pub. L. No. 110-173].

Fueling the debate about SCHIP, CMS issued a controversial directive to states on August 17, 2007 setting forth stricter requirements for expanding eligibility to children in families with higher incomes. The directive enumerated a number of “crowd-out” steps states should take before expanding eligibility beyond 250% of the federal poverty level (FPL), including establishing a minimum one-year period of uninsurance and requiring 95% enrollment of eligible children under 200% of FPL. A number of states have challenged the directive in court and some lawmakers are pursuing legislation to block its implementation.

**Electronic Health Records**

Although hard law is still evolving in this subject area, health lawyers recognize that the electronic collection and distribution of personal healthcare information will inevitably become the norm for both patients and providers. While government attempts to foster this transition, courts have begun to grapple with some of the unique legal issues generated by this evolution.

In October 2007, HHS Secretary Michael Leavitt announced a five-year demonstration project that will provide financial incentives to physician groups using certified electronic health records (EHRs). The program, which is designed to encourage small to medium-sized physician practices to adopt EHRs, will require all participating practices to use a certified EHR system to perform specific functions that can positively affect patient care processes, HHS said. The core incentive payment to practices will be based on performance for certain quality measures, with an enhanced bonus based on how well integrated the EHR is in helping manage patient care.

rule concern formulary and benefits (giving prescribers information about which drugs are covered by a Medicare beneficiary’s prescription drug plan), medication history (providing prescribers with information about medications a beneficiary is already taking, including those prescribed by other providers), and fill status notification (allowing prescribers to receive an electronic notice from the pharmacy telling them that a patient’s prescription has been picked up, not picked up, or has been partially filled). The final rule also adopts the National Provider Identifier as a standard for use in e-prescribing transactions among plan sponsors, prescribers, and dispensers.

A court in New York ruled that a physician’s communications with his attorney via his hospital-employer’s email system were not protected from discovery under the attorney-client privilege or work product doctrine in a subsequent employment dispute. According to the New York Supreme Court, New York County, because hospital policy explicitly prohibited personal use of its email system and informed employees of potential monitoring, the physician could not claim these communications were privileged. The court found the physician had actual and constructive knowledge of the email policy, given that the hospital had widely disseminated it and that the physician was a hospital administrator. The court also concluded that the work product doctrine was inapplicable, finding the attorney’s “pro forma notice” at the end of the emails was “not a reasonable precaution to protect its clients.” Scott v. Beth Israel Med. Ctr., Inc., No. 602736/04 (N.Y. Sup. Ct. Oct. 17, 2007).

In Maine, a federal trial court agreed to preliminarily enjoin the enforcement of a new state law restricting the collection and disclosure of physician prescribing information for marketing purposes that was set to go into effect January 1, 2008. The court found the Maine law’s (L.D. 4) attempt to regulate the use of prescription drug data violated the First Amendment by impermissibly restricting commercial speech. The statute is similar to New Hampshire’s Prescription Information Law, which was struck down as unconstitutional by the U.S. District Court for the District of New Hampshire. IMS Health Inc. v. Ayotte, No. 06-cv-280-PB (D.N.H. Apr. 30, 2007). The New Hampshire case currently is on appeal to the First Circuit. IMS Health Corp. v. G. Steven Rowe, No. CV-07-127-B-W (D. Me. Dec. 21, 2007).
Medicaid and State Law Enforcement

The Deficit Reduction Act of 2005 (DRA) provided additional incentives for states to increase their Medicaid enforcement activities. These legislative incentives, combined with the fact that Medicaid spending represents as much as a third of state expenditures, will generate more aggressive enforcement efforts on the part of state agencies in the year ahead, according to predictions by AHLA members. In 2007-2008, there were a number of events that illustrate the accuracy of these projections.

United Healthcare reached a $20 million multi-state settlement stemming from an investigation into complaints about United Healthcare’s claims practices. The investigation uncovered numerous problems, including not applying fee schedules and deductibles correctly, violating prompt pay rules, and being unable to correct problems pointed out by state regulators. Thirty-six states and the District of Columbia have signed on to the settlement agreement.

The California Department of Managed Health Care (DMHC) announced July 26, 2007 that it was fining Kaiser Foundation Health Plan $3 million after an investigation found oversight of quality assurance programs at its 29 medical centers lacking. DMHC said the fine would be reduced by $1 million provided Kaiser fully completed proposed corrective measures. In November 2007, the DMHC also fined Health Net $1 million for failing to disclose information about a bonus program paid to employees for canceling health policies. And finally, the California Insurance Commissioner announced in December 2007 that his office is pursuing $12.6 million in fines and penalties against insurer Blue Shield for improper healthcare rescissions and “shoddy” claims handling.

In July 2007, CMS issued a final rule [73 Fed. Reg. 39142] that changes how the government pays for prescription drugs under the Medicaid program. The changes implement DRA provisions that were prompted by reports from the Government Accountability Office (GAO) and the HHS OIG that Medicaid payments to pharmacies for generic drugs were much higher than what pharmacies actually paid for the drugs.

The DRA also requires CMS to disclose the average manufacturer price (AMP), which the agency says will help introduce transparency in Medicaid prescription drug pricing. “States will now be able to use actual AMP information as the basis for setting drug reimbursement,” CMS said. Drug makers will be required to report AMPs monthly,
as well as quarterly. In addition, the final 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.

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) filed a joint lawsuit November 7, 2007 to block these regulations affecting Medicaid reimbursements of generic drugs, warning they will spell dire consequences for community pharmacies. On December 14, 2007, a district court judge issued a preliminary injunction preventing CMS from posting data on the Internet related to generic pharmaceuticals’ AMP, or from implementing Medicaid reimbursement cuts, until a final decision on the merits of the lawsuit is rendered.

Subsequently, on March 14, 2008, CMS issued an interim final rule [73 Fed. Reg. 13785] revising the definition of “multiple source drug” for purposes of the Medicaid drug reimbursement rules. CMS said the change was intended to conform the definition to statutory language and address the concerns raised by NACDS and NCPA in their lawsuit.

In February 2008, Caremark LLC (Caremark), one of largest pharmacy benefit management companies in the United States, reached a $41 million settlement with 28 states and the District of Columbia to resolve prescription “switching” claims. Based on a four year, multi-state investigation, the complaint filed in the case alleged that Caremark (and its subsidiaries) engaged in deceptive business practices by encouraging physicians to switch patients to different brand-name prescription drugs to save money. In doing so, however, Caremark failed to disclose its own financial motivations for drug switching, or inform physicians of the effect this switch would have on costs to patients and health plans, the states alleged.

As part of the settlement, Caremark must make significant changes to its process for switching patients from the drugs originally prescribed by their physicians. In addition, Caremark agreed to pay $38.5 million to the states, including $22 million for making drugs more affordable for low-income, disabled, or elderly consumers and educating all consumers about the cost differences among medications and $16.5 million for investigative costs, fees, and consumer education. The remainder of the settlement, or
$2.5 million, will be used to reimburse patients who incurred expenses related to certain
drug switches. The settlement also prohibits Caremark from soliciting drug switches
when the cost to the patient for the proposed drug is greater than the cost to the patients
for the originally prescribed drug; the proposed drug does not have a generic equivalent
and the originally prescribed drug does; the patient was switched from a similar drug
within the past two years; or the originally prescribed drug’s patent is expected to expire
within six months.

In another case, CVS Caremark Corporation agreed to pay $37.5 million to
resolve claims that it improperly switched patients to a more expensive version of a
prescription drug used to treat heartburn and ulcers to increase its Medicaid
reimbursements. Under the settlement with CVS Caremark, the federal government will
receive roughly $21.1 million, with 23 states and the District of Columbia sharing about
$15.6 million pursuant to separate settlement agreements.

In North Carolina, a state appeals court found controlling a state supreme court
decision that held Medicaid may recover expenses paid from settlement amounts
regardless of whether the settlement funds were for pain and suffering or for medical
damages. In so holding, the appeals court held a contrary U.S. Supreme Court decision
was not applicable in North Carolina. The trustee of the settlement account argued that
the North Carolina Division of Medical Assistance (DMA) is only entitled to the
settlement funds that the patient received as compensation for medical expenses and not
any settlement funds due to her pain and suffering. The appeals court noted that the state
supreme court addressed the issue in Ezell v. N.C. Dep’t of Health & Human Servs., 631
S.E.2d 131 (2006), which held that the DMA was subrogated to the entire amount of the
settlement, regardless of whether the funds were for pain and suffering or medical
expenses. The trustee argued that the U.S. Supreme Court’s decision in Arkansas Dep’t of
HHS v. Ahlborn, 547 U.S. 268 (2006), should apply instead. That case held a state’s
ability to recover its Medicaid lien was limited to the pro-rata portion of the settlement
representing compensation for past medical expenses only, not the entire settlement. The
appeals court agreed, however, with the trial court that Ezell was controlling as it was
decided after the Ahlborn case and Ahlborn was interpreting an Arkansas statute, not one
from North Carolina. The appeals court said it “has no authority to overrule decisions of
our supreme court and we have the responsibility to follow those decisions until otherwise ordered” by the state supreme court. *Andrews v. Haygood*, No. COA06-1670 (N.C. Ct. App. Jan. 15, 2008).

**Physician-Vendor Relationships**

ALHA members cited the need to guard against conflicts of interest, perceived or otherwise, that arise when pharmaceutical companies provide gifts or other compensation to physicians, as a primary area of focus for them in 2008. The past year did in fact witness increased enforcement activity and numerous settlements with pharmaceutical manufacturers. The majority of states have also passed or proposed legislation regarding vendor gifts.

In April 2007, 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 government’s complaint alleged, among other things, that CTI paid illegal kickbacks to induce physicians to prescribe Trisenox. EMD Serono Inc., and Merck Serono International also agreed to pay $24 million to settle a class action alleging the company wrongfully encouraged doctors to prescribe its AIDS drug Serostim by providing them with travel stipends in exchange for their agreement to prescribe the drug.

Bristol-Myers Squibb Company (BMS) agreed to pay more than $515 million to resolve numerous federal and state civil allegations involving its drug marketing and pricing practices, U.S. Attorney for the District of Massachusetts Michael J. Sullivan announced September 28, 2007. The government had alleged that BMS “knowingly and willfully paid illegal remuneration to physicians and other healthcare providers to induce them to purchase BMS drugs from approximately 2000 through mid-2003.” Although BMS paid the physicians the remuneration in the form of consulting fees and expenses in exchange for the providers’ participation in various consulting programs, advisory boards, and preceptorships, the government alleged that one purpose of the programs, some of which involved travel to luxurious resorts, was to influence the providers’ prescribing habits. Under the settlement, BMS agreed to pay $499,000,000 plus interest
to resolve the federal and state civil claims. The interest as of the settlement date was $16,483,660.27, Sullivan said, bringing the total payment owing to $515,483,660.27.

However, several frameworks for transactions between medical clinics, physicians, and pharmaceutical manufacturers emerged over the past year that did pass muster with the OIG. For example, a nonprofit corporation’s program that arranges for pharmaceutical manufacturer patient assistance programs (PAPs) to provide donated drugs to free clinics and federally qualified health centers (FQHCs) for use by financially needy patients who lack any form of outpatient prescription drug coverage would not trigger administrative sanctions, the OIG said in an advisory opinion posted February 1, 2008. The OIG cited its main concerns as whether the arrangement could serve as a vehicle for the PAP sponsors to offer or pay remuneration to induce the clinics to purchase or order the sponsors’ products or to influence the prescribing patterns of clinic physicians. But the OIG ultimately concluded it would not impose sanctions in connection with the arrangement, finding no apparent remuneration provided by the PAPs to the affiliated free clinics. “[W]hile the Arrangement more generally benefits the affiliated free clinics through the conservation of clinic funds that might otherwise be used to purchase medications, the benefit inures to the public good in the form of increased availability of healthcare items and services for an underserved population,” the OIG said. Advisory Opinion No. 08-01 (Dep’t of Health and Human Servs. Jan. 28, 2008).

The OIG also blessed a market and research firm’s proposal to encourage physicians and other healthcare professionals to complete online surveys by offering to make a charitable contribution of their choosing. The OIG said in an advisory opinion posted February 5, 2008 that the proposal would not generate prohibited remuneration under the Anti-Kickback Statute. The requesting firm provides research services to pharmaceutical and medical companies to help them develop clinical, marketing, and other data about how physicians diagnose and treat certain illnesses relevant to the entities’ products. The firm has a web-based program to help gather real-time market research data from targeted clinicians to benchmark educational needs, current product usage by indication, brand awareness and effectiveness, clinician attitudes, effectiveness of detailing programs, current best practices, and competitive product analysis, the
opinion explained. The OIG concluded the proposed arrangement did not implicate the Anti-Kickback Statute because it “would be structured to prevent health care professionals from receiving any actual or expected economic or other actionable benefit from the charitable contributions.” *Advisory Opinion No. 08-02* (Dep’t of Health and Human Servs. Office of Inspector Gen. Jan. 29, 2008).

A manufacturer’s proposal to provide a one-time free trial of its medication to patients with hemophilia A, including Medicare and Medicaid beneficiaries, was structured to avoid triggering sanctions under the Anti-Kickback Statute, the OIG said February 12, 2008. The advisory opinion concluded the proposed arrangement mitigated concerns of “unscrupulous physicians reselling or billing” for the free samples because it was structured in a way that physicians would never have possession of the medication. The OIG also found the proposal included other safeguards that distinguished it from “problematic programs that offer free goods or remuneration to prescribers as a means to ‘seed’ or introduce new products into the marketplace.” *Advisory Opinion No. 08-04* (Dep’t of Health and Human Servs. Office of Inspector Gen. Feb. 5, 2008).

Finally, in an advisory opinion posted February 22, 2008, the OIG approved a pharmaceutical company’s proposal to place electronic kiosks that offer patients free disease screening questionnaires in certain physicians’ offices. The interactive questionnaires would consist of several questions on each of four disease states that patients would be able to answer using the kiosk keyboard. Upon answering all the questions, the patient could then generate a printout that would contain the screening questions along with the patient’s responses. The questionnaires would advise patient users to talk to their doctor about the screening results. In addition, the requestor explained that the questionnaires would not mention its drug products or contain any advertisement or incentives for using the kiosks. Moreover, the kiosk itself would display only a small image of the requestor’s logo, but would not mention any drug names. Because the questionnaires would not offer patients incentives for using the kiosks, the OIG concluded the proposed arrangement would not provide anything of value to patients and, therefore, would not implicate the Anti-Kickback Statute. *Advisory Opinion 08-05* (Dep’t of Health and Human Servs. Office of Inspector Gen. Feb. 15, 2008).
Plan-Provider Competition for Federal Funding

AHLA members recognized that competition between health plans and providers for increasingly scarce federal funds will only intensify in the foreseeable future, particularly as the baby boomers reach retirement.

In their annual report released March 25, 2008, the Medicare Trustees projected Medicare’s Hospital Insurance (HI) Trust Fund will be exhausted in 2019. According to the report, the HI Trust Fund this year will spend more than its income, and from 2009 through 2017, about $342 billion will need to be drawn from the federal treasury to cover beneficiaries’ hospital insurance costs. Over the next decade, the Trustees estimate that HI expenditure growth will average 7.4% annually, outpacing both the rate of increase of Gross Domestic Product and the Consumer Price Index. As required by the MMA, the Trustees again triggered a funding warning because Medicare program costs financed by general revenues, rather than by “dedicated revenues,” are projected to exceed 45% in 2014. The Trustees also triggered the warning last year, prompting the President to propose legislation in February 2008 for curbing program spending. The proposal focused on value-based purchasing, medical liability reform, and means-testing for Part D.

Also in March 2008, the Medicare Payment Advisory Commission (MedPAC) released its annual report to Congress making payment updates and policy recommendations for Medicare. “The report focuses on policy recommendations that create incentives for greater efficiency, reward quality, and modify payment rates to private plans and providers to ensure accuracy and equity,” MedPAC said. As for physician services, MedPAC found most indicators of payment adequacy to be stable. MedPAC cautioned, however, that consecutive annual cuts in physician payment rates, as indicated by the existing Sustainable Growth Rate formula, “would threaten beneficiary access to physician services over time.” While Congress has continued to step in and avert steep cuts in Medicare physician payments dictated by the current statutory formula, it continues to grapple with how to fund a permanent legislative fix. MedPAC also reiterated concerns about the Medicare Advantage (MA) program, noting MA payments are projected to be 113% of fee-for-service in 2008.
IRS Form 990

The Internal Revenue Service (IRS) issued December 20, 2007 an updated version of Form 990, the return that charities and other tax-exempt organizations are required to file annually. The final form retains the redesigned draft’s format of a core form and a series of schedules. The new form will be used for the 2008 tax year (returns filed in 2009). It allows an organization to describe its exempt accomplishments and mission upfront and provides more opportunities throughout the form for the organization to explain its activities. Other major changes were made to the form’s summary page, governance section, and various schedules, including those relating to executive compensation, related organizations, foreign activities, hospitals, non-cash contributions, and tax-exempt bonds. A checklist of schedules was also added.

On April 7, 2008, the IRS released the draft Instructions accompanying this new Form 990. These draft Instructions spell out how the IRS anticipates that organizations will make highly detailed disclosures regarding virtually every aspect of their operations, including compensation for top management and other financial transactions with “insiders” as well as descriptions of the kinds of policies and procedures the organization follows in reviewing and approving financial transactions with insiders. In addition, in the draft Instructions for Schedule H, the IRS sets forth what is very likely the IRS’ view of the factors it will look at to judge whether an organization continues to qualify as a tax-exempt organization under the community benefit standard, including highly detailed disclosures regarding how an organization identifies and computes the “community benefit” that is at the core of tax-exempt status, how the organization determines whether a patient is eligible for charity care, how the organization distinguishes between bad debt and charity care, how the organization educates patients about charity care and collection matters, and how the organization assesses the needs of the communities it serves.

These detailed disclosures will provide an in-depth look at the tax-exempt healthcare sector, and the information provided in the Form 990 will enable the IRS to engage in more focused and more effective audit and enforcement activities. In addition, because the Form 990 is a publicly available document, the disclosures required by the Form and its Instructions will be the principal way an organization presents itself not only to the IRS but also to federal, state, and local legislative bodies, to state regulators,
including state attorneys general and state taxing authorities, to the various media and to the general public, including various special interest groups that may not have the organization’s best interest at heart.

**Antitrust Enforcement**

Although last on the list of the “top issues,” antitrust enforcement generated a significant amount of activity, some of it in the wake of the highly publicized *Evanston* case, and a good portion of it the result of growing scrutiny of pharmaceutical manufacturers.

In a unanimous ruling released August 6, 2007, the Federal Trade Commission (FTC) found the 2000 merger of Evanston Northwestern Healthcare Corp. (ENH) and Highland Park Hospital violated federal antitrust laws. But significantly, the Commission’s ruling did not require ENH to divest its Highland Park acquisition as ordered by an agency Administrative Law Judge (ALJ) in 2005. Instead, the FTC ordered ENH to establish separate and independent contract negotiating teams—one for Evanston and Glenbrook Hospitals and another for Highland Park—to allow managed care organizations (MCOs) to again negotiate separately for the competing hospitals.

The Commission agreed with the ALJ that the deal violated § 7 of the Clayton Act, finding the transaction “enabled the merged firm to exercise market power and that the resulting anticompetitive effects were not offset by merger-specific efficiencies.” The Commission refused, however, to require divestiture, saying a “conduct remedy” was more appropriate given the “potentially high costs inherent in the separation of hospitals that have functioned as a merged entity for seven years.” According to the Commission, the separate negotiation teams would serve to “re-inject” competition between the hospitals for the MCOs’ business.

A federal court in Illinois refused to dismiss antitrust claims brought by long term care pharmacy Omnicare Inc. alleging the merger of UnitedHealth Group, Inc. and PacifiCare Health Systems, Inc. violated the Sherman Act. In July 2005, UnitedHealth entered into an agreement with Omnicare in which UnitedHealth would act as a Medicare Part D prescription drug plan (PDP), with Omnicare agreeing to accept reimbursement from UnitedHealth for providing pharmacy services to UnitedHealth’s enrollees.
PacifiCare subsequently merged with UnitedHealth. After the agreement to merge was made, PacifiCare notified Omnicare—after allegedly conferring with UnitedHealth—that it would not negotiate a contract; instead Omnicare must accept a noncompetitive reimbursement rate and offer no more than the statutory minimum package of services in order to do business with PacifiCare. Omnicare was compelled to accept the below-market offer and once the merger was completed, UnitedHealth, now the owner of PacifiCare, notified Omnicare that it was withdrawing the UnitedHealth plans from its original agreement with Omnicare, and then switched them to the PacifiCare plan, with its lower reimbursement rate, according to the opinion.

Omnicare filed a five-count complaint against UnitedHealth Group, Inc., PacifiCare Health Systems, Inc., and RxSolutions, Inc. d/b/a Prescription Solutions (collectively, defendants). Omnicare alleged that defendants violated the Sherman Act’s prohibition on contracts or conspiracies in restraint of trade, 15 U.S.C. § 1, as well as a parallel prohibition against antitrust conspiracies in the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.175. Omnicare also charged defendants with two state law counts of fraud, and one state law count of conspiracy to commit fraud. Defendants moved to dismiss.

As to Omnicare’s Sherman Act claim, the U.S. District Court for the Northern District of Illinois found that plaintiff “easily” met the test for proving an explicit agreement between the defendants. The court rejected defendants’ argument that the claim failed as a matter of law because after the merger they became a single entity for antitrust purposes. The court found it “at least plausible” that two competitor corporations going through a process of merger could continue to retain separate economic interests. The court next found the merger agreement was a per se unreasonable restraint of trade in the relevant market. Turning to Omnicare’s alleged antitrust injury, the court found “Omnicare has successfully alleged that UnitedHealth and PacifiCare were members of a per se unlawful buyers’ conspiracy, and that it received a significantly below-market reimbursement rate as a result of this conspiracy.” Finally, the court concluded that Omnicare is a proper plaintiff to bring the Sherman Act suit. Omnicare, Inc. v. UnitedHealth Group, Inc. No. 06-C-6235 (N.D. Ill. Sept. 28, 2007).
A significant portion of enforcement-related activities involve the entry of generics into the marketplace. On February 13, 2008, the FTC filed a complaint against Cephalon, Inc., alleging the pharmaceutical company unlawfully blocked the sale of generic versions of its brand name drug Provigil, a drug approved to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shift-work sleep disorder. According to the complaint, filed in the U.S. District Court for the District of Columbia, Cephalon entered into agreements with four generic drug manufacturers to pay the companies a total amount of more than $200 million so the companies would refrain from selling a generic version of Provigil until 2012. Cephalon allegedly paid the amounts to Teva Pharmaceuticals USA, Inc., Ranbaxy Pharmaceuticals, Inc., Mylan Pharmaceuticals Inc., and Barr Laboratories, Inc. In the complaint, FTC sought a permanent injunction against Cephalon that would allow generic Provigil entry before 2012. In addition, the complaint asked the court for a judgment against Cephalon declaring that its course of conduct violates § 5(a) of the FTC Act.

Barr Pharmaceuticals reached a $5.9 million settlement with 34 states and the District of Columbia to resolve allegations that it violated antitrust laws by conspiring with Warner Chilcott Ltd., a national drug distributor, to prevent a generic version of the prescription oral contraceptive Ovcon from reaching the marketplace. In June 2007, the states’ attorneys general reached a related settlement with Warner Chilcott in which the company agreed to pay $5.5 million in civil penalties and costs and to abide by an injunction that prevents it from entering into similar agreements with general drug manufacturers for ten years.

Finally, on March 18, 2008, 18 states and the District of Columbia filed a lawsuit in federal court alleging Abbott Laboratories and a French drug company engaged in an “elaborate scheme” to keep a cheaper generic version of the cholesterol-lowering drug TriCor off the market, according to a press release posted by California Attorney General Edmund G. Brown Jr. The complaint alleged Illinois-based Abbott and Fournier Industrie et Sante and Laboratories Fournier, S.A. “conspired to monopolize and implemented an anti-generic strategy” by orchestrating a scheme that included making trivial changes to TriCor to force the market to convert to new formulations before generic entry. These
product switches helped thwart generic competition and allowed the companies to charge monopoly prices for TriCor, the states contended.
ACADEMIC MEDICAL CENTERS

U.S. Supreme Court Declines To Consider Ruling That University Owned Donated Tissue Samples
The U.S. Supreme Court let stand January 22 a unanimous Eighth Circuit ruling that Washington University in St. Louis, Missouri, not individual participants in its cancer research studies, owned donated biological samples. The Eighth Circuit’s decision in June 2007 found individuals under Missouri law who make an informed decision to contribute their biological materials to a research institution do not retain an ownership interest that allows them to later transfer the samples to a particular researcher or another entity.

The case arose after Dr. William J. Catalona, who worked at WU from 1976 to 2003 and helped amass an extensive collection of tissue samples for prostate cancer research, accepted a faculty position at Northwestern University in Chicago and sought to have the biological materials transferred there. According to the Eighth Circuit’s opinion, Catalona sent release forms to between 50,000 and 60,000 individuals asking them to acknowledge that the samples were donated for his research studies and should follow him to Northwestern. Catalona obtained about 6,000 release forms in response.

A lower court found WU owned the biological samples, that neither Catalona nor any of the research participants had any ownership or proprietary interest, and none of the release forms could legally transfer ownership. Affirming, the Eighth Circuit concluded the research participants made informed and voluntary decisions to participate in genetic cancer research and therefore donated their biological materials to WU as valid inter vivos gifts under Missouri law. Washington Univ. v. Catalona, 490 F.3d 667 (8th June 20, 2007), cert. denied Nos. 06-2286 & 06-2301 (U.S. Jan. 22, 2008).

ANTITRUST

U.S. Court In Tennessee Refuses To Dismiss Nurses’ Claims Alleging Hospitals Conspired To Depress Wages
A federal trial court in Tennessee refused to dismiss an action brought against two healthcare corporations alleging they conspired to artificially depress nurses’ wages at their hospitals in the Memphis area. Plaintiffs Suzanne Clark and Conise Dillard sued Baptist Memorial Healthcare Corporation and Methodist Healthcare (defendants) alleging they violated the Sherman Act § 1 by conspiring to keep nurses’ wages artificially low and by exchanging compensation information. Dillard and Clark are both registered nurses and former employees of Baptist Memorial and Methodist Healthcare respectively.

Plaintiffs brought the action on behalf of themselves and a class consisting of all RNs who worked for defendants or a co-conspirator in a hospital in the Memphis Metropolitan Statistical Area (MSA) at any time from June 20, 2002 until the present. According to the complaint, defendants employ roughly 68% of the hospital RNs in the Memphis MSA. Plaintiffs contended that the alleged conspiracy has forced RNs to work harder for longer
hours, affecting the availability of healthcare personnel and reducing patient quality of care. Defendants moved to dismiss, arguing plaintiffs failed to allege a plausible product market and failed to plead facts sufficient to provide them with fair notice of the grounds on which relief should be granted.

Denying the motion, the U.S. District Court for the Western District of Tennessee found plaintiffs’ wage-fixing claim, like a price-fixing claim, stated a per se violation and therefore did not require them to allege a relevant market. The court also determined while plaintiffs failed to allege facts that, if proven, would provide direct evidence of a conspiracy, they did allege sufficient circumstantial evidence to support their conspiracy claim. Citing Sixth Circuit precedent, the court reasoned that paying below-market wages in a competitive market, absent a coordinated agreement among competitors, would be against an individual employer’s economic interest in terms of hiring and retention.

The court also refused to dismiss plaintiffs’ claim that defendants conspired to exchange compensation information, which the court analyzed under the rule of reason. Defendants argued that the relevant market asserted by plaintiffs—services provided to hospitals by RN employees—was implausible as a matter of law because hospital and non-hospital RN employment positions were reasonably interchangeable. But the court disagreed. “That different skills might be required and that substantially different wages might be paid by hospital and non-hospital RN employers suggest that Plaintiffs’ alleged product market is plausible,” the court said. Moreover, plaintiffs did not suggest that the only difference between hospital and non-hospital RN positions was salary; rather, both parties agreed that benefits, hours, working conditions, and other factors came into play. Clarke v. Baptist Mem’l Healthcare Corp., No. 06-2377 Ma/V (W.D. Tenn. May 17, 2007).

U.S. Court In Michigan Refuses To Dismiss Nurses' Suit Against Detroit-Area Hospitals Alleging Conspiracy To Depress Wages

A federal district court in Michigan refused March 31, 2008 to dismiss a lawsuit brought against eight Detroit-area health systems alleging they unlawfully conspired to depress nurses’ wages. In its motion to dismiss, Trinity Health Corp. argued plaintiff nurses failed to identify any actions taken by a particular defendant and failed to plead grounds for concluding that any particular defendant participated and did anything unlawful.

The complaint contended 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” through meetings, telephone conversations, and written surveys. The complaint asserted that, absent the alleged conspiracy, hospitals in the Detroit area would have responded to the national nursing shortage by “substantially increasing RN compensation.”

The U.S. District Court for the Eastern District of Michigan made a significant point of the fact that Trinity alone, and not any of the other defendants, brought the motion to dismiss. “[T]he other defendants here are in good company in their apparent belief that Plaintiffs’ allegations are likely to survive the challenge mounted by Trinity in this case,”
the court said. The court cited several nurse-wage suits pending in other jurisdictions, noting only one comparable motion to dismiss that ultimately was denied.

Turning to the merits of the complaint, the court said while plaintiff nurses’ allegations were not specific to each defendant, they were “sufficiently specific as to a common course of conduct to alert each defendant, including Trinity, to the factual basis underlying” their antitrust claims. The court distinguished the case on which Trinity relied, Jung v. Association of Am. Med. Colleges, 300 F. Supp. 2d 119 (D.D.C. 2004), on the grounds that here the defendants were similarly situated, making plaintiffs’ generalized allegations of common conduct more appropriate. Cason-Merenda v. Detroit Med. Ctr., No. 06-15601 (E.D. Mich. Mar. 31, 2008).

**Warner Chilcott To Pay $5.5 Million To Resolve Antitrust Claims**
Warner Chilcott, manufacturer of the oral contraceptive drug Ovcon, has agreed to a $5.5 million settlement with 34 states and the District of Columbia. The settlement resolves a 2005 federal antitrust lawsuit alleging that Warner Chilcott paid $20 million to Barr Pharmaceuticals to keep Barr’s generic version of Ovcon off the market, Arizona Attorney General Terry Goddard said in a press release.

**U.S. Court In Washington Dismisses Antitrust Suit Finding No Evidence Of Harm To Consumer Welfare**
The U.S. District Court for the Eastern District of Washington dismissed a physician's antitrust suit, finding the complaint offered “no more than conclusory allegations of antitrust injury under § 1 of the Sherman Act.” The court held the plaintiffs failed to show injury to competition, which was fatal to their claim. Plaintiffs John C. Perry, M.D. and Teddy Bear Obstetrics & Gynecology, of which Perry was the principal owner, sued the Associated Physicians for Women, P.L.L.C. (APW) and its individual members for alleged restraint of trade to accomplish an anticompetitive purpose.

Perry alleged that the APW conspired to drive him of business by improperly revoking his credentials at Kadlec Medical Center, where he was previously a member of the medical staff, by “falsely and/or discriminatorily asserting objections and obstacles to his clinical privileges and/or professional conduct and/or Medical Staff membership.” Perry alleged APW’s purpose was to injure or destroy his practice “as a tool to drive him and his practice from Richland, Washington,” and reduce or eliminate effective competition in the “Richland and/or Tri-City Area of Washington.”

The court found Perry’s complaint insufficient because the plaintiffs retained privileges to render services at a different hospital in the same “Tri-Cities” area, which “belie any injury to competition in that market.” Furthermore, the allegation did not indicate which “medical services” were affected, and the court determined that the use of the “and/or” language signaled uncertainty about the effect on competition. The complaint also focused on the impact on Dr. Perry of the alleged agreement, combination or conspiracy, rather than the injury to competition in general. Perry v. Rado, No. CV-07-5001-LRS (E.D.Wash. May 24, 2007).
DOJ Reaches Settlement With Federation Of Physicians And Dentists Resolving Allegations Of Antitrust Violations

The Department of Justice (DOJ) announced June 19, 2007 that it reached a settlement with the Federation of Physicians and Dentists and one of its employees regarding allegations that the Federation unlawfully coordinated its approximately 120 Cincinnati-area OB-GYN member physicians to negotiate or renegotiate higher fees in their contracts with local healthcare insurers. According to DOJ, the Federation's actions "caused Cincinnati-area health care insurers to raise fees paid to the Federation’s OB-GYN members above the levels that the OB-GYNs likely would have obtained if they had negotiated competitively with those insurers." The settlement prohibits the Federation and the employee from: negotiating or contracting with payors for healthcare services provided by the Federation’s private-practice members; representing any independent physician with any payor; reviewing or analyzing any proposed or actual contract or contract term negotiated between a physician and any payor; communicating with any independent physician regarding contracts or terms; and training or educating any independent physician about contracting or negotiating with any payor, DOJ said. The settlement is subject to approval by the federal district court in Cincinnati where the antitrust suit was originally filed.

Illinois AG Alleges Clinics Conspired To Turn Away Medicaid Patients In Effort To Increase Reimbursement Rates

Illinois Attorney General Lisa Madigan filed a lawsuit June 14, 2007 against Carle Clinic Association, P.C. and Christie Clinic, P.C., alleging the clinics violated the Illinois Antitrust Act by illegally agreeing to stop accepting new Medicaid-eligible patients seeking primary medical care. According to the complaint, the two clinics agreed to boycott new Medicaid patients seeking primary medical care by adopting virtually identical policies through which they refused to accept Medicaid patients: (1) who were not already registered with the clinic, or (2) who had not seen a clinic physician for at least three years.

The clinics entered the agreement in an effort to increase Medicaid reimbursement rates and to accelerate reimbursement payments from the state, Madigan said. Because the clinics employed more than 90% of the physicians in the county, the clinics in effect were denying Medicaid beneficiaries access to primary care, according to the complaint. The complaint asked the Champaign County Circuit Court to enter an injunction requiring the clinics to begin accepting new Medicaid patients and also sought civil penalties and damages to recover for the clinics’ anticompetitive misconduct.

FTC Rules Evanston-Highland Merger Anticompetitive But Declines To Order Divestiture

In a unanimous ruling released August 6, 2007, the Federal Trade Commission (FTC) found the 2000 merger of Evanston Northwestern Healthcare Corp. (ENH) and Highland Park Hospital violated federal antitrust laws. But significantly, the Commission’s ruling, written by Chairman Deborah Platt Majoras, did not require ENH to divest its Highland Park acquisition as ordered by an agency Administrative Law Judge (ALJ) in 2005. Instead, the FTC ordered ENH to establish separate and independent contract negotiating
teams—one for Evanston and Glenbrook Hospitals and another for Highland Park—to allow managed care organizations (MCOs) to again negotiate separately for the competing hospitals.

After ENH acquired Highland Park in 2000, the FTC filed an administrative complaint alleging ENH could now “raise its prices . . . far above increases of other comparable hospitals.” In October 2005, an ALJ found the merger “substantially lessened competition,” resulting in higher prices for insurers and consumers for general acute care inpatient services. The ALJ ordered ENH to sell Highland Park within 180 days.

The Commission agreed with the ALJ that the deal violated § 7 of the Clayton Act, finding the transaction “enabled the merged firm to exercise market power and that the resulting anticompetitive effects were not offset by merger-specific efficiencies.” The Commission refused, however, to require divestiture, saying a “conduct remedy” was more appropriate given the “potentially high costs inherent in the separation of hospitals that have functioned as a merged entity for seven years.” According to the Commission, the separate negotiation teams would serve to "re-inject" competition between the hospitals for the business of the MCOs.

In further developments, on April 28, 2008 the FTC issued a final order detailing the specific requirements ENH must implement to remedy the anticompetitive effects of its acquisition of Highland Park. At that time of its initial order, the FTC said it lacked sufficiently detailed information about ENH’s contract negotiations to craft a precise order and asked ENH to submit a more detailed proposal.

The latest order requires ENH to establish separate negotiating teams for both inpatient and outpatient services at Evanston and Highland Park. While ENH argued that separate negotiation should only apply to inpatient services, the FTC disagreed. According to the FTC’s unanimous opinion, written by Commissioner J. Thomas Rosch, “limiting separate negotiations to inpatient services would not effectively re-inject competition between Highland Park and Evanston for the business of MCOs because it does not comport with the reality of how payors contract for hospital services.”

Also in question was the appropriate definition of “payor” for purposes of the separate negotiation requirement. ENH argued that “government payors” such as Medicare and Medicaid should be excluded because the Commission only found harm as to commercial MCOs. The Commission agreed that government insurance programs should not be brought within the scope of the order, although it made clear that this exclusion applied only to payors like Medicare and Medicaid, not, for example, a municipality procuring healthcare coverage for its employees as a self-insured entity.

The Commission also ordered ENH to use separate negotiations as its status quo approach to dealings with MCOs, rather than placing the onus on payors to specifically request it. The Commission was dissatisfied with the “firewall” mechanisms ENH proposed for preventing Evanston and Highland Park negotiating teams from sharing information. Specifically, the Commission took issue with the proposal that the ENH
negotiating team effectively wear “two hats” and negotiate both separately for Evanston and collectively for all three hospitals when payors elect the joint negotiation option. Thus, the Commission’s order prohibits Evanston and Highland Park negotiation teams from engaging in the negotiations when a payor elects to negotiate jointly for all ENH hospitals.

Finally, the order and opinion set forth a detailed dispute resolution mechanism for disputes with payors over prices and/or terms arising from the separate negotiations. Under the order, ENH, at the request of a payor, must submit these disputes first to mediation, and, if that is not successful, to binding arbitration.

**Ninth Circuit Vacates $16.2 Million Antitrust Judgment In Hospital’s Suit Alleging Competitor Illegally Bundled Services**

The Ninth Circuit vacated September 4, 2007 a $16.2 million judgment awarded to Cascade Health Solutions, formerly known as McKenzie-Willamette Hospital (McKenzie), in its antitrust action alleging PeaceHealth bundled and discounted its services so that insurers would agree to exclusive preferred provider agreements to the detriment of competition. According to the appeals court, the lower court erred in instructing the jury on the standard for assessing McKenzie's attempted monopolization claim under federal law and price discrimination under state law, saying it failed to require a finding that PeaceHealth priced the bundled services below cost. The appeals court also vacated, however, the lower court's summary disposition of McKenzie's tying claim, finding genuine issues of fact existed on this cause of action.

McKenzie filed an antitrust action against PeaceHealth alleging monopolization, attempted monopolization, conspiracy to monopolize, tying, and exclusive dealing under federal law and price discrimination and intentional interference with prospective economic advantage under Oregon law. McKenzie, in its 114-bed hospital, provides primary and secondary care while PeaceHealth, in its three hospitals, offers primary, secondary, and tertiary care. McKenzie and PeaceHealth are the only two providers of hospital care in Lane County, Oregon. McKenzie claimed, among other things, that PeaceHealth engaged in anticompetitive conduct by offering insurers “bundled” or “package” discounts of 35% to 40% on tertiary services if the they made PeaceHealth their sole preferred provider for all services—primary, secondary, and tertiary.

The district court rejected McKenzie’s tying claim on summary judgment, but allowed the other causes of action to proceed. A jury ultimately found in favor of McKenzie on its attempted monopolization, price discrimination, and tortious interference claims, awarding $5.4 million in damages. The district court trebled that amount to $16.2 million and also awarded McKenzie over $1.5 million in attorneys’ fees.

With respect to the attempted monopolization claim, the Ninth Circuit agreed with PeaceHealth that the jury instruction, was erroneous because it focused on market structure rather than whether a defendant priced below cost. Instead, the Ninth Circuit adopted a “cost-based” rule, holding that “the exclusionary conduct element of a claim arising under § 2 of the Sherman Act cannot be satisfied by reference to bundled
discounts unless the discounts result in prices that are below an appropriate measure of the defendant’s costs.” Under the Ninth Circuit’s standard, a defendant’s bundled discounts are legal unless they have “the potential to exclude a hypothetical equally efficient producer of the competitive product.”

But the appeals court held the district court erred in granting summary judgment to PeaceHealth on McKenzie’s illegal tying claim. The appeals court found “genuine factual disputes about whether PeaceHealth forced insurers either as an implied condition of dealing or as a matter of economic imperative through its bundled discounting, to take its primary and secondary services if the insurers wanted tertiary services.” For example, the appeals court noted the fact that only 14% of the insurers operating in Lane County made a separate purchase from PeaceHealth could indicate some degree of coercion. The appeals court also found significant the substantial market power PeaceHealth enjoyed as the sole provider of tertiary services in the relevant geographic market.

Turning to the primary-line price discrimination claim under state law, the appeals court initially found the jury instruction lacking because it failed to require a finding that PeaceHealth priced below cost. But the appeals court subsequently decided to certify a question to the Oregon Supreme Court about what the jury instruction for this claim should be.

The appeals court acknowledged that the lower court based its jury instruction for the primary-line price discrimination claim under state law on the Oregon Supreme Court’s decision in *Redmond Ready-Mix, Inc., v. Coats*, 582 P.2d 1340 (Or. 1978), which was still technically good law. Since the *Redmond Ready* decision, however, the U.S. Supreme Court clarified that under federal price discrimination law a plaintiff must prove its rival priced below cost. *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993). “If the Oregon Supreme Court would still follow *Redmond Ready-Mix*, then the trial court’s jury instruction is valid,” the appeals court observed. But the appeals court questioned whether the state supreme court, if presented with the issue, would in fact deviate from the federal standard set by the High Court in *Brooke Group*, noting the Oregon price discrimination statute was nearly identical to and modeled on federal price discrimination provisions in the Robinson-Patman Act. Moreover, the Oregon Supreme Court previously stated that federal price discrimination law would guide its interpretation of Oregon price discrimination law. *Cascade Health Solutions v. PeaceHealth*, No. 05-35627 (9th Cir. Sept. 4, 2007); *Cascade Health Solutions v. PeaceHealth*, No. 05-35627 (9th Cir. Feb. 1, 2008).

**FTC Says It Would Not Challenge IPA Proposal To Negotiate Contracts On Behalf Of Members**
The Federal Trade Commission (FTC) would not challenge a physician group’s proposal to negotiate contracts on behalf of its members, according to an Advisory Opinion letter to law firm-requestor Ober, Kaler, Grimes & Shriver on behalf of its client, Greater Rochester Independent Practice Association, Inc. (GRIPA). GRIPA is an independent practice association that seeks to sell to various payors its members’ “clinical improvement services”—medical services intertwined with activities designed to improve
clinical outcomes. Under its proposed program, GRIPA would be collectively negotiating on behalf of its members, including price terms.

Because “GRIPA’s proposed program is both intended and structured to be likely to produce substantial integration among its participating physicians,” it should be evaluated under a rule of reason standard, the letter concluded. FTC further found the proposed joint pricing and collective negotiations were “ancillary” to the integration and achievement of efficiencies. Looking at the competitive effects of the proposal, FTC found the program would not result in an exercise of market power “as long as GRIPA physicians are available and willing to contract at competitive prices with payers who prefer not to contract with the network.” The staff letter concluded that it “would not recommend that the Commission challenge GRIPA’s proposed program unless it became apparent that GRIPA in fact was able to exercise market power or otherwise have an anticompetitive effect in a relevant market.”

The Federal Trade Commission (FTC) said that a proposal developed by the Massachusetts Department of Public Health (MDPH) to regulate and license “limited service clinics” (LSC), otherwise known as retail clinics, could expand access to basic healthcare services and spur price and quality competition with more traditional clinics or physician practices. In the October 2, 2007 letter to MDPH, FTC also commented that provisions in the proposed regulations requiring that all LSC advertising be pre-approved by MDPH “may be overly restrictive” and recommended such provisions be dropped from the regulations.

“We agree with the [MDPH] that a new category of limited service medical clinics has the potential to expand access to health care by making very basic medical care convenient and less costly,” the letter said. In addition, the letter said MDPH's proposed regulatory flexibility to waive certain requirements as appropriate “might be especially helpful in an emerging market, as health care providers explore different ways to deliver basic care on a competitive basis.” But the FTC took issue with the MDPH's proposed pre-screening requirement for all LSC advertising, including Internet sites. Recommending that this requirement be struck, the letter cautioned that pre-approval of all advertising materials might impose an “undue burden” on LSCs and deprive consumers of useful information about basic healthcare services provided by LSCs. “In addition, requiring pre-approval for LSC advertising alone, and not that of other health care clinics, might put LSCs at a competitive disadvantage without offering countervailing consumer benefits,” the letter said. FTC approved the filing of the letter with MDPH by a vote of 5-0.

U.S. Court In Illinois Refuses To Dismiss Antitrust Claims Alleging Merger Violated Sherman Act
A federal court in Illinois refused to dismiss antitrust claims brought by long term care pharmacy Omnicare Inc. alleging the merger of UnitedHealth Group, Inc. and PacifiCare Health Systems, Inc. violated the Sherman Act. In July 2005, UnitedHealth entered into
an agreement with Omnicare in which UnitedHealth would act as a Medicare Part D prescription drug plan (PDP), with Omnicare agreeing to accept reimbursement from UnitedHealth for providing pharmacy services to UnitedHealth’s enrollees. PacifiCare subsequently merged with UnitedHealth. After the agreement to merge was made, PacifiCare notified Omnicare—after allegedly conferring with UnitedHealth—that it would not negotiate a contract; instead Omnicare must accept a noncompetitive reimbursement rate and offer no more than the statutory minimum package of services in order to do business with PacifiCare. Omnicare was compelled to accept the below-market offer and once the merger was completed, UnitedHealth, now the owner of PacifiCare, notified Omnicare that it was withdrawing the UnitedHealth plans from its original agreement with Omnicare, and then switched them to the PacifiCare plan, with its lower reimbursement rate, according to the opinion.


As to Omnicare’s Sherman Act claim, the U.S. District Court for the Northern District of Illinois found that plaintiff “easily” met the test for proving an explicit agreement between the defendants. The court rejected defendants’ argument that the claim failed as a matter of law because after the merger they became a single entity for antitrust purposes. The court found it “at least plausible” that two competitor corporations going through a process of merger could continue to retain separate economic interests. The court next found the merger agreement was a per se unreasonable restraint of trade in the relevant market. Turning to Omnicare’s alleged antitrust injury, the court found “Omnicare has successfully alleged that UnitedHealth and PacifiCare were members of a per se unlawful buyers’ conspiracy, and that it received a significantly below-market reimbursement rate as a result of this conspiracy.” Finally, the court concluded that Omnicare is a proper plaintiff to bring the Sherman Act suit. Omnicare, Inc. v. UnitedHealth Group, Inc. No. 06-C-6235 (N.D. Ill. Sept. 28, 2007).

U.S. Court In California Allows Physician To Proceed With Antitrust Action Against Hospital And Medical Staff
A physician who alleged a hospital and its medical staff conspired to exclude him from providing certain pediatric critical care services at the hospital to the detriment of patient welfare could proceed with his antitrust claims against them, a federal trial court ruled in denying defendants’ summary judgment. Plaintiff Richard B. Fox, M.D. is a physician certified in pediatric pulmonology and pediatric critical care medicine. He was a member of the medical staff at Good Samaritan Hospital in San Jose, California where he held privileges for “Pediatric Critical Care Without Consultation in the ICU” (PICU) and “Pediatric Ventilator Management” (PVM). Good Samaritan subsequently instituted a
new “identical privileges” rule for the Pediatrics Department requiring members holding the PICU or PVM privileges to designate alternate call coverage of physicians who held the same privileges. The hospital suspended Fox’s PICU and PVM privileges after he failed to designate alternate call coverage in accordance with the “identical privileges” rule, which it said was aimed at improving patient care. Fox filed an antitrust action in federal court against Good Samaritan and its medical staff (defendants) alleging conspiracy to violate §§ 1 and 2 of the Sherman Act among other things.

The U.S. District Court for the Northern District of California refused to grant summary judgment to defendants on Fox’s antitrust claims under a rule of reason analysis. As a threshold matter, the court found Fox had antitrust standing to pursue his claims because he raised a triable issue of fact that defendants’ conduct may have adversely impacted the quality of pediatric critical care services at the hospital. The court also rejected defendants’ argument that the hospital and the medical staff were legally incapable of forming a § 1 conspiracy to exclude Fox from offering his PICU and PVM care at Good Samaritan. For example, the court noted an unlawful conspiracy could be inferred from the facts that Fox had undisputed credentials and experience in his field, that his suspension occurred relatively shortly after he had expressed concerns about patient rights and objected to certain patient transfers; and that the hospital failed to approve or timely approve privileges applications by physicians Fox designated for alternate care coverage. The court did find, however, that Fox could not support his claim for per se liability because “a decision about privileges involves much more than a simple economic calculation.”

Turning to a rule of reason analysis with respect to the Sherman Act § 1 claim, the court acknowledged “persuasive evidence that the identical privileges rule was implemented for the improvement of patient care and did not have significant anticompetitive effects.” At the same time, the court refused to grant the hospital summary judgment, finding some evidence to infer that the rule was targeted at precluding competition from Fox and that patient welfare suffered as a result. Likewise, the court found some evidence to support Fox’s allegations under § 2 of the Sherman Act of a conspiracy to obtain monopoly power and accordingly denied summary judgment on this claim as well. Fox v. Good Samaritan Hosp., No. C-04-00874 RMW (N.D. Cal. Oct. 9, 2007).

U.S. Court In Kansas Allows Specialty Hospital To Proceed With Antitrust Claims Against Hospitals, Insurers

A specialty hospital in Kansas may proceed with its conspiracy claims against various hospitals and managed care organizations (MCOs), a federal trial court in Kansas has ruled. Denying defendants summary judgment, the court found sufficient direct and circumstantial evidence, as well as a plausible economic rationale, that the hospitals and the MCOs conspired between and among themselves to keep the specialty hospitals out of the MCOs’ networks. In particular, the court noted that the hospitals struck deals with the MCOs to keep them from allowing physician-owned specialty hospitals into their networks but did not demand the same treatment for similar facilities that were majority owned by their fellow hospital-competitors.
Heartland Surgical Specialty Hospital, LLC brought an antitrust action in April 2005 against various MCOs, including Aetna Health Inc. and Coventry Healthcare, and hospitals located in Kansas. Forty-eight bed Heartland, in Johnson County Kansas, is owned by physicians specializing in orthopaedic, neurological, plastic, pain management, and general surgery, the opinion said. Heartland alleged conspiracy to boycott in violation of the Sherman Act § 1; tortious interference with prospective business relationships; and civil conspiracy. According to Heartland, it tried to negotiate in-network contracts with the MCO defendants but was refused.

Heartland alleged the hospital defendants viewed Heartland as a competitive threat and conspired to prevent it from obtaining in-network contracts with the MCO defendants. The MCO defendants agreed to participate in the conspiracy to exclude Heartland so that none of them would have a more attractive network of physicians and facilities to offer their customers, Heartland contended. Specifically, Heartland alleged MCO defendants agreed to include “network configuration” clauses in their participating provider agreements with the hospitals that prevented the MCOs from adding limited service hospitals owned by physicians to their networks absent the hospitals’ consent. In return, according to the allegations, the MCOs were able to negotiate lower reimbursement rates with the hospitals. In January 2007, Heartland settled its claims against five defendants including United Healthcare and Cigna. Defendants Aetna and Coventry moved for summary judgment on all Heartland’s claims and the hospital defendants moved for summary judgment as to the allegations of a horizontal conspiracy among them.

The U.S. District Court for the District of Kansas denied defendant MCOs’ motion and also, with the exception of one hospital, denied defendant hospitals’ motion, concluding Heartland met its initial burden of showing an agreement to restrain trade. The court found “weak direct evidence” of a conspiracy in testimony that the MCOs had an “understanding, unwritten but understood” that they would not extend managed care contracts to specialty hospitals; although, the testimony did not identify who was included in this "understanding." The court also noted circumstantial evidence of a conspiracy, including that the hospital defendants openly expressed their concerns about specialty hospitals at public gatherings with the MCO defendants and directly communicated their desires to keep specialty hospitals out of the MCOs’ networks. “The Hospital Defendants’ communications to the MCO Defendants could be viewed by the jury as veiled threats that the MCO Defendants either cooperate or risk losing the Hospital Defendants from their network,” the court commented.

In addition, the court concluded that Heartland had presented a “plausible economic theory”—that the hospital defendants sought to keep a highly competitive new entrant from the market and that the MCO defendants agreed to include the network configuration clauses in their provider agreement to obtain lower reimbursement rates from the hospitals. The court found particularly significant the fact that the hospital defendants “were willing to work with their competitors to allow those competitors’ majority-owned facilities into the MCO networks, while keeping physician-owned facilities out of a network.” The court likewise noted an unexplained discrepancy in the MCOs’ conduct absent an agreement—i.e. excluding a provider, Heartland, that could
make their networks more attractive to customers. “Therefore, the reasonable inference, and the only way to keep the Hospital Defendants happy while ensuring that one MCO Defendant’s network was not more attractive than the others, was to agree to exclude Heartland,” the court concluded. *Heartland Surgical Hosp., LLC v. Midwest Div., Inc.*, No. 05-2164-MLB (D. Kan. Oct. 17, 2007).

In further developments, the action was dismissed with prejudice in February 2008 after Heartland reached a settlement with the remaining defendants. The terms of the settlement were not disclosed.

**FTC Reaches Settlement With Barr Involving Oral Contraceptive Drug**

The Federal Trade Commission (FTC) said November 29, 2007 that it reached a settlement of its complaint against Barr Laboratories concerning its alleged anticompetitive agreement with Warner Chilcott, manufacturer of the oral contraceptive drug Ovcon 35. The FTC filed the complaint in 2005, alleging the two drug makers conspired to keep a generic version of Ovcon off the market. According to the FTC complaint, which was filed in the U.S. District Court for the District of Columbia, Barr agreed not to sell a generic version of Ovcon until May 2009 in exchange for $20 million. The FTC said Warner Chilcott last year abandoned the portion of the agreement keeping Barr from marketing a generic version of Ovcon and shortly thereafter Barr began selling Ovcon tablets in the U.S. Under the settlement, Barr must refrain from entering into anticompetitive supply agreements with branded companies, refrain from entering other agreements with branded manufacturers that unreasonably restrain competition, and notify the Commission of a broader group of agreements with branded companies that have the potential to harm competition, the FTC said. The settlement will expire in 10 years.

**U.S. Court In Illinois Allows Physician Center To Proceed With Certain Antitrust Claims Against Hospital**

A developer that planned to build a physician center that offered diagnostic imaging services could continue with certain antitrust claims against a hospital for reportedly inappropriately interfering with the zoning process, a federal trial court ruled. The court dismissed, however, the center’s due process claims against the municipal board and officials that refused to grant a permit or approve its site plan, finding the proper avenue for redress was under state law.

Mercatus Group LLC in 2004 began plans to build a physician center that would offer diagnostic imaging services three miles from Lake Forest Hospital (LFH). According to Mercatus, the land where it planned to build the center was zoned for such a purpose and it sought approval of its site plan from the Village of Lake Bluff (Village). Mercatus alleged it was only after LFH voiced its opposition to the center that the Village informed Mercatus that approval of the site plan was contingent on the group obtaining a “special use” permit. Although Mercatus was initially granted permission to build the center, the Village Board later denied the “special use” permit and site plan approval. Mercatus sued LFH, alleging it improperly intervened in the Village Board’s deliberations to the
Mercatus also asserted claims against the Village and certain individual Trustees alleging, among other things, procedural and substantive due process violations under 42 U.S.C. § 1983. LFH and the Village defendants moved to dismiss.

The U.S. District Court for the Northern District of Illinois denied LTC’s motion as to most of Mercatus’ claims. Citing the Noerr-Pennington doctrine, LFH alleged it was entitled to immunity from Mercatus’ antitrust claims because its allegedly anticompetitive actions of participating in Village Board meetings and pressuring members to change their vote were the type of lobbying activities protected by the First Amendment. Mercatus argued Noerr-Pennington immunity was inapplicable because the Village Board proceedings were an adjudicative (rather than legislative) setting and that LFH used the government process as a "sham" to interfere with Mercatus’ business. The court concluded the Noerr-Pennington doctrine applied and further rejected Mercatus’ contention that the “sham” exception was triggered, finding no evidence LFH was not genuinely attempting to obtain legitimate government action in its favor. The court ultimately determined, however, that it could not rule out at this stage of the proceedings that the Village Board was acting in an adjudicatory capacity, which would render Noerr-Pennington immunity unavailable.

Mercatus also argued that LFH engaged in other anticompetitive conduct, including interfering with Mercatus’ business relationships. On most of these claims, the court held Mercatus failed to allege an antitrust injury. The court refused to dismiss, however, Mercatus' claim that LFH suggested agreements with Mercatus in restraint of trade in other markets, noting the parties had failed to address the factors and facts applicable to the analysis of antitrust standing.

As to the Village defendants, the court granted their motion to dismiss on all claims. Specifically, the court concluded Mercatus was afforded procedural due process, pointing out that it attended relevant meetings and was given the opportunity to be heard. The court also found no substantive due process violation, noting Mercatus failed to show it lacked adequate remedies under Illinois law. Mercatus Group LLC v. Lake Forest Hosp., No. 07C2042 (N.D. Ill. Nov. 15, 2007).

FTC Opposes Proposed Bill In Puerto Rico That Would Allow Healthcare Providers To Bargain Collectively On Fees
The Federal Trade Commission (FTC), by a vote of 5-0, approved issuance of a FTC staff letter opposing proposed legislation in Puerto Rico that would allow “diverse health care providers and their representatives” to bargain collectively on fees, reimbursement methods, and other matters, according to a staff press release issued February 1, 2008. The letter to a request fir a staff opinion on the implications of Puerto Rico Senate Bill (S.B.) 2190, which would amend the Puerto Rico Insurance Code to “authorize collectively negotiated fees by health care providers,” the release said. In the letter, FTC staff expressed concern that S.B. 2190, if enacted, would likely foster anticompetitive conduct that is inconsistent with federal antitrust law and policy, and, as a result, “would
be detrimental to Puerto Rican health care consumers,” the release said. “Since the advent of active antitrust enforcement in health care services markets, health care providers have sought antitrust exemptions in state and federal legislatures,” the letter said. “[S]uch proposals have all, at bottom, sought protection from antitrust scrutiny for anti-competitive conduct that would tend to raise the prices of health care services without conferring countervailing benefits on health care consumers, . . . [and] the FTC consistently has opposed [them].”

**FTC Sues Cephalon Alleging Drug Maker Unlawfully Entered Into Agreements To Block Sale Of Generics**
The Federal Trade Commission (FTC) filed a complaint February 13, 2008 against Cephalon, Inc., alleging the pharmaceutical company unlawfully blocked the sale of generic versions of its brand name drug Provigil, a drug approved to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shift-work sleep disorder. According to the complaint, filed in the U.S. District Court for the District of Columbia, Cephalon entered into agreements with four generic drug manufacturers to pay the companies a total amount of more than $200 million so the companies would refrain from selling a generic version of Provigil until 2012. Cephalon allegedly paid the amounts to Teva Pharmaceuticals USA, Inc., Ranbaxy Pharmaceuticals, Inc., Mylan Pharmaceuticals Inc., and Barr Laboratories, Inc. In the complaint, FTC seeks a permanent injunction against Cephalon that would allow generic Provigil entry before 2012. In addition, the complaint asks the court for a judgment against Cephalon declaring that its course of conduct violates § 5(a) of the FTC Act.

**FTC Says Ohio Executive Order Allowing Collective Bargaining For Home Healthcare Workers Would Violate Antitrust Laws**
The Federal Trade Commission (FTC) staff said February 14, 2008 in a comment letter to Ohio state Senator William J. Seitz that an executive order seeking to establish collective bargaining for independent home healthcare providers (IHCPs) is likely to foster anticompetitive conduct to the detriment of Ohio home healthcare consumers. The executive order in question was issued by Ohio Governor Ted Strickland in July 2007. The order stipulates state recognition of “one representative as the exclusive collective bargaining representative for all IHCPs” and also stipulates that “the State, acting throughout the Office of the Governor or his designee, shall engage in collective bargaining with the elected representative of IHCPs regarding reimbursement rates, benefits, and other terms.” According to the FTC staff comment, “the Order would permit competing providers to agree on the prices they would accept for their services, which constitutes per se illegal price fixing.” The staff also noted that the anti-consumer effects of the order could spill over into other segments of the market for home healthcare services beyond Medicaid.

One Commissioner, Jon Leibowitz, issued a dissenting statement arguing the FTC did not have “enough information about the context and circumstances in which the Executive Order operates to offer a thoughtful evaluation of its likely effects.” Leibowitz noted the order has not yet been enacted; therefore, “the primary effect of the letter may be to
discourage home health care workers from participating in the state’s effort to expand access to Medicaid home health services,” he argued.

**Barr Pharmaceuticals Reaches $5.9 Million Settlement With States On Charges Of Blocking Market Entry Of Generic Oral Contraceptive**

Barr Pharmaceuticals has reached a $5.9 million settlement with 34 states and the District of Columbia to resolve allegations that it violated antitrust laws by conspiring with Warner Chilcott Ltd., a national drug distributor, to prevent a generic version of the prescription oral contraceptive Ovcon from reaching the marketplace, according to Massachusetts Attorney General Martha Coakley. In June 2007, the states’ attorneys general reached a related settlement with Warner Chilcott in which the company agreed to pay $5.5 million in civil penalties and costs and to abide by an injunction that prevents it from entering into similar agreements with generic drug manufacturers for ten years.

The civil complaint in the case was filed in U.S. District Court for the District of Columbia in 2005. According to the complaint, Ovcon has been sold in the United States since 1976, and Warner Chilcott became the exclusive U.S. distributor of Ovcon in 2000. In early 2003, Barr publicly announced that it planned to have a generic version of Ovcon on the market by the end of that year. Allegations in the complaint charged Warner Chilcott paid Barr a total of $20 million to keep it from marketing its generic version of Ovcon. After the states’ attorneys general along with the Federal Trade Commission filed actions against the two companies, Warner Chilcott abandoned the part of the agreement that prevented Barr from bringing its generic version of Ovcon to the market. Shortly thereafter, Barr began selling lower-cost generic Ovcon tablets in the United States.

In addition to paying $5.9 million in civil penalties and costs, for the ten-year term of the settlement agreement, Barr must comply with provisions prohibiting it from entering into any agreement that would have the effect of limiting the manufacture, marketing, or distribution of its generic products. Barr also must notify the states of certain agreements it enters into with brand-name drug manufacturers that have the potential to harm competition, and make its records available to the states for inspection to determine its compliance with the settlement agreement.

**DOJ Approves UnitedHealth-Sierra Health Merger With Divestiture Of Las Vegas Medicare Advantage Business**

The Department of Justice (DOJ) said February 25, 2008 it would drop its opposition to the combination of UnitedHealth Group Inc. and Sierra Health Services, Inc. if United divests assets relating to its Medicare Advantage business in Las Vegas. DOJ’s Antitrust Division filed a civil antitrust lawsuit in the U.S. District Court for the District of Columbia to block United’s proposed acquisition of Sierra, noting the merged company would control 94% of the Medicare Advantage health insurance market in the Las Vegas area. At the same time, DOJ filed a proposed settlement that would resolve its competitive concerns provided United “promptly divest” most of its Medicare Advantage business in Las Vegas. According to a DOJ, the Department tentatively approved Humana Inc. as the acquirer, and United must first attempt to sell the assets to Humana before seeking another purchaser.
The Nevada Attorney General’s office separately announced its own settlement with United and Sierra. Under that settlement, in addition to shedding its Las Vegas Medicare Advantage division, United must contribute $15 million to state organizations and agencies to demonstrate its dedication to improving the quality of and access to healthcare.

Multi-State Antitrust Suit Alleges Abbott, Fournier Thwarted Generic Competition For Cholesterol Drug
Eighteen states and the District of Columbia filed a lawsuit in federal court March 18, 2008 alleging Abbott Laboratories and a French drug company engaged in an “elaborate scheme” to keep a cheaper generic version of the cholesterol-lowering drug TriCor off the market, according to a press release posted by California Attorney General Edmund G. Brown Jr. The complaint, filed in the U.S. District Court for the District of Delaware, alleges Illinois-based Abbott and Fournier Industrie et Sante and Laboratories Fournier, S.A. “conspired to monopolize and implemented an anti-generic strategy” by orchestrating a scheme that included making trivial changes to TriCor to force the market to convert to new formulations before generic entry. These product switches helped thwart generic competition and allowed the companies to charge monopoly prices for TriCor, the states contend.

According to the complaint, the companies also obtained multiple patents through “inequitable conduct” and then filed “sham patent litigation” for purposes of delaying generic entry. Citing “willful, egregious and [the] repeated nature of these violations,” Brown said the states are seeking triple damages incurred by their public health agencies and individual consumers. According to the states, TriCor accounted for more than $1 billion of Abbott’s sales last year.

The states joining the lawsuit are Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Iowa, Kansas, Maine, Maryland, Minnesota, Missouri, New York, Nevada, Oregon, Pennsylvania, South Carolina, Washington, and West Virginia.

ARBITRATION/MEDIATION

Arkansas High Court Refuses To Compel Physician To Arbitrate Claims In Employment Dispute
A physician was not required to arbitrate a dispute with a medical corporation because his employment contract did not involve interstate commerce and therefore the Federal Arbitration Act (FAA) was inapplicable to the agreement’s arbitration provision, the Arkansas Supreme Court ruled May 31, 2007.

Dr. Abdalla Tahiri entered into an employment contract with Arkansas Diagnostic Center, P.A. (ADC) that contained an arbitration provision. Tahiri later filed a complaint against ADC in state court, alleging he was forced to cease providing services under the employment agreement because he found the working conditions to be intolerable. Tahiri sought to have the arbitration provision declared invalid and unenforceable pursuant to
the Arkansas Uniform Arbitration Act (AUAA), which states that it does not apply to employer-employee disputes. ADC moved to compel arbitration, arguing the employment contract was subject to the FAA. Tahiri countered that the contract did not evidence “a transaction involving commerce” as required by the FAA (9 U.S.C. § 2), and the contract was simply “between a local doctor and a local employer for medical services to local patients.”

Affirming a lower court decision, the high court concluded the FAA did not apply to the arbitration provision at issue because ADC failed to show that its employment of Tahiri was a transaction “involving interstate commerce.” ADC had claimed a number of interstate connections, including the purchases of medical and cleaning supplies from out-of-state vendors, the receipt of payment from out-of-state insurance companies, treatment of three out-of-state patients, and payment for physician travel to out-of-state conferences. Although the evidence “demonstrates that ADC did have interstate ties, just like many other corporations,” this evidence did not demonstrate ADC “considered itself, or operated as, an interstate business,” the high court reasoned. *Arkansas Diagnostic Ctr., P.A. v. Tahiri*, No. 06-667 (Ark. May 31, 2007).

**Fifth Circuit Holds Arbitration Clause Enforceable Against Non-Signatory Nursing Home Patient**

The Fifth Circuit held July 16, 2007 that an arbitration clause was enforceable against a plaintiff-patient whose mother had signed a nursing home admission agreement on her behalf. According to the opinion, Delores Conegie suffers from a condition causing severe physical and neurological problems, including dementia psychosis. She was admitted to a nursing home in Mississippi. Her mother signed the admissions documents, which included an arbitration clause, on Conegie's behalf.

The issue before the Fifth Circuit was whether Conegie, as a non-signatory to the admissions agreement, was bound by the arbitration clause. Although the parties disputed whether state or federal law controlled the issue, the appeals court said it need not resolve this dispute since both Mississippi and federal law compelled arbitration. Specifically, the appeals court cited the Mississippi Supreme Court's recent decision in *Covenant Health Rehab of Picayune, L.P., v. Brown*, 949 So. 2d 732 (2007), which held that under applicable state law (Miss. Code Ann. § 41-41-211), a surrogate had authority to sign a nursing home admissions agreement on behalf of an individual who lacked capacity even where there was no specific declaration to this effect by her primary physician before the admissions agreement was signed.

The Fifth Circuit determined that Conegie’s admissions, like that in *Brown*, satisfied the Mississippi statute allowing a surrogate to make healthcare decisions because she admitted in her brief that she had been diagnosed with dementia and did not have “the capacity to sign the Admission Agreement.” Furthermore, Conegie’s mother was “an appropriate member of the classes from which a surrogate could be drawn.” Thus, she “could contractually bind [Conegie] in matters of health care,” the appeals court said. The result would be the same even assuming in the alternative that federal law applied, the appeals court reasoned. According to the appeals court, Conegie was a third-party
beneficiary of the admissions agreement, and therefore bound to the arbitration clause, since the agreement expressly named her as the resident receiving care and services from the nursing home. *JP Morgan Chase & Co. v. Conegie ex rel. Lee*, No. 06-60603 (5th Cir. July 16, 2007).

**Alabama High Court Finds Arbitration Agreement Signed By Brother Of Nursing Home Resident Is Valid**
The Alabama Supreme Court held July 20, 2007 that a plaintiff was required to arbitrate his claims against a nursing home in which his sister was a resident when she died. The arbitration agreement, which plaintiff signed on his sister’s behalf, was valid, the high court held. Plaintiff Richard Carraway, as his sister’s legal representative, signed several admissions documents, including an arbitration agreement, for his sister to become a resident of a nursing home owned by Beverly Enterprises Alabama. Plaintiff’s sister died while at the nursing home, and plaintiff sued Beverly and others for wrongful death. Several of the defendants moved to compel arbitration. The trial court granted the motion and plaintiff appealed.

The high court rejected plaintiff’s contention that the arbitration agreement he signed on his sister’s behalf was valid only if she was physically unable to sign the agreement herself or if she was mentally incompetent. According to the high court, plaintiff signed as an “authorized representative,” which gave him apparent authority to sign the document. Plaintiff also alleged that defendants withheld material facts concerning the rules governing the arbitration process, including fee amounts, discovery limitations, admissibility of evidence, and damages awards. However, the high court found the document expressly stated that signatories have the right to have the document reviewed by a lawyer and referenced the terms set out by the National Arbitration Forum. The high court also rejected plaintiff’s argument that the terms set out by the National Arbitration Forum were "grossly favorable" to the nursing home defendants. The high court found plaintiff offered “no authority establishing the unreasonableness” of the terms he objected to. In addition, the high court found plaintiff failed to prove the nursing home had “overwhelming bargaining power.” In this regard, the high court pointed to the arbitration agreement itself, which expressly stated that it was not a condition of admission and that it could be rescinded within 30 days. *Carraway v. Beverly Enter. Ala., Inc.*, No. 1051409 (Ala. July 20, 2007).

**Kentucky Appeals Court Finds Nursing Home Resident’s Daughter Lacked Authority To Sign Arbitration Agreement**
The daughter of a deceased nursing home resident did not have authority to enter into an arbitration agreement on behalf of her mother; therefore, the agreement was not binding on the estate and could not prevent the daughter from filing a wrongful death lawsuit against the nursing home, a Kentucky appeals court ruled July 27, 2007. Susan Luttrell signed an arbitration agreement on behalf of her mother, Altha Duncan, as part of admissions admitted to Liberty Care Center (Liberty), a nursing home owned and operated by Kindred Hospitals Limited Partnership (Kindred). The arbitration agreement at issue was a stand-alone document, and according to testimony from the nursing
home's admissions staff, signing the agreement was not a pre-condition to admission to Liberty.

Prior to admitting Duncan to a nursing home, Luttrell, a high school dropout who has difficulty reading, assisted her mother and took her to her medical appointments. Duncan paid for her own medical care through Medicare and Medicaid. In addition, Luttrell routinely took Duncan’s social security checks, which Duncan endorsed, to the bank to cash them and then purchased money orders to pay Duncan’s bills. Luttrell signed the admissions documents and the separate arbitration agreement on behalf of Duncan, but later testified she did not read the documents, nor did she understand their specific provisions. Although Luttrell told the admissions person at Liberty that she was authorized to sign all documents on behalf of Duncan, the admissions person later admitted she knew Luttrell did not have power of attorney and was signing the documents based solely on her familial relationship.

The trial court denied Kindred’s motion to dismiss and/or to stay the litigation, finding Luttrell was not authorized to waive a jury trial on behalf of Duncan. Affirming, the Kentucky Court of Appeals concluded that Luttrell had no actual, apparent, implied, or statutory authority to sign the arbitration agreement for Duncan. Kindred argued Luttrell had actual authority to sign documents on behalf of Duncan, even without power of attorney, because Luttrell routinely took cash from Duncan to pay Duncan's bills and was a co-signer on Duncan’s savings account. But this activity, the appeals court said, constituted “little more than running errors.” As to apparent authority, the appeals court said Luttrell could not “create apparent authority, absent some affirmation by [Duncan], simply by holding herself out as having it.” The appeals court also rejected Kindred’s arguments that Luttrell had statutory authority to make healthcare decisions on behalf of Duncan under Ky. Rev. Stat. § 311.631, because Luttrell managed Duncan’s financial affairs. The arbitration agreement did not involve “health care decisions” covered under § 311.631, i.e., medical procedures, judgments, or interventions, but rather set forth the available methods for resolving disputes, the appeals court pointed out. Kindred Hosps. Ltd. Partnership v. Luttrell, No. 2006-CA-000221-MR (Ky. Ct. App. July 27, 2007).

**Mississippi High Court Finds Family Of Deceased Nursing Home Resident Not Bound By Arbitration Provision Signed By Relative**

The family of a deceased nursing home resident, who was mentally competent at the time he was admitted to the nursing home, was not bound by the terms and conditions of the arbitration provision contained in the nursing home admissions contract signed by the resident’s half-sister, the Mississippi Supreme Court ruled July 26, 2007. The Mississippi high court found no contract ever existed between the nursing home and the deceased nursing home resident and therefore he was not bound by the arbitration provision in the nursing home admissions contract. Thus, the family of the later deceased nursing home resident could sue the nursing home for wrongful death as they were not bound by the arbitration provision at issue.

Cephus Coleman, Jr., a paralyzed World War II veteran, was living with his half-sister, Anne Donaldson, when she decided to place him in a nursing home. He became a
resident of Grenada Living Center (GLC) in July 2003 where he died six months later. After his death, Coleman’s son, Cephus Coleman III, brought a wrongful death action against GLC, which moved to dismiss in favor of arbitration. The parties stipulated that Coleman Jr. was mentally competent when Donaldson had him placed at GLC, and that he was not present when Donaldson signed GLC’s admissions agreement and initialed its arbitration provision. The parties also stipulated that, at the time of Coleman’s admission to GLC, Donaldson did not retain power of attorney, a conservatorship, a guardianship, or any other legal power over her half-brother. Although Coleman did later execute a power of attorney in favor of Donaldson while he was a resident of GLC, the parties agreed that this document was not retroactive.

The Mississippi Supreme Court summarily rejected GLC’s assertion that Donaldson was legally authorized to bind Coleman to the arbitration provision in the GLC’s admissions agreement because she acted as Coleman’s healthcare surrogate under the provisions of the Uniform Healthcare Decisions Act, Miss. Code § 41-41-203 et seq. The high court pointed out that GLC’s claim was procedurally barred because it was never raised before the trial court, but then opted “for the sake of guidance” to examine the language of the Uniform Healthcare Decisions Act.

“[A] close reading of the statute reveals that a prerequisite before any other analysis is that a patient may only have a surrogate if they do not have mental capacity to make decisions and they do not have any other person legally available to care for them,” the high court said. Thus, Donaldson could not have been Coleman’s healthcare surrogate because the parties stipulated Coleman was competent at the time of his admission, and no physician had declared him incompetent.

The high court also rejected GLC’s argument that Donaldson’s actions bound Coleman through express agency, or in the alternative, implied agency. GLC stipulated that, at the time of Coleman’s admission, Donaldson had no express authority under a power of attorney or other legal document; therefore, the express agency claim must fail. In addition, GLC’s implied agency claim was procedurally barred because it was never presented to the trial court. *Grenada Living Center LLC v. Coleman*, No. 2006-CA-00169-SCT (Miss. July 26, 2007).

**Arizona Appeals Court Finds Wife Of Rehab Facility Resident Acted As Agent In Signing Arbitration Agreement**

The wife of a man who was “virtually non-responsive” after suffering a heart attack and massive stroke acted as an agent in signing a rehabilitation facility’s arbitration agreement and other admissions documents, the Arizona Court of Appeals ruled July 18, 2007. The appeals court affirmed a trial court’s decision in favor of the rehabilitation facility, which held the arbitration agreement signed by the resident's wife was binding and therefore his estate must arbitrate any claims arising out of his care and treatment at the facility.

Florentine Ruesga’s husband, Robert Ruesga, was “severely compromised” when she admitted him in November 2003 to Desert Life Rehabilitation and Care Center (Desert
Life), a rehabilitation center operated by Kindred Nursing Centers West, L.L.C. At the time of admission, Mrs. Ruesga signed a number of documents, as well as a six-page arbitration agreement, which contained a certification that the signatory was authorized to act as the prospective resident’s agent. It was undisputed that at the time Mrs. Ruesga signed the arbitration agreement, she was not acting under any power of attorney or as legal guardian for her husband, nor had her husband expressly or specifically granted her such authority.

Mrs. Ruesga subsequently sued Desert Life, alleging claims of negligence, violations of Arizona’s Adult Protective Services Act, breach of contract, and fraud. Desert Life moved to dismiss the complaint and compel arbitration. Mr. Ruesga’s estate was later substituted as plaintiff after Mr. and Mrs. Ruesga died. The trial court ultimately ordered the parties to arbitrate the claims.

Affirming, the appeals court found sufficient facts to show both Mr. Ruesga’s actions and Mrs. Ruesga’s long history of making decisions on Mr. Ruesga’s behalf gave rise to an implied agency relationship. “Absent any contrary evidence, the records Desert Life produced reflect that [Mr. Ruesga] intended his wife to act as his agent,” the appeals court said, concluding that this agency relationship could bind Mr. Ruesga to the arbitration agreement signed by Mrs. Ruesga. The appeals court clarified that “apparent agency” did not apply in this case as Mr. Ruesga was “non-responsive” when he was admitted to Desert Life. *Ruesga v. Kindred Nursing Centers. L.L.C.*, No. 2 CA-CV 2006-0114 (Ariz. Ct. App. July 18, 2007).

**Fifth Circuit Finds Fact Issues Exist On Issue Whether Illiterate Nursing Home Resident Agreed To Arbitration**

Material issues of fact existed as to whether a deceased nursing home resident who was illiterate understood the contents of an arbitration agreement at the time of admission, precluding summary judgment on a nursing home’s attempt to compel arbitration, the Fifth Circuit ruled August 3, 2007 in an unpublished decision. Charles McAlister was admitted to a nursing home facility owned and operated by Beverly Enterprises-Mississippi, Inc. (Beverly). McAlister purportedly executed an admissions agreement that contained an arbitration provision.

After his death, McAlister’s sister sued Beverly in state court for wrongful death, negligence, medical malpractice, fraud, and breach of fiduciary duty. Beverly brought an action in federal district court to compel arbitration of the dispute. The district court refused, holding Beverly engaged in fraud-in-the-inducement by having McAlister sign the agreement without properly explaining it to him.

On appeal, the Fifth Circuit reversed, finding conflicting testimony as to whether Beverly employees explained the agreement to McAlister and whether he understood its contents. The appeals court also noted a case cited by Beverly that under Mississippi law “illiteracy alone is not a sufficient basis for the invalidation of an arbitration agreement.” *Beverly Enters.-Miss. Inc. v. Powell*, No. 06-60468 (5th Cir. Aug. 3, 2007).
California Appeals Court Finds Patient's Claim That Physician Violated Her Privacy Rights Subject To Arbitration

A patient must arbitrate claims that her former physician violated her privacy rights when he forwarded her medical file to her disability insurer and informed the insurer that she was not disabled, a California appeals court ruled November 28, 2007. At the time plaintiff Marie L. Titolo sought treatment from Dr. Luz Elena Cano, a clinical neurologist she signed a physician-patient arbitration agreement, which stated that “any dispute as to medical malpractice, that is as to whether any medical services rendered under this contract were unnecessary or unauthorized or were improperly, negligently, or incompetently rendered, will be determined by submission to arbitration as provided by California law.” After commencing treatment with Cano, Titolo signed an authorization for use and disclosure of medical information, requesting and permitting Cano to disclose Titolo’s privileged and confidential medical information to her disability insurer, Provident Life and Accident Insurance Company (Provident).

Cano subsequently informed Provident that Titolo was not disabled, that she was a “fraud,” and that her disability claim was a “scam.” Cano also sent Provident a copy of Titolo’s medical file. Provident later denied Titolo’s disability claim. Titolo sued Cano for violating her privacy rights, breach of fiduciary duty, and intentional interference with prospective economic advantage. Cano filed a petition to compel arbitration. The trial court denied the petition, concluding that Titolo was “seeking damages for actions not part of the provision of medical services,” and therefore, the arbitration agreement did not apply to the parties’ dispute.

Reversing, the appeals court concluded that Titolo’s claims fell within the scope of the arbitration agreement and its definition of “any dispute as to medical malpractice,” i.e., a dispute “as to whether any medical services rendered . . . were unnecessary or unauthorized or . . . improperly, negligently, or incompetently rendered.” The appeals court found Cano’s actions in communicating with Provident and providing the insurer with Titolo’s medical records, at Titolo’s request, constituted the “rendering of medical services” by a physician to a patient. “Communications between physicians and insurance companies regarding the diagnosis and treatment of patients are a necessary part of the provision of medical services to those patients,” the appeals court said. Titolo v. Cano, No. G037641 (Cal. Ct. App. Nov. 28, 2007).

Tennessee Appeals Court Overturns Decision Finding Arbitration Provision In Nursing Home Admission Contract Unconscionable

A Tennessee trial court erred in finding the arbitration provision contained in a nursing home admission contract to be unconscionable and oppressive, the Tennessee Court of Appeals ruled December 12, 2007. When plaintiff Gary Philpot admitted his mother to National Healthcare Corp.’s (NHC’s) residential facility, he signed an admissions contract that contained an arbitration clause in his legal capacity as his mother’s attorney-in-fact pursuant to a durable power of attorney for healthcare, as well as a general and durable power of attorney.

Less than three months later, Philpot’s mother died while a resident at NHC.
Philpot brought a wrongful death action against Tennessee Health Management Inc., NHC, and other related entities (collectively, defendants), asserting numerous claims, including negligence and gross negligence, medical malpractice, and violations of the Tennessee Adult Protection Act. Defendants moved to compel arbitration. After two separate hearings, the state trial court denied defendants' motion, finding "the agreement to arbitrate unenforceable as it is one of adhesion, oppressive, and unconscionable."

The appeals court reversed. The appeals court commenced its analysis by citing *Owens v. National Health Corp.*, No. M2005-01272-SC-R11-CV (Tenn. Nov. 8, 2007), in support of its finding that the Tennessee Uniform Arbitration Act (TUAA), rather than the Federal Arbitration Act (FAA), governed the arbitration provision at issue. The appeals court refused to hold, as a matter of Tennessee law, that pre-dispute arbitration agreements executed upon a resident’s admission to a nursing home violate public policy and therefore are invalid, noting a recent high court decision rejecting this argument.

While the nursing home conceded that the arbitration agreement constituted a contract of adhesion, the appeals said it was well established that the contract could still be enforceable. The key consideration is whether the contractual language or circumstances surrounding the contract’s execution rendered it unconscionable. Although Philpot’s contended the circumstances surrounding the signing of the agreement rendered it unconscionable due to the “urgency” of the situation, the appeals court noted NHC was not the only facility in the area and Philpot was aware of this fact. Moreover, there was “nothing in the record suggest[ing] that plaintiff’s educational background or abilities prohibited him from comprehending the agreement he signed.” In addition, the appeals court found the arbitration provision and jury trial waiver were prominently disclosed in the contract in several places. Finally, Philpot failed to provide sufficient evidence to support his argument that the arbitration procedure specified in the agreement would be cost prohibitive, the appeals court concluded. *Philpot v. Tennessee Health Management Inc.*, No. M2006-01278-COS-R3-CV (Tenn. Ct. App. Dec. 12, 2007).

**Mississippi Appeals Court Finds Daughter Of Deceased Nursing Home Resident Must Arbitrate Wrongful Death Claims**

A state trial court erred in denying a nursing home’s motion to compel arbitration of wrongful death claims brought by a deceased resident’s daughter who signed, on behalf of her mother, the home’s admissions agreement containing an arbitration provision, a Mississippi appeals court ruled January 8, 2008. In January 2001, Elzenia Johnson admitted her mother, Mary Scott, to Trinity Mission Health & Rehabilitation of Clinton (Trinity), and signed an admissions agreement, as well as other documents. Johnson later signed an amended admissions agreement containing an arbitration section. Mary Scott died while residing at the facility in January 2004. Six months later, Johnson filed in state court a wrongful death suit against Trinity, alleging her mother suffered injuries at the home that caused her death.

Trinity moved to stay the proceedings and compel arbitration pursuant to the admissions agreement. Johnson contended the arbitration agreement was unenforceable because she
never had the authority to waive her mother’s right to a jury trial. A state trial court denied Trinity’s motion and Trinity appealed.

The appeals court first rejected Johnson’s argument that she was not bound by the arbitration provision because Scott never signed the admissions agreement. “Since Scott received services from a contract that was executed for her benefit, her wrongful death beneficiaries are bound to the contract including arbitration,” the appeals court said. “The facts of this case clearly establish that Scott was a third-party beneficiary of the contract" and therefore "was bound to arbitrate any claims within the scope of the arbitration provision,” the appeals court continued. Moreover, “[s]ince this suit is a derivative action, Johnson must stand in the position of the decedent.” The appeals court next found the dispute was within the scope of the arbitration provision because all of Johnson’s claims arose out of “the acts or omissions that Trinity agreed to provide in the contract.”

Finally, the appeals court determined that the arbitration section was enforceable, even though certain provisions of the admissions agreement were found to be unconscionable and therefore unenforceable. Among the offending provisions that the appeals court struck down were those that: waived liability for criminal acts against individuals; placed a limit on actual damages at $50,000; waived punitive damages; and required legal action within one year of the alleged event. Despite these provisions, the appeals court noted the agreement contained a savings clause specifically stating that if any provision was found to be unenforceable the remainder of the agreement would remain in effect. Trinity Mission Health & Rehabilitation of Clinton v. Estate of Scott, No. 2006-CA-01053-COA (Miss. App. Ct. Jan. 8, 2008).

Mississippi High Court Finds Caretaker’s Negligence And Abuse Claims Against Nursing Home Subject To Arbitration
A state trial court erred in refusing to compel arbitration of a complaint filed against a nursing home by the caretaker of a mentally incompetent former resident who signed the home’s admissions agreement containing an arbitration provision, the Mississippi Supreme Court ruled January 10, 2008. Reversing the lower court’s decision, the state high court concluded the caretaker qualified as the resident’s healthcare surrogate under Mississippi law, and therefore could bind the resident to the arbitration provision.

Barbara Jean Barnes, who is an adult with the mental capacity of a three-year-old, moved in with her cousin, Atwood Grigsby, and his wife, Shirley, who became her primary caretakers. When Atwood became seriously ill, Shirley admitted Barnes into Magnolia Healthcare, Inc., d/b/a Arnold Avenue Nursing Home (defendant). Two-and-a-half years later, Shirley Grigsby (plaintiff), acting as the next friend and conservator of Barnes’ estate, filed a complaint in state court alleging that Barnes was negligently treated, abused, and sexually assaulted while she was a resident at the nursing home. Defendant moved to compel arbitration pursuant to the arbitration provision in the admissions agreement signed by plaintiff. The trial court denied defendant’s motion, finding that plaintiff did not possess the statutory or agency authority to bind Barnes to the arbitration agreement.
On appeal, defendant argued plaintiff had the authority under the Uniform Health-Care Decisions Act (UHCDA), Miss. Code Ann. § 41-41-201 et seq., to bind Barnes to the arbitration agreement as her healthcare surrogate. Under the UHCDA, “a surrogate may make a health-care decision for a patient who is an adult . . . if the patient has been determined by the primary physician to lack capacity” and no agent or guardian has been appointed (or the agent or guardian is not reasonably available). Miss. Code Ann. §41-41-211(1). In agreeing with defendant’s argument, the Mississippi Supreme Court cited its recent decision Covenant Health Rehab of Picayune, L.P. v. Brown, 949 So. 2d 732 (Miss. 2007), which held a surrogate, as defined under § 41-41-211, who satisfies the requirements of the UHCDA can bind the patient contractually in matters of healthcare.

_Covenant_ held that the person found to be a surrogate could bind the patient contractually, even though the record lacked a declaration by the patient’s primary physician that she was incapable of managing her affairs at the time she entered the hospital, but relied instead on the opinion of the hospital’s admitting physician. “Here, as in _Covenant_, we do not have a declaration by Barnes’s primary physician that she was incapable of managing her affairs" but "[i]t is clear from the undisputed facts that Barnes was incapable of managing her affairs when she was admitted to the nursing home,” the high court said. Therefore, the high court concluded the statutory requirement of § 41-41-211(1) was satisfied.

One dissenting opinion argued the majority erred in concluding a “decision to arbitrate” is a “health-care decision” as defined in Miss. Code Ann. § 41-41-203(h), noting that “arbitration is not among those matters specifically delineated in the statute as a health-care decision.” Another dissenting opinion objected to the majority’s conclusion that plaintiff met all statutory requirements set forth in § 41-41-211, when “the record contains not one grain of evidence” that Barnes’ primary physician made any findings regarding Barnes’ lack of capacity. Magnolia Healthcare Inc. v. Barnes, No. 2006-CA-00427-SCT (Miss. Jan. 10, 2008).

**California Appeals Court Says Wife Could Not Bind Husband To Arbitration In Nursing Home’s Admissions Agreement**

Arbitration agreements signed by a nursing home resident's wife on his behalf during the admissions and re-admissions process were not valid or binding on the resident or his wife with respect to subsequent claims brought against the nursing home, a California appeals court ruled January 30, 2008 in an unpublished decision. Overturning a state trial court’s order granting the defendant-nursing home’s motion to compel arbitration of the a negligence and wrongful death action against it, the California Court of Appeal, Fifth District, said the resident's wife did not have authority to bind him to an arbitration agreement based on the spousal relationship alone.

The nursing home resident, James Hatley, was admitted to Hanford Nursing Home and Rehabilitation Hospital (Hanford) on six different occasions, beginning in September 2005. Sometime after December 2005, Hatley’s wife, Una Hatley, signed admissions paperwork that included the arbitration agreements. Una Hatley, as successor in interest of the decedent, filed a complaint against Hanford and the individual manager at the
hospital (collectively, defendants), alleging causes of action for negligence and elder abuse. The trial court granted defendants’ petition, and plaintiff appealed, arguing she was not authorized to execute arbitration agreements on her husband's behalf.

According to the appeals court, the trial court found plaintiff, as decedent's wife, had the authority to bind him to arbitration of his claims. But the appeals court concluded plaintiff's status as decedent's wife did not authorize her to sign an arbitration agreement on his behalf. The appeals court relied in part on *Flores v. Evergreen at San Diego, LLC*, 148 Cal.App.4th 581 (2007), which held "absent a legislative directive, the spousal relationship alone is insufficient to confer authority to agree to an arbitration provision in a nursing home admission contract." While plaintiff was permitted by statute to consent to medical treatment on decedent’s behalf, defendants failed to cite any statute that authorized plaintiff, as decedent’s spouse, to sign an arbitration agreement on decedent’s behalf,” the appeals court said. Moreover, “[w]here a durable power of attorney or other authorization as agent is absent,” as was the case here, “the spouse’s duty of support [under state statute, Cal. Family Code § 4300] does not provide authority to enter into an arbitration agreement with . . . [a] nursing facility on behalf of the patient spouse.” *Hatley v. Superior Ct. of King County*, No. F052747 (Cal. Ct. App. Jan. 30, 2008).

**U.S. Court In Oklahoma Says FAA Preempts State Law Concerning Nursing Home Arbitration Provision**

The U.S. District Court for the Northern District of Oklahoma found January 29, 2008 that a nursing home’s admission agreement evidenced a transaction involving interstate commerce and therefore the Federal Arbitration Act (FAA), not contrary state law requirements, governed the arbitration clause therein. The court permanently enjoined the Oklahoma State Department of Health (OSDH) from enforcing the state’s Nursing Home Care Act (Act), Okla. Stat. tit. 63, § 1-1900.1 et seq., as to Rainbow Health Care Center, Inc.’s arbitration provisions.

The Act provides that a nursing home resident can not waive his or her right to a jury trial. OSDH had threatened to revoke Rainbow’s license to operate its nursing home unless it removed the arbitration provision from its resident admissions agreement. Rainbow sought a declaration in federal district court that the FAA preempted the Act. OSDH argued the FAA did not apply because the operation of a nursing facility is a purely intrastate activity.

The court distinguished the instant case from the Oklahoma Supreme Court’s decision in *Bruner v. Timberland Manor Ltd. Partnership*, 155 P.3d 16 (Okla. 2006), which citing the Act refused to compel arbitration of a wrongful death suit involving a nursing home. According to the court, in the *Bruner* decision, the parties had selected Oklahoma law to govern the arbitration provisions at issue. “The *Bruner* court’s holding was therefore predicated on the choice-of-law provision contained within the agreement,” unlike the clause in Rainbow’s agreement, which specifically said the FAA controlled, the court here said.
The district court also disagreed, however, with the Oklahoma high court’s reasoning “in dicta” that the execution of a nursing home admissions contract did not involve interstate commerce. Citing extensive precedent broadly interpreting Congress’ Commerce Clause powers, the court found at least a portion of Rainbow’s economic activity, including purchases of food, medicines, durable medical equipment, and other supplies, could be traced to interstate transactions. "Standing alone, these purchases of goods . . . which have moved in interstate commerce is enough to classify Rainbow’s nursing home care as ‘interstate commerce,’” the opinion said. The court also noted further evidence to support its conclusion, including that Rainbow occasionally sent personnel out-of-state to meet potential applicants, accepted resident admissions from out-of-state, and received payments from across state lines.

The only remaining issue, the court said, was whether certain federal Medicaid statutes and regulations, 42 U.S.C. § 1396a, 42 U.S.C. § 1396r(c)(5)(A)(iii), and 42 C.F.R. § 483.75, overrode the FAA’s coverage of nursing home admissions agreements. Section § 1396a directs states to establish and maintain “health standards” for private and public institutions under Medicaid. But the court noted no explicit congressional directive prohibiting arbitration agreements in the nursing home context, and saw no inherent conflict with § 1396a’s requirements. The court said OSDH’s interpretation would give state agencies a “blank check” to enact any rules and regulations, even those that conflict with preexisting federal law. The court also found § 1396r(c)(5)(A(iii), which prohibits nursing homes from demanding any consideration as a precondition to admitting Medicaid eligible residents, evidenced no congressional intent to preclude non-mandatory arbitration agreements from the FAA’s coverage. Rainbow’s admissions agreement gave resident the unilateral right to revoke the arbitration provision for up to 10 days after signing the agreement, the court noted. Finally, the court rejected OSDH’s contention that § 483.75, which requires nursing home facilities to be licensed under state law to participate in Medicaid, precluded the FAA from preemptioning the Nursing Home Care Act. That section, the court explained, does not apply to state and local laws that are invalid, illegal, or otherwise preempted. Rainbow Health Care Ctr., Inc. v. Crutcher, No. 07-CV-194-JHP (N.D. Okla. Jan. 29, 2008).

Tennessee Supreme Court Holds Attorney-In-Fact Could Bind Resident To Arbitration Agreement
A durable power of attorney for healthcare authorizes the attorney-in-fact to enter into an arbitration agreement on behalf of a resident as part of a nursing home’s admissions process, the Tennessee Supreme Court has concluded. The high court did remand for further proceedings, however, on whether the arbitration agreement was an unconscionable contract of adhesion.

The dispute arose in connection with Mary Francis King’s admission to a nursing home operated by National Health Corporation (NHC). King had executed a durable power of attorney for healthcare naming Gwyn C. Daniel as her attorney-in-fact. At the time of King’s admission, Daniel signed an admission agreement containing a pre-dispute arbitration clause and a jury trial waiver. After King died, the conservator of her estate (plaintiff), sued NHC, d/b/a/ NHC Healthcare, Murfreesboro, for negligence and other
claims. NHC moved to compel arbitration. The trial court denied the motion, holding the power of attorney did not authorize the attorney-in-fact to make “legal decisions” for King. The appeals court reversed, concluding the power of attorney authorized Daniel to make healthcare decisions on King’s behalf and the decision to admit King to a nursing home was a healthcare decision.

The Tennessee Supreme Court agreed that the attorney-in-fact had the authority to bind King to the arbitration agreement. The high court first confirmed that the case was governed by the Tennessee Uniform Arbitration Act, not the Federal Arbitration Act. The high court did not decide the issue of whether the contract involved interstate commerce and therefore was governed by the FAA, noting instead that the agreement itself specified that Tennessee law controlled.

Plaintiff argued that under state law the decision to sign an arbitration agreement and to waive a jury trial is a legal decision, not a healthcare decision. But the high court found this position untenable, noting Tennessee statutory provisions authorizing attorneys-in-fact, absent a limitation to the contrary, to make the same types of healthcare decisions as the principal herself could make. Moreover, the high court continued, “[h]olding that an attorney-in-fact can make some ‘legal decisions’ but not others would introduce an element of uncertainty into health care contracts signed by attorneys-in-fact that likely would have negative effects on their principals.”

In addition, the high court refused to find pre-dispute arbitration agreements in nursing home contracts per se invalid as a matter of public policy. To hold otherwise, the high court said, “would amount to a public-policy ‘exception’ to the Tennessee Uniform Arbitration Act,” a matter that should be left to the legislature. The high court ultimately remanded the action, however, for further proceedings on plaintiff’s claims that the contract was unconscionable, citing the “scant” factual record on this issue. Owens v. National Health Corp., No. M2005-01272-SC-R11-CV (Tenn. Nov. 8, 2007).

CORPORATE GOVERNANCE

This section is comprised of excerpts from the Corporate Governance Quarterly Review.

Delaware Court Of Chancery Clarifies Blasius “Compelling Justification Standard” in Mercier v. Inter-Tel

In the important case of Blasius Industries Inc. v. Atlas Corp., 564 A.2d 651 (Del. Ch. 1988), the Delaware Court of Chancery established that a corporation’s board of directors could take action with the purpose of making it more difficult for stockholders to exercise their voting rights to achieve a particular result if the board could show that it had a “compelling justification” for its action. On August 14, 2007, Vice Chancellor Leo E. Strine, Jr. applied this standard to hold that a special committee of a governing board has the right to reschedule a special stockholder meeting to vote on a proposed merger even where the effect was to prevent the stockholders from defeating that merger. Vice Chancellor Strine determined that the “compelling justification” standard was satisfied when the directors (in this case, a special committee of the board formed to consider
potential merger transactions) believed that: (i) stockholders are about to reject a third-party merger proposal that such special committee believes is in stockholders’ best interests; (ii) material information related to the voting on the proposed merger has not been considered adequately by stockholders; and (iii) if stockholders vote “no” on the merger, the opportunity to receive the bid would be irretrievably lost. Mercier v. Inter-Tel, 929 A.2d 786 (Del. Ch. 2007). This excerpt is from a summary prepared by Ethan E. Rii, Esquire, Sonnenschein Nath & Rosenthal LLP.

SDNY Addresses Key Element Of SOx Whistleblower Claim

As part of its scheme to promote corporate accountability, the Sarbanes-Oxley Act of 2002 (SOx) included a provision insulating employees of public companies from employment-related discrimination, including harassment, threats, discipline, and termination, arising because such an employee acted as a whistleblower with respect to a potential violation of the federal mail and wire fraud statutes, Securities and Exchange Commission rules and regulations, or any federal law “relating to fraud against shareholders.” This provision, codified at 18 U.S.C. § 1514A, is administered by the Occupational Safety and Health Administration (OSHA) and thus far has been somewhat limited in its application. A key principle demonstrating such limitations was explored by the U.S. District Court for the Southern District of New York in Portes v. Wyeth Pharmaceuticals, Inc., Case No. 06 Civ. 2689 (WHP) (Aug. 20, 2007).

In Portes, the plaintiff/whistleblower was a project manager for Wyeth’s “Sustainable Compliance Initiative” (SCI), a program implemented under a consent decree Wyeth had entered into with the Food and Drug Administration. Believing that he had discovered problems indicating that certain Wyeth lab operations were in violation of the consent decree and U.S. and European legal requirements, Portes reported his concerns to Wyeth’s Director of Quality. Wyeth’s supervisor, the head of the SCI department (and the person whom Portes believed to be responsible for the alleged issues), reported to the Director of Quality. Thereafter, Portes alleged that Wyeth had retaliated against him, pressured him to resign, and took disciplinary action against him. Portes continued to report alleged violations of pharmaceutical manufacturing regulations within Wyeth, as well as filing complaints of “whistleblower retaliation.” His employment was terminated approximately seven months after he first began to raise his concerns. He then filed an OSHA claim under § 1514A and received a right-to-sue notice. He brought suit, and Wyeth moved to dismiss.

The court noted that, in order for a claim to survive under § 1514A, the plaintiff must show, among other things, that he or she had engaged in a “protected activity” under the statute and that the employer knew of such protected activity. Wyeth asserted that Portes’ claim was insufficient to show that he engaged in protected activity, because none of his reports “were sufficiently related to securities fraud or any violation enumerated in [§ 1514A].” In response, Portes did not argue that he had expressly referred to the statute or to purported violations of the laws identified in the statute, but asserted that if the violations of manufacturing regulations he had reported were found to have occurred, he had a reasonable belief that Wyeth would have to publicly report such violations and would have suffered a significant adverse effect on its stock price.
The court rejected Portes’ argument. The court found that his disclosures concerning alleged manufacturing violations were not of a type that would have alerted Wyeth that it was potentially violating any federal law relating to securities fraud. Further, the court found that Wyeth’s job responsibilities as a chemist and product manager could not reasonably support an inference that he was concerned with securities fraud. The court contrasted these findings with an earlier decision in which the plaintiff’s reports to his employer had at least obliquely raised the possibility that the employer was committing securities fraud (although, interestingly enough, with respect to third-party securities and not securities of the employer itself). By contrast, the Portes court found that neither the specific contents of the communications made by Portes nor his position within Wyeth made such communications protected activity. This excerpt is from a summary prepared by William W. Horton, Haskell Slaughter Young & Rediker LLC.

SEC Issues Guidance On Improving Executive Compensation Disclosure
On October 9, 2007, the Securities and Exchange Commission’s (SEC’s) Division of Corporate Finance published observations of its initial review of the executive compensation and related disclosures for 350 public companies. The Division’s review identified two themes that reporting companies should address to improve the quality and usefulness of compensation disclosures: (1) the need to improve the manner in which information is presented; and (2) the need for more clarity related to the required Compensation Discussion and Analysis Disclosures. The Division’s review generally determined that disclosures that emphasize material information while de-emphasizing less critical data allow investors to gain a better understanding of the reporting company. For example, the Division suggests that companies can increase the quality and usefulness of executive compensation disclosures by emphasizing how and why certain compensation decisions were made, while shortening and placing less attention on the actual mechanics of the compensation process.

The report indicates that companies should focus on presenting the disclosure information in a manner to generate overall “readability.” For example, the report cited benefits of having the narrative overview required as part of the Compensation Discussion and Analysis precede the numeric compensation tables used to explain the process. The Division’s report also lauds the benefits of explanatory charts, tables, and graphs and suggests that the additional disclosure of the total compensation due to an executive upon termination or change-of-control would be beneficial to investors. The report also suggests that companies should utilize clear and concise language to explain their compensation decisions. This additional clarity can be obtained without more lengthy narratives, so long as companies carefully draft their disclosures to provide clear and concise analysis and insight related to the particular compensation programs. This excerpt was taken from a summary by Robert A. Wells, Bailey & Glasser LLP.

Ryan v. Gifford: New Shoals For Special Committee Counsel
Over the past quarter century, the use of special committees of the Board of Directors has become a mainstay practice for corporate lawyers advising clients on matters involving derivative litigation, internal investigations, and change of control transactions. Most
lawyers have understood that, while the special committee should retain outside independent counsel to provide advice on its work, such counsel is ultimately retained for the benefit of the corporation and owes its professional duties there. In a recent ruling by Vice Chancellor Chandler in Ryan v. Gifford, No. 2213-CC (complaint filed, June 2006 Del. Ch.), the relationship of special committee counsel to a corporation was defined in terms that have significant implications for the protection of privilege attaching to the special committee’s work.

The Ryan case is a derivative action filed in June 2006, by shareholders of Maxim Integrated Products, Inc. (Maxim) arising from alleged backdating of stock options by Maxim. Shortly after the litigation was filed, Maxim’s Board formed a Special Committee to investigate whether backdating of options had in fact occurred. Some of the subjects of the Special Committee’s investigation are sitting members of Maxim’s Board of Directors, who have been named as individual defendants. The Special Committee retained the firm of Orrick Herrington and presented an oral report of its findings to the full Board of Maxim on January 18-19, 2007.

The plaintiffs in Ryan filed a motion on July 3, 2007, seeking discovery of all communications between Orrick and the Special Committee as well as its presentation to the Board of Directors and materials prepared by LECG, a forensic accounting firm retained by Orrick to assist in the investigation. Maxim and the individual defendants opposed the motion on the basis that the communications between Orrick, the Special Committee, and the Board were privileged. Maxim contended that the Special Committee was operating at the direction of its Board and that, even acknowledging that the Special Committee might have an independent privilege with Orrick, at a minimum Maxim should enjoy a joint privilege as to the legal advice sought in response to the litigation.

Vice Chancellor Chandler, in an order dated November 30, 2007, ordered the production of materials by Orrick and LECG, holding that even if a privilege might exist between Maxim and counsel for the Special Committee, the privilege had been waived. It is important at the outset to note that apparently the Special Committee was not constituted to evaluate the shareholder derivative action as such, and lacked authority to assert claims on behalf of Maxim. This fact was troubling to Vice Chancellor Chandler, who (in a very convoluted footnote) suggested that the Special Committee might not be sufficiently independent of Maxim such that it could share a joint privilege with Maxim. It is hard to reconcile this conclusion with his statement that the Special Committee was apparently sufficiently separate that it could enjoy the benefits of privilege in communications with its own counsel. If the Special Committee were not truly independent of Maxim, then one would assume that Orrick should be considered counsel to Maxim, in the same manner that a lawyer working at the behest of a corporate officer is considered counsel to the corporation rather than counsel to the officer. Rather than explain this apparent discrepancy, the Vice Chandler merely assumed that a joint privilege could exist, as that assumption did not change his ultimate conclusion.

Two other factors were highly significant to the Vice Chancellor’s ruling. First, he found that the plaintiff shareholders had established good cause to reject the assertion of
attorney-client privilege against them. Under *Garner v. Wolfinbarger*, 430 F.2d 1093, 1103-04 (5th Cir. 1970), *cert. denied*, 401 U.S. 974 (1971), and its Delaware progeny, corporate attorney-client privilege is not absolute in the case of shareholder litigation. Rather, if the plaintiffs can demonstrate (1) a colorable claim, (2) the unavailability of necessary information from other sources than the privileged materials, and (3) specific identification of the information sought to be discovered, then a court may find good cause to vitiate the privilege. The Vice Chancellor attached special importance to the fact that the plaintiffs would be unable to replicate the investigation conducted by Orrick in the absence of discovery of its work.

The second, and perhaps more significant, point was that even if a joint privilege were found to exist and were not vitiated by good cause in the present action, the privilege had nonetheless been waived in the Special Committee’s presentation to the Board of Directors. The Vice Chancellor cited two important facts that supported this conclusion. First, even though the report of the Special Committee was delivered orally, and no materials prepared by Orrick were distributed to the Board, the commentary was so extensive (occupying two full days, during which Orrick lawyers were present) that it necessarily included disclosure of privileged materials constituting the report of Orrick to the Special Committee. Given that two of the directors present at the meeting were subjects of the investigation and had their own counsel present, the disclosures by the Special Committee constituted a waiver of the privilege, since not all parties present at the meeting had a common interest. Applicable Delaware law, and for that matter the law of most other states, premises the common interest or joint defense doctrine on the basis that the parties’ interests in the privileged matter are “so parallel and non-adverse. . . they may be regarded as acting as joint venturers.” Since the defendant directors who participated in the alleged backdating of options could not fairly be characterized as non-adverse or joint venturers with Maxim or the Special Committee, the common interest privilege could not apply and disclosure of the privileged materials constituted a general waiver.

The Vice Chancellor did respect one limitation on discovery of Orrick’s work, namely various notes and documents generated in the course of its interviews of individuals during the investigation. Orrick asserted that these materials constituted attorney work product, as they were not verbatim transcripts, but rather attorney notes containing thoughts, impressions opinions and conclusions, and which were thereby protected under Delaware Chancery Court Rule 26(b)(3). The Vice Chancellor agreed that a higher standard exists for disclosure of such materials and ordered an *in camera* inspection of the materials to determine whether any of them need be produced. *This excerpt is from a summary by Andrew J. Demetriou, Fulbright & Jaworski LLP.*

**CRIMINAL LAW**

**Eighth Circuit Reinstates Jury's Conviction Of Clinic Manager In Connection With Billing Scheme**

The Eighth Circuit reinstated May 29, 2007 a jury verdict finding James F. Boesen, Jr., the office manager and administrator of a medical clinic, guilty of conspiracy and
healthcare fraud for executing a scheme to bill for certain procedures that were not performed or were medically unnecessary. While the jury convicted Boesen on all counts, the district court granted his motion for judgment of acquittal finding that, as a non-medical professional, he relied on the medical judgment of his brother Dr. Boesen who owned the clinic, and therefore a reasonable jury could not conclude he knowingly and willfully engaged in healthcare fraud.

Reversing, the appeals court concluded that a reasonable-minded jury could find Boesen guilty, beyond a reasonable doubt, of conspiracy and healthcare fraud. At trial, several witnesses testified that Boesen, whose job was to submit claims from the Boesen Clinic for reimbursement to federal healthcare programs and private insurance companies, regularly discussed money concerns and ideas to generate more revenue. A former physician at the clinic testified that she was asked to leave when Boesen complained she was not performing enough high-paying procedures and threatened to take her patients off her schedule. A consultant hired by the clinic to review its billing codes also testified that Boesen ignored her advice to stop using certain incorrect codes. According to the consultant, her company had reviewed the patient notes at the clinic’s request and found them “fairly incriminating.” United States v. Boesen, No. 06-3290 (8th Cir. May 29, 2007).

Sixth Circuit Upholds Medicare Fraud Convictions, But Remands For Evidentiary Hearing On Documents Government Withheld

The Sixth Circuit upheld June 11, 2007 the convictions of two individuals on Medicare fraud charges. At the same time, the appeals court vacated the district court's denial of defendants' motion for a new trial. The appeals court remanded for a hearing on evidence defendants said could be favorable to them but to which the government denied them access.

Defendants Richard B. White and Michael A. Suhadolnik were indicted on charges of conspiracy, defrauding Medicare, and money laundering. The case arose from an alleged scheme to defraud Medicare by violating the “related party” rules. White owned and operated a number of health-related businesses. White also owned a financial management and consulting company that prepared cost reports for many of these businesses but failed to identify third-party and management service providers as “related parties” in accordance with Medicare requirements.

At trial, the government called various Medicare auditors to testify about their understanding regarding the related party rules. The government also introduced evidence that Medicare reimbursed over $14 million in 1997 and 1998 to providers controlled by White and another individual. A jury found White guilty on all counts. The district court sentenced him to 60 months' imprisonment on the first five counts, and 90 months' imprisonment on the remaining counts. It also ordered him to pay nearly $7.3 million in restitution. The jury found Suhadolnik guilty of wire fraud, but acquitted him on all other counts. He was sentenced to 37 months' imprisonment and to pay $10,000 in restitution. Defendants moved for a new trial based on newly discovered evidence. The district court refused and defendants appealed.
The Sixth Circuit concluded that the district court erred in part by allowing certain government witnesses to testify as lay witnesses without qualifying them as experts. The appeals court acknowledged that the distinction was “far from clear” in that the challenged witnesses had personal knowledge of facts relevant to the case through the auditing process, but at the same time relied on their specialized knowledge to a significant degree in testifying on the Medicare program. Despite this error, the appeals court held defendants’ substantial rights were not harmed, noting the government “adduced overwhelming evidence of defendants’ guilt” beyond the erroneously admitted evidence, which largely consisted of background information.

The appeals court vacated, however, the district court's order denying defendants' motion for a new trial. According to the appeals court, the district court abused its discretion in failing to hold an evidentiary hearing to consider the nature of evidence sought by defendants that could be favorable to their case. "Because Defendants succeeded in obtaining only relatively few of the documents notwithstanding their persistent and diligent attempts, the government effectively foreclosed them from making the requisite showing that the documents were material and favorable (whether exculpatory or impeaching), and that the suppression prejudiced them," the appeals court found. Absent a more detailed examination, the appeals court said it could not determine whether the government violated defendants' Fifth Amendment Due Process rights in withholding the materials. Thus, the appeals court remanded to the district court for an evidentiary hearing.

The appeals court also vacated White’s sentence, concluding the district court erred in failing to explain its factual determinations and in calculating the loss amount. In fact, the government conceded on appeal that the loss amount was too high and should have been set at $6.7 million. “This only buttresses the need for the district judge, on remand, to make some record of her factual findings in support of the loss calculation, and to cite to the government’s evidence where appropriate.” Moreover, White on remand may offer evidence of actual costs or comparables to aid the district court’s determination, the appeals court said. United States v. White, Nos. 05-3403, 05-3422, 06-3239, 06-3240 (6th Cir. June 11, 2007).

**Seventh Circuit Finds Lower Court Erred In Not Granting New Trial To Physician Convicted Of Fraudulent Billing**

A federal trial court erred in not declaring a mistrial in a criminal case against a physician alleged to have bilked insurance companies by ordering unnecessary tests where a juror had notified the court that just prior to jury deliberations she discovered the word “GUILTY” written in the middle of her notebook, the Seventh Circuit ruled September 17, 2007. Reversing the physician's conviction on 20 counts of healthcare fraud and seven counts of mail fraud, the federal appeals court reasoned that the notebook incident gave rise to a presumption of prejudice to the defendant and therefore it was error for the lower court to refuse to declare a mistrial.
Nine days into the original trial of defendant Dr. Felix Vasquez-Ruiz, a juror complained to the presiding federal district court judge that the word “GUILTY” had mysteriously appeared written in the notebook she had been using during trial. At that time, the juror said she felt that the anonymous message was meant to intimidate her. Vasquez-Ruiz moved for a mistrial, which the district court denied. The jury subsequently found Vasquez-Ruiz guilty on all counts of the indictment and he was later sentenced to 14 years' imprisonment.

The Seventh Circuit found the trial court should have granted a mistrial. Under the circumstances, the appeals court concluded that a presumption of prejudice against Vasquez-Ruiz arose, and that the government failed to rebut that presumption. “[W]here a mysterious note simply appears in a juror’s notebook, and where we cannot even say with assurance that it was another juror who wrote the note in the first place, there was a need to make a greater effort to find out what had happened before declaring that it did not make any difference,” the Seventh Circuit said. United States v. Vasquez-Ruiz, No. 06-2180 (7th Cir. Sept. 17, 2007).

**Ninth Circuit Upholds Conviction Of Mental Health Clinic Owner For Defrauding Medicaid**

The Ninth Circuit upheld September 25, 2007 a jury’s conviction of a mental health clinic owner on 32 counts of aiding and abetting healthcare fraud in connection with improper Medicaid billings. Arthur Dearing, who had a background in civil engineering, and his brother Rodger operated a mental health clinic called Life Springs Mental Health L.L.C. in Nampa, Idaho, which participated in Medicaid. Rodger, a registered nurse, ran the clinic’s day-to-day operations with consultant Greg Hassakis.

In October 2002, a Medicaid investigator audited Life Springs and informed Art and Rodger about three improper billing practices—billing for services performed by an employee lacking the qualifications necessary to perform Medicaid-funded services; billing for services without a treatment plan signed by a physician; and billing for services provided outside the Life Springs facility. Medicaid continued to investigate the company and in 2005 Art, Rodger, and another employee were indicted on various counts of aiding and abetting healthcare fraud in violation of 18 U.S.C. § 1346. Rodger pled guilty before trial and a jury found Art guilty on 32 counts. Art received a five-month sentence on each count.

The Ninth Circuit affirmed the conviction, finding Art “had knowledge of the ongoing fraud and misrepresented or covered up inquiries into that fraud, while continuing to profit from the venture.” The appeals court noted testimony presented at trial that, following the October 2002 audit, Life Springs continued its fraudulent billing although various employees continued to point out improper billing practices. While Art argued no evidence showed he acted with willful intent, the appeals court disagreed, noting

[A] reasonable juror could have found that Art was put on notice of Life Springs’ fraudulent billing practices by the October 2002 audit, knew that the company
continued these practices after the audit, yet took no action to correct these actions and, in fact, dissuaded serious investigation into the company’s problems, all while continuing to profit from the company’s illegal conduct.

The appeals court also said the jury could have found Art had knowledge of the company’s ongoing billing issues by his presence at meetings in which Rodger warned one employee “loose lips sink ships” in response to her billing concerns. Finally, the appeals court found no error in the lower court’s jury instruction that “intent to defraud” may be proven through “reckless indifference to the truth or falsity of statements.” *United States v. Dearing*, No. 06-30606 (9th Cir. Sept. 25, 2007).

**U.S. Court In Ohio Denies Motion To Withdraw Guilty Plea Filed By Owner Of Chiropractic Clinics One Year After Signing Plea Agreement**

The owner and operator of several chiropractic clinics who pled guilty to healthcare fraud charges and then filed a motion to withdraw his plea over a year later failed to demonstrate ineffective assistance of counsel or that he was coerced into signing his plea agreement, a federal district court in Ohio ruled October 4, 2007. Defendant Paul M. Neumann owned and operated chiropractic clinics, known as the MedBack Clinics, throughout Toledo, Ohio. For each of the clinics, Neumann hired a medical doctor and then billed insurers for services rendered by chiropractors at the rate applicable to services provided by doctors, the opinion said.

After a government investigation, a federal grand jury indicted Neumann and other co-defendants. The government subsequently proposed a package plea under which Neumann and one of his brothers, Timothy Neumann, would plead guilty to charges of healthcare fraud and money laundering, but other potential co-defendants including Neumann’s wife, another brother, and a close friend, would not be charged. The plea also would preserve Neumann’s substantial assets from forfeiture. Neumann signed the binding guilty plea agreement in August 2005, and then moved to withdraw his plea over a year later. Neumann filed his motion shortly after a co-defendant, James Altiere, who had formerly worked as MedBack Clinics’ lawyer, was acquitted following a trial on related charges.

In his motion, Neumann asserted his counsel provided constitutionally inadequate representation by failing to adequately investigate the government’s case, conduct adequate research into applicable defenses, or inform him about such defenses. Neumann also alleged his plea was coerced and not supported by an adequate factual basis.

Rejecting Neumann’s claims that his counsel failed to adequately investigate the government’s case, the district court noted the government’s file had been substantially open to counsel at all relevant times. In addition, the court concluded that counsel had been amply apprised of the government’s evidence and theory in the case. The court also highlighted testimony from Neumann’s primary attorney indicating that he had discussed with Neumann a number of defenses, including a general good faith defense, a reliance on counsel defense, and a defense based on Neumann’s “incident to” billing theory.
The district court also found no merit in Neumann’s contention that he was coerced into signing the plea agreement. The "package nature [of the plea] may have contributed to defendant’s decision to accept the offer, but that does not mean that he was coerced into entering his plea," the court said. The delay and timing of Neumann’s motion to withdraw his plea, i.e., after Altiere was acquitted, also favored denying his motion, the district court concluded. Although Altiere may be entitled to assert his innocence after his acquittal, “it does not make [Neumann’s] late-revived claims of innocence credible, much less sufficient,” the court said. United States v. Neumann, No. 3:05CR777 (N.D. Ohio Oct. 4, 2007).

In a related case, Paul Neumann’s brother, Timothy Neumann, who worked as an administrator and billing supervisor for the chiropractic clinics, also sought to withdraw his guilty plea asserting ineffective assistance of counsel. The U.S. District Court for the Northern District of Ohio on November 14, 2007 likewise overruled Timothy’s motion. The court said its ruling, in part, was based on an assessment of Timothy’s credibility, who now attempted to claim he had no prior knowledge of the billing improprieties, despite extensive evidence to the contrary. The court rejected Timothy’s argument that his discussions with Paul’s attorney represented a conflict of interest that justified granting his motion to withdraw his plea, finding evidence that Timothy was repeatedly told Paul’s attorney was not his lawyer. The court also concluded that Timothy “got the best advice possible under all the circumstances,” noting it may have been inadequate counsel if his attorneys had advised him to go to trial. Given the evidence, the court continued, “the government would, in all likelihood, have persuaded the jury beyond any doubt that the defendant was an important member of and played an active role in a conspiracy to defraud the government of millions of dollars, and that he acted knowingly, deliberately, and intentionally.” United States v. Neumann, No. 3:05CR778 (N.D. Ohio Nov. 14, 2007).

Sixth Circuit Upholds Sentence Of 188 Months’ Imprisonment For Physician Convicted Of Administering Partial Chemotherapy Doses

A Tennessee physician who was convicted of healthcare fraud and making false statements for administering partial doses of chemotherapy medications to cancer patients while billing for full doses received a “reasonable” prison sentence of 188 months (15 years, eight months), the Sixth Circuit ruled January 16. The Sixth Circuit concluded the district court did not err in increasing the physician’s sentencing range under federal Sentencing Guidelines because her conduct created a risk of death or serious bodily injury, affected a large number of “vulnerable victims,” and also constituted obstruction of justice.

The physician, Dr. Young Moon, formerly operated a medical practice in Tennessee specializing in oncology and hematology. Moon routinely used chemotherapy medications (e.g., Taxol, Procrit) in her treatment of cancer patients insured under the state’s Medicaid program or private insurance companies. As part of a federal and state investigation, agents made an unannounced visit to Moon’s offices and explained the general nature of the complaint filed against her. When the agents requested permission
to “scan” particular patient records, Moon consented. In addition, during an interview with the agents, Moon stated she always prescribed full doses of chemotherapy medication and never instructed her staff to give partial doses.

The federal government subsequently sought and obtained Moon’s indictment for three counts of healthcare fraud and one count of making false statements to government agents. After a two-week trial, Moon was convicted on all four counts. At the sentencing hearing, the district court heard testimony from family members of a number of Moon’s deceased cancer patients. The district court also considered a presentence report recommending sentencing enhancements for risk of serious bodily harm or death, vulnerable victims, and obstruction of justice. The district court ultimately applied the enhancements to increase the sentencing range, but then sentenced Moon at the lower end of that range, i.e., 188 months’ imprisonment, followed by two years of supervised release. The court also ordered Moon to pay $432,238 in restitution to the state Medicaid program, Blue Cross and Blue Shield, and other private health plans.

The Sixth Circuit found the sentence reasonable given that Moon’s “act of depriving her patients of the opportunity to receive the full benefit of their treatment through her failure to administer the recommended dosage of medication” qualified as “harm” within the meaning of the vulnerable victims enhancement, and as “risk of serious bodily injury or death” within the meaning of that enhancement.

The appeals court also rejected Moon’s argument that the lower court erred in applying the enhancement based on obstruction of justice because it constituted impermissible “double counting” since she was already convicted of making false statements to government agents. The appeals court found the sentencing scheme did not constitute “double counting” because the obstruction of justice enhancement was applied only to Moon’s conviction on three healthcare fraud counts.

The appeals court also rejected Moon’s argument that the district court considered an inappropriate factor when it heard testimony from family members of deceased patients regarding the emotional harm they suffered as a result of not knowing whether sufficient medication was administered to their loved ones. In this case, “[t]he fact that Defendant involved patient care in her fraud offenses separates her from others who may defraud the government by other means,” the appeals court said. “Clearly, the proximity of the fraud to patient care is an appropriate consideration for the district court to weigh as it determined the proper sentence to impose in the exercise of judicial discretion.” United States v. Moon, No. 06-5581 (6th Cir. Jan. 16, 2008).

**Prominent Plaintiffs’ Attorney Indicted For Attempting To Bribe Judge**

Richard F. Scruggs, along with several other attorneys, was indicted in a six-count indictment filed November 28, 2007 in the U.S. District Court for the Northern District of Mississippi. The indictment alleges that Scruggs, along with David Zachary Scruggs, Sidney A. Backstrom, Timothy R. Balducci, and Steven A. Patterson, tried to bribe circuit court judge Henry L. Lackey. According to the indictment, the defendants attempted to influence Judge Lackey by giving him $50,000 in return for a ruling
favorable to The Scruggs Law Firm in a pending case regarding a dispute over the division of $26.5 million in attorneys’ fees. Lackey reported the bribery attempt to the Federal Bureau of Investigation. The government further alleged that Scruggs tried to cover his tracks by falsely creating documents to show that he hired defendant Balducci to do jury selection work when in fact he was reimbursing Balducci for the bribes paid to Lackey.

The indictment asks for five years in prison and a $250,000 fine for count one; 10 years in prison and a $250,000 fine for counts two, three, and four; and 20 years in prison and a $250,000 fine for counts five and six. The Scruggs Law Firm is a civil litigation practice specializing in class action suits. The firm has brought hundreds of suits against nonprofit hospitals on behalf of uninsured patients alleging the hospitals violated their charity care obligations as tax-exempt entities.

Sixth Circuit Vacates Sentence Excusing Physician Convicted Of Healthcare Fraud From Any Imprisonment
In an April 11, 2008 decision, the Sixth Circuit vacated and remanded for further consideration a sentence excusing a physician convicted of healthcare fraud from any imprisonment. The appeals court found in a 2-1 opinion the sentence of five years’ probation, in addition to fines and a restitution order, to be “substantively unreasonable” where the Sentencing Guidelines range applicable to the physician’s convictions was 27-33 months’ imprisonment, and the sentencing court appeared to have relied in substantial part on its doubt that the physician intended to commit fraud. The appeals court also affirmed the physician’s convictions for healthcare fraud, conspiracy to commit healthcare fraud, and making false statements relating to healthcare fraud.

The convicted physician, Russell Wayne Hunt, formerly operated his own private practice in Nashville, Tennessee. Shortly after opening his practice, Hunt met Mark Noble, who owned and operated two mobile diagnostic testing companies that performed carotid artery ultrasound tests. Hunt agreed to evaluate patients on behalf of Noble’s company, for which he reviewed a medical history questionnaire filled out by a patient, performed a brief examination of the patient, and then made a determination as to whether the carotid artery ultrasound test was medically necessary.

Eventually, Hunt informed Noble that he was too busy in his private practice to continue seeing patients on behalf of Noble’s company. Hunt later testified that he provided Noble with a list of nurse practitioners (NPs) and suggested that Noble hire one of them to examine patients under Hunt’s license. Noble never hired an NP, however, and instead began bringing medical history questionnaires and unsigned orders to Hunt after the tests already had been performed. Hunt would sign these orders, receiving $10 per signature from Noble, without seeing or examining any patients. Noble would then submit the claims to Medicare and other private insurance companies.

After a government investigation, Hunt and Noble, as well as one of Noble’s employees, were indicted for healthcare fraud. Noble subsequently pled guilty, and was sentenced to 37 months’ imprisonment, three years of supervised release, and ordered to pay
restitution of over $240,000. Hunt’s case proceeded to trial, and a jury convicted him on all counts (i.e., healthcare fraud, conspiracy to commit fraud, and making false statements). Although the Sentencing Guidelines range for his convictions was from 27 to 33 months, the district court sentenced Hunt to five years’ probation. The district court also ordered Hunt to pay a $7,200 in fines and assessments, and restitution of over $150,000 (which he would owe jointly and severally with the other defendants).

In explaining the sentence at the sentencing hearing, the court engaged in “a lengthy discussion of the evidence that it believed to be indicative of a lack of fraudulent intent on Hunt’s part,” according to the Sixth Circuit. In addition, the district court gave weight to the fact that Hunt was a “well-liked” and “well-respected” physician.

The Sixth Circuit summarily rejected Hunt’s arguments for overturning his convictions, finding that the district court had not erred in making the evidentiary rulings at issue, and that the evidence was for the “rational trier of fact” to have found the essential elements of the crimes charged beyond a reasonable doubt. The appeals court agreed, however, with the government’s argument that the lower court imposed a substantively unreasonable sentence because it apparently relied on its doubt that Hunt intended to commit fraud. “If the district court did so rely, then it is necessary for us to remand . . . because it would be improper for the judge in sentencing to rely on facts directly inconsistent with those found by the jury beyond a reasonable doubt,” the Sixth Circuit explained. “It is true that the district court also relied on a number of factors that were either proper or arguably proper, such as . . . the personal circumstances of the defendant . . . and how valuable [he] was to the community,” the appeals court continued, “But such . . . proper reliance does not cure actual reliance on the perceived innocence of the defendant.” A dissenting opinion said the district court did not rely on Hunt’s perceived “innocence,” but rather found him less culpable than other defendants in the case and sentenced him accordingly. United States v. Hunt, Nos. 06-6300, 06-6301 (6th Cir. Apr. 11, 2008).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Congress Passes Omnibus Spending Measure With $65.6 Billion In FY 2008 Funding For HHS

Congress approved in mid December 2007 a massive omnibus spending measure (H.R. 2764) that provides $65.6 billion in fiscal year 2008 for the Department of Health and Human Services (HHS), $1.5 billion above 2007 levels. The House passed the bill by a 253-154 margin on December 18, the Senate followed suit with a 76-17 vote.

The bill includes $29.2 billion for the National Institutes of Health (NIH), $329 million above 2007, avoiding $480 million in NIH funding cuts under the President’s budget request. In addition, the bill provides $287 million for rural healthcare, $5 million above 2007 levels. Under the measure, the Centers for Disease Control and Prevention would saw a bump of $173 million in FY 2008 to $6.4 billion. The bill also provides $2.1 billion for community health centers to provide access to medical and dental services for an additional 280,000 uninsured Americans.
The measure, which includes funding for a host of federal agencies, also provides $1.7 billion for Food and Drug Administration salaries and expenses. This amount is $147 million above 2007 and $79 million above the President’s request. According to the summary of the bill, the increases will be used to help transform food safety regulation, improve drug safety, monitor prescription drug advertisements, and review generic drug applications. The bill also includes a provision that to allow individuals to import a 90-day supply of prescription drugs from Canada for personal use. The provision does not apply to imports of controlled substances or biological products. President Bush signed the measure December 26, 2007.

HHS Issues Proposed Rule Allowing Secretary To Review DAB Decisions
The Department of Health and Human Services (HHS) issued a proposed rule December 28, 2007 (72 Fed. Reg. 73708) that would amend Departmental Appeals Board (DAB) regulations to permit the HHS Secretary to review DAB decisions to correct errors in the application of law, or deviations from published guidance. HHS noted in the proposed rule that, currently, the DAB decision is the final administrative decision of HHS and “there is no Secretarial review of this final decision.” The proposal to allow the Secretary to review DAB decisions will “ensure that the final administrative decision of the Department reflects the considered opinion” of the Secretary, according to the rule.

The rule also proposes to require that the DAB “follow published guidance that is not inconsistent with applicable statutes and regulations.” The rule defines "published guidance" to include guidance that has been publicly disseminated, including, for example, guidance issued through manual provisions, State Medicaid Directors letters, or posting on the CMS website. The rule also noted that “[w]hen there is no published guidance on an issue, or when there is ambiguity in the published guidance, we would expect the Board to review relevant unpublished issuances for direction in interpreting such an issue.” Comments on the proposal were due January 28, 2008.

EMPLOYMENT AND LABOR

Third Circuit Upholds EEOC Rule Exempting Retiree Health Plans From ADEA
The Third Circuit upheld June 4, 2007 an Equal Employment Opportunity Commission (EEOC) proposed rule that would exempt employers from the federal age discrimination law if they decide to reduce or eliminate retirees’ health coverage when they become eligible for Medicare at age 65. The appeals court’s decision affirms, albeit on different grounds, a September 2005 district court ruling to lift an injunction enjoining the EEOC from implementing the proposed rule. According to the appeals court, the EEOC, in promulgating the proposed rule in July 2003, was acting pursuant to its express authority under the Age Discrimination in Employment Act (ADEA) to establish “reasonable exemptions” from the Act that are “necessary and proper in the public interest.”

The lawsuit, brought by the seniors group AARP, alleged that the EEOC acted illegally in limiting the provisions of the ADEA by allowing companies to discriminate against those over 65. The regulation was prompted by concerns about the implications of a Third
Circuit decision holding a county may have violated the ADEA by treating Medicare-eligible retirees differently than non-eligible retirees. See Erie County Retirees Ass’n v. County of Erie, 220 F.3d 193 (3d Cir. 2000). The regulation allows employers to coordinate retiree health benefits with Medicare eligibility and state-sponsored benefits without running afoul of the ADEA. According to the EEOC, the regulation is necessary to ensure that employers continue to offer retiree health benefits.

Affirming, the Third Circuit found the ADEA expressly authorizes the EEOC to establish exemptions from “any or all provisions” of the Act provided they are “reasonable” and “necessary and proper in the public interest.” The appeals court concluded the EEOC properly exercised this unambiguous authority based on its findings that the regulation would help “encourage[e] employers to provide the greatest possible health benefits for all retirees” and counteract the effect of rising healthcare costs. The appeals court also upheld the regulation under the Administrative Procedure Act. Although the regulation represented a change in agency policy, it was supported by “a reasoned analysis” and therefore was not arbitrary and capricious. AARP v. EEOC, No. 05-4594 (3d Cir. June 4, 2007).

Following the Third Circuit decision, the EEOC issued a final rule December 26, 2007 (72 Fed. Reg. 72938) allowing employers to legally coordinate retiree health benefit plans with eligibility for Medicare or a comparable state-sponsored health benefit.

The final regulation, EEOC said, expressly allows employers’ longstanding practice of coordinating retiree health benefits with Medicare by supplementing the government healthcare or by offering retirees a “bridge” benefit until they become Medicare-eligible. “Millions of retirees rely on their former employer to provide health benefits, and this rule will help employers continue to voluntarily provide and maintain these critically important benefits in accordance with the law,” said EEOC Chair Naomi C. Earp.

AARP called the EEOC move "a civil rights and economic fiasco." In a statement, AARP Legislative Policy Director David Certner said the decision "legalize[d] discrimination, allowing employers to back off their health care commitments based on nothing more than age." The final rule was effective as of December 26, 2007.

On March 24, 2008, the U.S. Supreme Court declined to review the Third Circuit’s decision.

Ohio Appeals Court Finds Physician Noncompete Clause Not Per Se Illegal
An Ohio appeals court held August 16, 2007 that a trial court erred in finding a noncompete clause invalid per se because it involved a physician. While such contract clauses are disfavored in the medical profession, they are not per se illegal, the appeals court said. Plaintiff General Medicine filed an action for declaratory judgment that the noncompete clause in its employment contract with Dr. Petricia Manolache was valid and enforceable. The trial court declared the noncompete clause invalid. The Ohio Court of Appeals reversed, holding the trial court “was required to enforce the covenant to the

**Second Circuit Allows Physician’s Antidiscrimination Action Against Hospital To Proceed, Finds Issue Of Employee Status Open**
A physician’s antidiscrimination lawsuit against a hospital where she had held staff privileges should not have been dismissed on the ground that she was an independent contractor and not an employee, the Second Circuit ruled January 16. The appeals court found a genuine issue of material fact as to the level of control the hospital exerted over the physician’s work through its peer review process, leaving open the ultimate issue of whether she was an employee for purposes of the antidiscrimination laws.

Plaintiff Dr. Barbara Salamon sued Our Lady of Victory Hospital (OLV) and several of its physicians (collectively, defendants) alleging sexual discrimination in violation of Title VII. According to Salamon, one of the hospital physicians, Dr. Michael C. Moore, sexually harassed her and, when she complained, used his position as a hospital administrator to subject her to negative performance reviews that damaged her reputation.

Defendants moved for summary judgment, arguing Salamon, a board-certified gastroenterologist, was an independent contractor and not a hospital employee; thus, falling outside of the antidiscrimination laws. Salamon asserted, however, that the hospital’s “quality assurance program included detailed requirements as to when and how her work was to be performed, requirements intended in some cases to maximize profits, not patient care.” Applying the Supreme Court’s non-exclusive list of 13 factors for analyzing employment status, the district court concluded Salamon was an independent contractor.

The Second Circuit reversed, finding a genuine issue of material fact on what it called the “most important factor” to determine the existence of an employment relationship—i.e. “the hiring party’s right to control the manner and means” by which the work is accomplished. Taking Salamon’s allegations as true, the appeals court found the hospital exercised “substantial control” over her treatment outcomes and the details and methods of her work. Specifically, the appeals court noted, Salamon contended OLV’s quality management standards went further than measuring quality to mandating the performance of certain procedures and impacting her choices about which medications to prescribe “to maximize hospital profit.” The hospital’s review of Salamon’s practice resulted in a detailed “reeducation” program designed to change the methods she used to diagnose and treat patients, the appeals court observed. Thus, “a reasonable fact-finder could conclude . . . that the quality assurance standards extended beyond mere health and safety concerns or ensuring Salamon’s qualifications,” the appeals court said. *Salamon v. Our Lady of Victory Hosp.*, No. 06-1707-cv (2d Cir. Jan. 16, 2008).

**Ninth Circuit Upholds Dismissal Of Physician’s Discrimination Claims Against Hospital**
The Ninth Circuit upheld February 13, 2008 the dismissal of a physician’s hostile work environment claim under § 1981, finding he failed to allege “severe and pervasive
discrimination.” The appeals court also said the physician could not maintain his civil rights claims under California law because his relationship with the hospital was closer to that of an employee than a customer or patron.

Christopher Lynn Johnson, an African American physician who also identifies himself as bisexual, sued Riverside Community Hospital, the medical staff, and several others (collectively, defendants) in federal district court, asserting discrimination claims based on his race, sexual orientation, and perceived disability. Johnson held privileges at Riverside from October 1999 until February 2002, when he was terminated for failing to pay his membership dues on time. He had worked at Riverside pursuant to a professional services agreement, which identified him as a “contractor,” not an employee. According to Johnson, the physicians and nurses at Riverside regularly harassed him because of his sexual orientation and one colleague used a racial slur after Johnson operated on the doctor’s patient.

Johnson’s lawsuit against defendants alleged racial discrimination in violation of 42 U.S.C. § 1981; racial and sexual orientation discrimination in violation of the California Unruh Civil Rights Act (Cal. Civ. Code §§ 51 and 51.5); and racial and sexual orientation discrimination in violation of California’s Fair Employment and Housing Act (FEHA). The trial court dismissed Johnson’s state law claims under §§ 51 and 51.5 with prejudice and dismissed his remaining claims without prejudice and granted leave to amend. The Ninth Circuit affirmed, finding first that Johnson failed to raise a triable issue of fact as to whether he suffered “severe and pervasive” discrimination to support a prima facie claim for hostile work environment under § 1981. Aside from the allegation against one physician for using a racial slur, and another claim alleging bias against someone else, Johnson asserted no other claims showing he was subject to racial discrimination. While Johnson’s allegations against other physicians and nurses may have shown they treated him in an offensive manner, he provided no evidence that they were motivated by racial animus rather than personal dislike, the appeals court said.

The appeals court also affirmed the dismissal of Johnson’s § 51 claim under California law, which declares all persons in the state are “free and equal” and entitled to “the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments.” Case law has held § 51 applies only to the “customer-proprietor relationship” rather than to employment discrimination claims. Johnson claimed, however, that a subsequent California appeals court decision changed the analysis by finding a physician could assert a § 51 claim against a hospital where he treated patients because the physician did not have the type of employment relationship that foreclosed relief. See Payne v. Anaheim Mem’l Hosp., 130 Cal App. 4th 729 (2005). Distinguishing Payne, the appeals court noted that unlike the relationship at issue there, Riverside compensated Johnson and maintained control over all material aspects of his activities at the hospital Thus, Johnson’s relationship with Riverside was more akin to that of an employee than that of a “client patron, or customer.” Johnson v. Riverside Healthcare Sys., LP, No. 06-55280 (9th Cir. Feb. 13, 2008).
Indiana Supreme Court Upholds Physician Non-Compete Agreement But Finds Geographic Scope Unreasonable
Non-competition agreements between a physician and a medical group are not per se void as against public policy and are enforceable to the extent they are reasonable, the Indiana Supreme Court held March 11. According to the high court, a geographically reasonable agreement is one that encompasses only the area in which the physician developed patient relationships using the practice group’s resources.

The instant case involved a non-competition clause in a series of employment agreements between podiatrist Kenneth Krueger and Central Indiana Podiatry, P.C. (CIP), which had a number of offices throughout the state of Indiana. The clause barred Krueger from practicing podiatry in 42 Indiana counties for a period of two years upon his termination from the group. After CIP terminated Krueger, he entered into an employment agreement to practice podiatry in a county covered by the non-compete clause and sent letters to his previous patients announcing his new practice. CIP sought an injunction against Krueger, citing the non-competition agreement. The trial court found the geographic restriction unenforceable and denied CIP’s request but the appeals court reversed.

Although the case was moot by the time it reached the Indiana Supreme Court because the two-year period of restriction had expired, the high court nonetheless decided to consider the action citing significant policy concerns that would recur frequently.

The high court acknowledged unique public policy concerns that non-competition agreements could interfere with the physician-patient relationship, which set restrictive covenants in this context apart from other employment settings. At the same time, the high court refused to rule all such agreements are unenforceable per se, saying a complete ban should be left to the legislature’s discretion.

The high court also recognized that “good will” and investment in developing a patient base constitutes a “protectible interest” for employers such as CIP. This protectible interest is qualified, however, by the reasonableness of the restrictive covenant in terms of time, activities, and geographic area. Here, the high court found the agreement was reasonable as to time and activities but overly broad, and therefore unenforceable to an extent, as to geographic area.

While CIP had offices throughout the state, the high court found it unreasonable to restrict Krueger’s ability to work beyond those areas where he had specifically practiced while under CIP's employment. “We agree with the courts that have held that noncompetition agreements justified by the employer’s development of patient relationships must be limited to the area in which the physician has had patient contact,” the high court concluded. Thus, the high court continued, the restrictive covenant was only valid as to the three counties where Krueger practiced within two years of his termination from CIP. The high court also found that in many instances, including this case, injunctive relief, rather than money damages, is appropriate for breach of a non-competition agreement. Central Indiana Podiatry, P.C. v. Krueger, No. 29S05-0706-CV-256 (Ind. Mar. 11, 2008).
Sixth Circuit Finds Retiree Health Benefits Were Vested Under Labor Agreements

Vacating a lower court ruling, the Sixth Circuit in a 2-1 panel decision held March 19, 2008 that certain retiree health benefits were vested under various labor agreements such that any termination of those benefits constituted a violation of the Labor Management Relations Act (LMRA). The case involved a number of retirees (plaintiffs) of B.F. Goodrich Co.’s Geon Vinyl Division (BFG), now PolyOne Corp. During their employment, plaintiffs’ union had entered into a series of collective bargaining agreements (CBAs) with BFG, none of which specifically addressed the issue of health benefits. BFG negotiated a series of additional employee benefit agreements (EBAs) with other unions, which provided that retirees were not required to contribute to their health insurance premiums, they were reimbursed for Medicare Part B, and they paid $1.00 per prescription medication. Plaintiffs argued the EBAs were extended to them via a memorandum of agreement (MOA) entered into by their union and BFG.

Plaintiffs received the health benefits described in the EBAs until March 2006, when PolyOne ceased reimbursing their Part B premiums, required them to contribute towards their insurance premiums, and instituted higher prescription drug copayments. The district court found the EBAs did not manifest intent to vest retiree health benefits and therefore held plaintiffs could not maintain their action under the LMRA.

The Sixth Circuit concluded the district court improperly granted summary judgment in PolyOne’s favor. As a threshold matter, the appeals court determined that the MOA incorporated the health benefits provisions of the EBAs, clearing the way for plaintiffs’ lawsuit alleging PolyOne’s conduct violated the LMRA. Next, the appeals court held the durational language in the MOA and the EBAs was general in nature and did not preclude a finding that plaintiffs’ health benefits had vested. The appeals court noted the language at issue did not specifically state that retiree health benefits expired upon termination of the agreement, but rather spoke generically of all benefits for all employees. Thus, the majority went on to examine other provisions of the EBAs to determine whether intent to vest plaintiffs’ health benefits existed.

Finding such intent evident, the appeals court relied on the facts that the agreement tied eligibility for retiree health benefits to eligibility for a pension and promised a lifetime special Medicare benefit that would be illusory if plaintiffs’ retiree benefits had not vested. The majority acknowledged that “rising healthcare costs and foreign competition have certainly placed corporations such as PolyOne in a difficult economic position,” but added that “in the absence of impossibility of performance, it is not the prerogative of the judiciary to rewrite contracts in order to rescue parties from ‘their improvident commitments.’” Noe v. PolyOne Corp., No. 07-5068 (6th Cir. Mar. 19, 2008).

EMTALA

U.S. Court In Virginia Holds State Hospital’s Agreement To Comply With EMTALA Did Not Waive Virginia's Sovereign Immunity

The U.S. District Court for the Western District of Virginia held May 24, 2007 that a state hospital’s agreement to meet the requirements of the Emergency Medical Treatment
and Labor Act (EMTALA), 42 U.S.C. § 1395dd, for purposes of Medicare reimbursement did not amount to an implied waiver of the state’s sovereign immunity from suit. The court interpreted the state’s agreement with the terms of EMTALA as simply willingness to forego its Medicare reimbursement in the event that EMTALA requirements were not being followed.

Plaintiff Wilbert V. Johnson alleged the University of Virginia Medical Center (UVMMC) failed to provide him with an adequate medical examination and necessary stabilization treatment. Johnson sued the Commonwealth of Virginia (Commonwealth) pursuant to EMTALA, since UVMMC is not a legal entity capable of being sued. Defendants moved to dismiss, arguing sovereign immunity under the Eleventh Amendment barred Johnson’s EMTALA claim.

Granting the motion, the court noted two exceptions to sovereign immunity relevant to the instant case: (1) if Congress, in passing EMTALA, unequivocally expressed its intent to abrogate the Commonwealth’s immunity and acted pursuant to a valid exercise of its power, or (2) if the Commonwealth consented to suit under EMTALA.

The court determined Congress could not have abrogated the Commonwealth’s immunity from suit under EMTALA because it was acting pursuant to its Article I powers in enacting the statute. The Supreme Court has held Congress may not abrogate a state's immunity from suit when acting pursuant to its Article I powers to tax and regulate interstate commerce, the court noted. The court also found defendants had not waived their immunity expressly or impliedly. Although the Virginia Tort Claims Act was considered a limited waiver, it did “not waive the state’s Eleventh Amendment immunity.” Moreover, the Commonwealth’s agreement to meet EMTALA’s requirements did not amount to an implied waiver. The court was unwilling to find a waiver of sovereign immunity based merely on a public hospital’s agreement to adopt and enforce a policy to comply with EMTALA. *Johnson v. Virginia*, No. 3:06cv00061 (W.D. Va. May 24, 2007).

**U.S. Court In Michigan Denies Request For Hospital Peer Review Documents Allegedly Relevant To EMTALA Claim**

The plaintiff in a medical malpractice case involving state law claims as well as a “failure to stabilize” claim pursuant to the Emergency Medical Treatment and Labor Act (EMTALA) cannot obtain through discovery requested peer review documents from the defendant-hospital by alleging that such documents are relevant only to the EMTALA claim, a federal trial court in Michigan ruled June 22, 2007. Plaintiff Jonella Richmond Moses sued Providence Hospital and Medical Center Inc. (Providence) after her daughter, Marie Moses-Irons, was murdered by her husband, Christopher Howard, who had recently received psychiatric treatment at the hospital. In December 2002, Moses-Irons took Howard to Providence’s emergency room where he received treatment for physical complaints, including high blood pressure and disorientation. Howard was then admitted to the hospital for psychiatric evaluation and treatment; he remained at the hospital for one week during which he received medication and other treatment, but then was discharged. Ten days after his discharge, Howard murdered Moses-Irons.
Seeking money damages, Moses alleged Providence violated EMTALA by releasing Howard before he was “stabilized.” During the discovery process, Moses requested materials related to Providence’s peer review procedures. Specifically, Moses sought to discover Performance Improvement Committee documents, particularly any documents related to the medical treatment provided to Howard. Providence objected to this request, asserting that such documents were “protected by Michigan’s Public Health Code and Peer Review Privilege.” Moses moved to compel discovery, arguing she sought the documents only for the EMTALA claim and not the state law malpractice claims.

The court summarily rejected Moses’ argument that the requested documents would be relevant to the EMTALA claim. “The sole issue in this EMTALA claim,” the court continued, “is whether Mr. Howard was diagnosed with an emergency condition, a fact which can be established from the medical records, and if so, whether the hospital transferred (i.e. discharged) him when he was not stable.”

With respect to Moses’ failure to stabilize claim, the court determined that a hospital’s failure to diagnose a mental illness likely to result in danger to others or to foresee that a patient’s mental condition might worsen cannot be the basis for a violation of EMTALA’s stabilization requirements. “[I]nterpreting EMTALA to require stabilization treatment after diagnosis of an emergency condition and outside the context of a transfer [or discharge],” the court observed, “raises questions not answered by Congress, such as: when the duty to provide stabilization treatment terminates; if treatment is prolonged and transfer is not imminent, how long treatment must be provided; and when the temporal delay between a determination of an emergency medical condition and the initiation of treatment constitutes a violation of a duty to provide stabilization treatment.” Moses v. Providence Hosp. and Med. Ctr. Inc., No. 04-74889 (E.D. Mich. June 22, 2007).

U.S. Court In Texas Finds Hospital Must Produce Certain Documents Sought By Plaintiffs In EMTALA Lawsuit

A hospital must produce certain documents sought during the discovery process in a lawsuit brought under the Emergency Medical Treatment and Labor Act (EMTALA) by the estate of an uninsured patient who suffered a fatal heart attack shortly after being discharged from the hospital’s emergency department, a federal district court in Texas ruled August 14, 2007. The U.S. District Court for the Northern District of Texas overruled the hospital’s objections to producing the documents requested by the estate of the deceased heart attack victim, finding parts of the plaintiff-estate’s discovery request to be reasonably limited and not unduly burdensome on the hospital.

The estate of Troy Lee Aylor brought an EMTALA lawsuit in federal district court against United Regional Health Care System (United Regional), the hospital where Aylor presented in the emergency room with heart-related symptoms. According to plaintiff-estate, United Regional failed to provide Aylor, who lacked health insurance, with an “adequate medical screening” and discharged him while he was in an “unstable emergency medical condition,” which ultimately resulted in his suffering a fatal heart attack the next day. In a July 2007 ruling, the district court denied United Regional’s
motion to dismiss the case, concluding plaintiff-estate’s allegations—that Aylor did not receive the full range of diagnostic tests provided to other insured patients presenting to the emergency department with similar symptoms, and that United Regional failed to stabilize Aylor before his release—were sufficient to support the EMTALA claim. The court therefore ruled that the case should proceed to trial.

In rejecting United Regional’s objections to the production of hospital records of patients other than Aylor, the district court concluded plaintiff-estate had reasonably limited its document request to a single one-year time period preceding Aylor’s death. In addition, plaintiff requested only records of patients presenting with any of seven symptoms they alleged Aylor presented to the ER personnel and who received diagnostic cardiac tests while at the emergency department. The district court also concluded that plaintiff-estate’s production requests pertaining to other patient records were reasonable because they sought only evidence relevant to the alleged EMTALA claim. In this case, “[n]ecessarily, a comparison must be made between and among the symptoms presented by Aylor, the tests run and the diagnoses made as compared to other patients,” the court said.

The district court did find it unduly burdensome on United Regional to produce documents that were of marginal relevance to plaintiffs, i.e., records of patients who had been admitted to the hospital’s critical care unit (CCU) or progressive care unit (PCU) for the purpose of “ruling in” or “ruling out” certain conditions. Identifying such records could not be accomplished through a computer search and would require the medical judgment of a medical professional, the court pointed out. The district court also sustained as unduly burdensome United Regional’s objections to producing all patient records over the relevant time period that contained a copy of the hospital’s chest pain care management guidelines. Finally, the district court sustained United Regional’s objections to producing records relating to the credentialing of the emergency room physician who treated Aylor, finding such records were “wholly irrelevant” in an EMTALA case and also were protected from disclosure under Texas peer review laws. Southard v. United Reg’l Health Care Sys. Inc., No. 7:06-CV-011 (N.D. Tex. Aug. 14, 2007).

U.S. Court In Iowa Finds Genuine Issue Exists Whether Pregnant Woman Having Contractions Was Stabilized Under EMTALA Prior To Transfer
The U.S. District Court for the Northern District of Iowa, in an unpublished decision, dismissed state law claims brought against a hospital for the wrongful death of a premature fetus, but refused to grant summary judgment on claims that the hospital violated the Emergency Medical Treatment and Labor Act (EMTALA) by transferring the mother during her contractions. Laura Heimlicher, who was eight months pregnant, was transported to the emergency room at Dickinson County Memorial Hospital (hospital) after she began bleeding. At the hospital, she was seen by Dr. James O. Steele. Heimlicher was eventually transferred to Sioux Valley Hospital in Sioux Falls. Upon her arrival, she was taken to the operating room where her baby was stillborn. Heimlicher and her husband (plaintiffs) sued the hospital for the wrongful death of her baby alleging violations of EMTALA and claims under state law.
As to the EMTALA claims, the court found genuine issues of material fact regarding whether Heimlicher was stabilized prior to transfer. According to the court, “[t]here is substantial evidence in the record that Mrs. Heimlicher was having contractions while at the Hospital, so she could not have been ‘stabilized’ for purposes of the EMTALA before delivery of the child and the placenta. The court next addressed the hospital’s argument that a pregnant woman who is having contractions and has not been stabilized may be transferred under EMTALA if a physician signs a certification that, based upon the available information, the medical benefits reasonably expected from the transfer outweigh the increased risks to the mother and the unborn child. Although Steele did sign such a certification in this case, the court found that whether he “adequately deliberated and weighed the medical risks and benefits” of a transfer was a question for the jury. *Heimlicher v. Steele*, No. C05-4054-PAZ (D. Iowa Aug. 17, 2007).

**U.S. Court In Arkansas Dismisses EMALA Claims Against Hospital, Says Protections Ended On Admission**

A federal trial court in Arkansas rejected October 5, 2007 claims brought under the Emergency Medical Treatment and Labor Act (EMTALA) against a hospital, finding the plaintiff failed to show a disparate medical screening and that EMTALA no longer applied once the patient was admitted to the hospital. Plaintiff Cheryl Lynn Prickett, as Executrix of Shirley Harmor's estate, brought an action under EMTALA against Hot Spring County Medical Center in Malvern, Arkansas and two physicians who treated Harmor. Harmor went to Hot Spring’s emergency department complaining of abdominal pain and various other symptoms. After performing various tests, she was diagnosed with a non-emergent condition and admitted to the hospital. As her condition deteriorated, Harmor was transferred to another hospital where she suffered a cardiac event and eventually died.

The U.S. District Court for the Western District of Arkansas dismissed the EMTALA claims with prejudice, finding the statute inapplicable. Citing Eighth Circuit precedent, the court noted that EMTALA does not provide a cause of action for damages against an individual physician and accordingly summarily dismissed that aspect of the case. The court also noted that under federal regulations, 42 C.F.R. § 489.24, a hospital’s obligation ends once the hospital admits an inpatient for further treatment. The court rejected plaintiff’s argument that § 489.24 was merely an interpretative rule, relying on a federal district court case from Puerto Rico that held EMTALA protection should continue even after a patient is admitted to a hospital. Instead, the court opted to follow “the clearly stated interpretation of the EMTALA provisions” detailed in the regulation as well as decisions from the Fourth, Ninth, and Eleventh Circuits.

As to the inappropriate medical screening claim, the court noted EMTALA is implicated only when individuals who are perceived to have the same medical condition receive disparate treatment, emphasizing that the statute is not intended as a federal malpractice law. “A hospital must have actual knowledge of an individual’s un-stabilized emergency medical condition if a claim under EMTALA is to succeed,” the court said. Here, the plaintiff failed to show the medical screening was disparate as compared to other patients with the same complaints. Plaintiff’s allegations of negligence for failing to properly

**U.S. Court In Florida Rejects EMTALA Action Against Hospital That Lacked Backup For On-Call Neurosurgeon**

A hospital that did not have a backup for an on-call neurosurgeon who was unavailable due to illness was not liable under the Emergency Medical Treatment and Labor Act (EMTALA), a federal trial court in Florida ruled October 22, 2007. In August 2005, plaintiff William Dabney was taken to H.C.A. Fort Walton Beach Medical Center’s (FWBMC’s) emergency department. Plaintiff required a neurosurgical consult, but the neurosurgeon on-call at FWBMC was unable to respond because of an illness. FWBMC did not have a backup neurosurgeon and therefore tried to secure a transfer to three nearby hospitals that had the capacity to stabilize plaintiff’s emergency medical condition. All three hospitals refused to accept the transfer.

Plaintiff brought an action against FWBMC under EMTALA. FWBMC moved to dismiss. The U.S. District Court for the Northern District of Florida granted the motion. The court found FWBMC lacked the capacity to stabilize plaintiff because the on-call neurosurgeon was unavailable due to illness. “The statute does not require a hospital to have a back-up plan when an on-call physician is unavailable,” the court said. Nor does the statute “require that a hospital have a procedure in place guaranteeing transfer of a patient,” the court added. Thus, because plaintiff failed to allege FWBMC could have successfully transferred him but failed to do so, the action was properly dismissed. *Dabney v. H.C.A. Fort Walton Beach Med. Ctr.*, No. 3:07cv331/RS/EMT (N.D. Fla. Oct. 22, 2007).

**U.S. Court In Indiana Finds Plaintiff Alleging EMTALA Violations Cannot Amend Complaint To Seek Damages Under § 1983**

The plaintiff in a lawsuit against a hospital and emergency room physician and nurse alleging they inadequately screened him in violation of the Emergency Medical Treatment and Labor Act (EMTALA) cannot amend his complaint to add claims under 42 U.S.C. § 1983 based on the alleged EMTALA violations, a federal trial court ruled November 9, 2007. The U.S. District Court for the Southern District of Indiana concluded that, because EMTALA provides a comprehensive mechanism for injured plaintiffs, the plaintiff in this case was preempted from bringing § 1983 claims against the defendants premised on violations of EMTALA.

Plaintiff Kevin Lewellen was in a car accident in June 2003 and was taken by a police officer to Schneck Medical Center (SMC). The police officers told emergency room staff that Lewellen was suspected of driving while under the influence of alcohol. Emergency room nurse, Amanda Davis, admitted Lewellen and completed an initial assessment. Shortly thereafter, attending physician, Dr. John M. Reisert, examined Lewellen, ordered x-rays, and then discharged him. After discharge, Lewellen was taken to jail, and he later suffered a burst fracture in his spine, which resulted in permanent damage to his spinal
cord. Lewellen sued SMC, Reisert, and Davis (defendants), alleging they had failed to provide an adequate “screening” of his condition in violation of EMTALA.

Although the district court allowed Lewellen to proceed with his EMTALA claims against SMC, it dismissed these claims against Reisert and Davis because EMTALA does not provide a private right of action against an individual physician or other healthcare provider. Lewellen then moved for leave to amend his complaint, seeking to recover damages by adding § 1983 claims against defendants based on violations of the federal EMTALA statute. Specifically, Lewellen sought to add one count alleging Reisert and Davis, acting under color of state law and in their capacity as SMC's agents, deprived Lewellen of his rights under EMTALA to an adequate screening exam and to not be released until his medical condition was stable.

The district court acknowledged that the U.S. Supreme Court has held claims may be brought under § 1983 for violations of certain federal statutes that did not provide a private remedy. However, citing Middlesex County Sewerage Auth. v. Nat’l Sea Clammers Ass’n, 453 U.S. 1 (1981), the district court determined that, because of the enforcement procedures already present under EMTALA, plaintiff was precluded in this case from asserting additional causes of action under § 1983. In Sea Clammers, the U.S. Supreme Court held “[w]hen the remedial devices provided in a particular Act are sufficiently comprehensive, they may suffice to demonstrate congressional intent to preclude the remedy of suits under §1983,” the district court said.

Here, "EMTALA provides for effective remedies that place the burden of compliance upon the medical institution” the district court said, noting EMTALA also "provides a comprehensive enforcement mechanism that provides sufficient remedies to encourage enforcement of EMTALA.” In addition, the district court found EMTALA provides “that both physicians and hospitals will be held accountable for damages with the provision of a civil penalty,” but then specifically includes only hospitals as liable for penalties brought under EMTALA’s civil enforcement section. “[B]ecause the remedies provided in EMTALA’s enforcement scheme are sufficiently comprehensive, § 1983 may not be used as a vehicle to allege EMTALA violations against a hospital,” the court concluded. Lewellen v. Schneck Med. Ctr., No. 05-83 (S.D. Ind. Nov. 9, 2007).

**Wisconsin Appeals Court Finds Newborn Is An Inpatient For EMATLA Purposes**

The Wisconsin Court of Appeals found the Emergency Medical Treatment and Labor Act’s (EMTALA’s) screening requirement does not apply to a newborn born to a mother who was an inpatient at a hospital. According to the appeals court, because the mother was an inpatient for EMTALA purposes, so was the newborn.

Shannon Preston was admitted to Meriter Hospital’s birthing center when she was just over 23 weeks pregnant. She gave birth to a son who weighed only one and a half pounds and could not survive without resuscitation and the administration of oxygen and fluids. Except for nursing care, Meriter did not resuscitate or treat the child, who subsequently died. Preston sued Meriter hospital for (1) medical negligence; (2) failing to obtain informed consent; (3) neglecting a patient in violation of Wisconsin law; and (4)
violating EMTALA. The circuit court granted Meriter Hospital’s summary judgment motion as to all four claims.

The Wisconsin Court of Appeals affirmed, finding that because the child entered the hospital via the birthing center and not through the emergency room, EMTALA did not apply. At the outset, the appeals court noted several other jurisdictions have determined that EMTALA does not apply to inpatients and pointed to Department of Health and Human Services regulations providing that the EMTALA stabilization requirement does not apply to inpatients. The appeals court rejected Preston’s argument that the regulations should not be controlling here because they were issued in 2003 and the alleged violation in this case took place in 1999. Instead, the appeals court found it appropriate to accord controlling weight to the agency’s interpretation of the stabilization requirement even though the clarification occurred after the alleged violation.

The appeals court found “no principled basis upon which to distinguish between the screening requirement and the stabilization requirement in the context of a person’s status as an inpatient.” Thus, “the EMTALA screening requirement ceases to apply once an individual has been admitted to a hospital for inpatient care,” according to the appeals court. Finally, the court found “for purposes of coverage under the EMTALA screening requirement, both Shannon and [her child] were inpatients at the time of [the child’s] birth as a matter of law.” Preston v. Meriter Hosp., Inc., No. 2006AP3013 (Wis. Ct. App. Jan. 24, 2008).

U.S. Court In Pennsylvania Dismisses EMTALA Stabilization Claim, Finds Insufficient Evidence Hospital Knew Of Emergency Medical Condition

A women whose baby was born with permanent brain damage could not maintain an action against the hospital where she went for fetal monitoring under the Emergency Medical Treatment and Labor Act (EMTALA) because she failed to show the physician who treated her had actual knowledge that an emergency medical condition existed, a federal court in Pennsylvania held.

Honey Toretti, who had been previously treated for pre-term labor and suffered from insulin dependent diabetes among other things, was 34 weeks pregnant when she went to a testing center at Paoli Memorial Hospital (Paoli) where her obstetrician Dr. Andrew Gerson performed a scheduled fetal non-stress test. At the time, Toretti said she was experiencing contractions and Gerson told her husband to take her to Lankenau Hospital where his practice delivered babies. Gerson later testified that he did not believe an ambulance was necessary because Toretti was not an acute emergency. Toretti’s son was born at Lankenau later that day; he suffered permanent mental and physical damage. Toretti and her son and husband (plaintiffs) sued Paoli, alleging the hospital was liable under EMTALA for transferring her without stabilizing her emergency medical condition. Plaintiffs also asserted state law medical malpractice claims.

The U.S. District Court for the Eastern District of Pennsylvania granted Paoli’s motion to dismiss the EMTALA claim, finding plaintiffs failed to show the hospital had actual knowledge that Toretti had an emergency medical condition. Although plaintiffs’ expert
opined that based on the medical record Toretti’s case was “consistent with labor” and fetal distress and Gerson should have treated her as such, the court said these observations were relevant to a medical malpractice claim, not to EMTALA liability.

Concluding the evidence did not point to Gerson, and by extension the hospital, had the requisite level of knowledge, the court distinguished the instant action from other cases where hospitals have been found liable under EMTALA’s stabilization requirement. Here, Toretti did not present herself to the hospital as an emergency patient; rather, she went to Paoli for a scheduled appointment. Moreover, Torretti did not describe her condition as an emergency during the stress test, nor did Gerson exhibit any indication that her condition was an emergency, the court said. Unlike cases that have survived summary judgment, Toretti “did not present symptoms as obvious as a bone protruding through skin . . . or vaginal bleeding,” nor did she document a denial of treatment despite repeated trips to an emergency room. Toretti v. Paoli Mem’l Hosp., No. 06-3003 (E.D. Pa. Jan. 29, 2008).

First Circuit Says EMTALA Covers Patient In Ambulance En Route To Hospital

The Emergency Medical Treatment and Labor Act (EMTALA) applies where a woman suffering from symptoms of an ectopic pregnancy was in an ambulance on its way to the hospital, and the hospital’s emergency department was notified of her imminent arrival, the First Circuit held April 18, 2008 in a 2-1 decision. The federal appeals court reversed a lower court decision that granted summary judgment in the hospital’s favor based on the conclusion that EMTALA did not apply to the patient until she reached the hospital.

Plaintiff Carolina Morales was at work when she began experiencing severe abdominal pain. Her co-workers called an ambulance, and Morales informed the paramedics that her obstetrician had diagnosed her with a possible ectopic pregnancy two days earlier. The ambulance headed for Hospital Español Auxilio Mutuo de Puerto Rico (Hospital), where Morales’ obstetrician regularly practiced. The ambulance was not owned by the Hospital and the paramedics who manned it were not Hospital employees, the appeals court emphasized.

While in transit to the Hospital, the paramedics called ahead to the emergency department and notified Dr. Salvador Marquez, the department’s director, of Morales’ condition and her imminent arrival. Marquez initially told the paramedics that he was very busy and asked them to call back with more information about the patient. When the paramedics called back, Marquez allegedly asked whether Morales had health insurance coverage. “Receiving no such assurances, [Marquez] abruptly terminated the call (an action that the paramedics interpreted as a refusal to treat [Morales] at the Hospital’s emergency department),” the appeals court explained. The paramedics then took Morales to another hospital for treatment.

Morales sued the Hospital and individual defendants in the U.S. District Court for the District of Puerto Rico, alleging EMTALA violations and state law tort claims. The Hospital moved for summary judgment on the EMTALA claim, arguing that EMTALA is not triggered until the prospective patient physically passes through the hospital’s
entrance and arrives on its premises. Agreeing with this argument, the district court granted the Hospital’s motion and dismissed the supplemental state law tort claims without prejudice. Morales appealed.

“[T]his appeal turns on a singular and quintessentially legal question,” the First Circuit said, “whether, on the plaintiff’s version of the facts, a reasonable jury could find that she had ‘come to’ the Hospital’s emergency department as required under EMTALA.” Under EMTALA, 42 U.S.C. § 1395dd(a), “if any individual . . . comes to the emergency department [of a covered hospital] and a request is made on the individual’s behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination,” the appeals court noted.

The appeals court pointed out that the statute does not define the phrase “comes to the emergency department,” and found that the statute’s legislative history “is not fully illuminating.” The appeals turned to the relevant regulatory provisions, particularly 42 C.F.R. § 489.24(b)(4), which states that “an individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital’s emergency department, even if a member of the ambulance staff contacts the hospital . . . and informs the hospital that they want to transport the individual to the hospital for examination and treatment.”

The appeals court emphasized, however, that this language, when read with other text in the provision regarding a hospital’s ability to direct an ambulance elsewhere when the hospital is in diversionary status, is ambiguous. In addition, the appeals court cited Arrington v. Wong, 237 F.3d 1066 (9th Cir. 2001), in which the Ninth Circuit concluded that an individual in an ambulance en route to a hospital can qualify as an individual who has come to the hospital for EMTALA purposes.

The appeals court said that, “in the face of such ambiguity,” it was “appropriate to resolve the ambiguous ‘comes to’ language in accordance with statutory intent.” According to the appeals court, an “interpretation of the statute concluding that an individual en route to the hospital, under the plaintiff’s version of the facts, has ‘come to’ the emergency department . . . comports with EMTALA’s primary goal and hinders efforts to turn away prospective patients because of their economic status.” The district court’s contrary interpretation “encourages easy evasion of the statutory mandate and opens a gaping hole in the fabric of the remedial scheme,” the appeals court said.

A dissenting opinion argued the phrase “comes to an emergency department” unambiguously means arrives at an emergency department, rather than “moves toward or approaches” such department. Morales v. Sociedad Española de Auxilio Mutuo y Beneficencia, No. 07-1951 (1st Cir. Apr. 18, 2008).

**U.S. Court In California Dismisses EMTALA Screening Claim On Causation Grounds**

The U.S. District Court for the Eastern District of California dismissed April 10, 2008 a patient’s claim alleging a hospital violated the Emergency Medical Treatment and Labor
Act (EMTALA) screening requirement by failing to run additional tests to rule out a bacterial infection that later developed into septic shock. The court found even if the emergency department (ED) physician who treated the patient had performed a blood culture, the only test that could have definitely established a bacterial infection, the results would not have come back within the window of time to make a difference in her treatment. Moreover, the court rejected the patient’s argument that “prophylactic therapy,” such as administering intravenous antibiotics, is in itself a screening tool as contemplated by EMTALA.

Plaintiff Donna Hoffman presented to Memorial Medical Center’s (MMC’s) ED where she was seen by Dr. Kent Tonnemacher. Following an x-ray and urinalysis, Tonnemacher diagnosed Hoffman as having bronchitis with a differential diagnosis of pneumonia and discharged her the same day with antibiotics. A day later, Hoffman returned to the ED in septic shock, requiring extensive medical treatment. Hoffman later sued MMC, alleging she failed to receive an adequate screening under the statute and asserting medical malpractice claims under state law.

According to deposition testimony, MMC’s EMTALA policy required ED physicians to rule in or rule out suspected bacterial infections. Hoffman’s expert testified that Tonnemacher could have accomplished this determination by ordering additional tests, including a blood culture. Based on this testimony, the court denied MMC’s first motion for summary judgment.

Hoffman’s expert also opined at trial that Hoffman had presented to the ED in the beginning stages of sepsis and an EMTALA-compliant screening would have resulted in early intervention to avoid the more serious condition she later developed. MMC again moved for summary judgment this time on causation, arguing Hoffman could not establish her injuries were a direct result of an EMTALA violation. Specifically, MMC contended that even if Tonnemacher had ordered a blood culture, the results would not have been back within the six-hour window for early treatment interventions.

The U.S. District Court for the Eastern District of California granted MMC summary judgment. The court found the only screening test Tonnemacher could have ordered that would have actually identified and ruled in a bacterial infection was a blood culture. This test, however, would not have produced results within the six-hour treatment window. “To the extent that Hoffman argues . . . that the administration of intravenous antibiotics and the administration of early goal directed therapy or prophylactic therapy are themselves screening tools, the Court cannot agree,” the opinion said. “[S]creening is an examining process, it is not a treatment,” the court reasoned. Hoffman v. Tonnemacher, No. Civ F 04-5714 AWI DLB (E.D. Cal. Apr. 10, 2008).
ERISA

Eighth Circuit Reverses Decision Upholding Health Plan Insurer’s Retroactive Rescission Of Plan Participant’s Coverage
A health plan insurer's decision to retroactively rescind a participant’s coverage under his employer-sponsored plan may have been an abuse of discretion even though the participant failed to disclose an expected neck surgery on his benefits enrollment form, the Eighth Circuit ruled May 29, 2007. Plaintiff Kenny Werdehausen became a participant in his employer’s group health plan in 1994. Defendant Benicorp Insurance Company (Benicorp) became the plan insurer in 2002. When Benicorp took over as the plan insurer, it required Werdehausen and other employees to complete an enrollment application form disclosing their medical history. The information on the enrollment forms was then used by Benicorp’s underwriters to set the group health plan premium, 75% of which was paid by the employer.

Werdehausen disclosed that he had previously undergone lower back surgery, but not that his doctor had recently told him he would eventually need surgery for a herniated disk in his neck. When Werdehausen later submitted a benefits claim form following his neck surgery, Benicorp discovered his failure to disclose the need for neck surgery on his enrollment form and determined that this omission was a “material misrepresentation” that would have substantially raised his employer’s group health plan premium. Benicorp retroactively rescinded his coverage under the plan, and denied all pending claims.

Reversing a lower court ruling in favor of Benicorp, the appeals court found a genuine issue of material fact on the Werdehausen’s ERISA claim as to whether the rescission constituted an arbitrary exercise of fiduciary discretion. “If an ERISA fiduciary decides to retroactively rescind an employee’s coverage solely on the basis of an automatic rescission policy, when it could have recouped any loss to the plan by retroactively increasing the employer’s premium,” this decision would reflect “an arbitrary exercise of the fiduciary’s discretion that conflict[ed] with the fiduciary’s obligation to discharge its duties with respect to a plan solely in the interest of the participants and beneficiaries,” the appeals court said. The appeals court concluded that if Werdehausen’s non-disclosure was inadvertent, rather than intentional fraud, the decision to rescind should be reversed. The appeals court also pointed out that the record did not sufficiently establish the applicability or effect of a specific provision in the plan that restricted Benicorp from adjusting the plan premium for the first twelve months of coverage. “This is highly relevant,” the appeals court concluded, noting that Werdehausen’s neck surgery occurred during this twelve-month period. Werdehausen v. Benicorp Ins. Co., No. 06-2818 (8th Cir. May 29, 2007).

U.S. Court In Texas Remands Hospital's Action Against Managed Care Firm To State Tribunal, Finding ERISA Did Not Completely Preempt Claims
A federal court in Texas found a hospital's state law claims against a managed care company were not completely preempted by the Employee Retirement Income Security Act (ERISA) § 502(a), 29 U.S.C. § 1132(a), and therefore remanded the action to state court. Plaintiff, Memorial Hermann Hospital System (Memorial), originally sued Aetna...
Health, Inc. (Aetna) for breach of managed care contracts between the parties and misrepresentations of the admission and treatment of the plan’s members. Under the agreement, Memorial had lowered its rates for medical services in return for Aetna’s obligation to encourage their members to choose Memorial as their healthcare provider. Aetna also agreed to pay Memorial’s claims promptly—45 days for mailed claims and 30 days for electronic claims—as required by the Texas Insurance Code and Deceptive Trade Practices Act (DTPA). According to Memorial, Aetna’s “investigations” of its member’s claims were in fact a “subterfuge for delays in promptly paying for services rendered.” Even when Aetna partially paid for Memorial’s services, they often failed to pay the full amount due under the agreements in a timely manner, Memorial alleged.

Aetna removed the case to federal court on the grounds that Memorial’s claims were completely preempted by ERISA and therefore arose under federal law. The court determined that federal question jurisdiction was present only if (1) Memorial could have brought its state-law claims under ERISA, and (2) where there was no other independent legal duty implicated by Aetna’s actions. The court determined Memorial had standing to assert an ERISA denial of benefits claim regardless of its status as an assignee of a participant or beneficiary in order to claim plan benefits. However, the court found that Memorial’s rights did not derive entirely from the particular rights and obligations established by the ERISA benefit plan because they asserted related violations of the Texas Insurance Code that are not protected by ERISA’s civil enforcement provision. Furthermore, Memorial’s petition included additional claims for deceptive acts in the business of insurance and negligence/intentional tort claims, which the court determined did not derive entirely from the legal duties created by ERISA. Therefore, the case was not completely preempted. Memorial Hermann Hosp. Sys. v. Aetna Health Inc., No. H-06-00828 (S.D. Tex. June 11, 2007).

U.S. Court In New York Holds ERISA Preempts Suffolk County’s “Fair Share for Health Care Act”
A federal district court in New York ruled July 14, 2007 that the Employee Retirement Income Security Act (ERISA) preempted a Suffolk County law that would have required certain large retail stores selling groceries to make minimum “employee health care expenditures.” The court found the statute at issue, the Suffolk County Fair Share for Health Care Act (Act), was substantially similar to a Maryland law that was struck down by another federal district court and the Fourth Circuit last year. See Retail Ind. Leaders Ass’n v. Fielder, 475 F.3d 180 (4th Cir. 2007). Agreeing with those decisions, the court concluded that the Act had an “obvious ‘connection with’ employee benefit plans” because it would effectively require employers to alter their ERISA plans thereby disrupting uniform plan administration.

The Act, as amended on April 4, 2006, requires covered employers to make minimum “employee health care expenditures” equivalent to the “public health care cost rate” of providing healthcare to an uninsured employee “multiplied by the total number of hours worked” by their employees in Suffolk County. The Act defines five categories of “employee health care expenditures”—contributing additional amounts to an ERISA plan, contributing to a health savings account, reimbursing health expenses, providing
health services in the workplace, or contributing to a community health center. Any covered employer whose healthcare expenditures fall below the Act’s requirements must pay a penalty equal to the shortfall. The Act was intended in part to protect small retailers in Suffolk County from large employers like Wal-Mart with less generous health benefits.

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. Although not bound by the Fourth Circuit’s decision in *Fielder*, the U.S. District Court for the Eastern District of New York agreed with the appeals court’s analysis and concluded that ERISA preempted the Suffolk County Act at issue here. In particular, the court noted the similarities between the Act and the Maryland “fair share” legislation in *Fielder*, which required employers with 10,000 or more workers to spend at least 8% of their payroll on healthcare benefits or pay the difference to the state. The court found the alternative options for complying with the Act provided no meaningful choice for employers seeking to increase healthcare spending other than altering or contributing to ERISA plans. Echoing the Fourth Circuit’s decision, the district court said “it is unreasonable to expect employers to contribute to the community or directly to the state, rather than to their own employees.” In the court’s view, the only realistic way for employers such as Wal-Mart to comply with the Act was to “change how they structure their employee benefit plans.” *Fielder*, 475 F.3d at 197.

*Retail Ind. Leaders Ass’n v. Suffolk County*, No. 06-CV-00531 (E.D.N.Y. July 14, 2007).

**U.S. Court In New Jersey Finds Hospital Lacked Standing To Sue Patient And Insurer Under ERISA**

A hospital that sued a patient and the patient’s health plan, which was governed by the Employee Retirement Income Security Act (ERISA), to recover on outstanding bills lacked standing to bring a lawsuit under ERISA, a federal court in New Jersey held August 17, 2007. Remanding the case back to state court, the U.S. District Court for the District of New Jersey also determined that ERISA did not completely preempt the hospital’s claims.

Cooper Hospital University Medical Center (CHUMC) admitted Rufus Pritchett as an inpatient, and provided care and treatment to him for a one-month period. Pritchett was insured under Seafarers Health and Benefits Plan (Seafarers), an ERISA-governed employee benefit plan. After discharging Pritchett, CHUMC billed Seafarers over $360,000 for services rendered to Pritchett. Seafarers subsequently paid CHUMC $160,482 but refused to pay the remaining $203,330, asserting that this amount exceeded the plan’s allowances for reasonable and customary charges based on a regional comparison. CHUMC then filed suit in state court, seeking to recover from Pritchett and Seafarers the outstanding amount on its bills. Seafarers removed the case to federal court, asserting that CHUMC’s claims were completely preempted by ERISA.

The district court distinguished the facts of the case from the typical ERISA action, i.e. where an employee brings state common law claims against his employer and insurer to recover benefits allegedly due. The present case, however, involved a plaintiff hospital
seeking payment of its bill from both the insurer and the employee. The district court cited *Pasack Valley Hosp., Inc. v. Local 464A UFCW Welfare Reimbursement Plan*, 388 F.3d 393 (3d Cir. 2004), in which the Third Circuit considered a similar fact situation and concluded the plaintiff-hospital lacked standing to assert an ERISA claim under 29 U.S.C. § 1332(a) because it was not a “participant” or “beneficiary” under ERISA and therefore could not sue in its own right. In *Pasack Valley*, the Third Circuit also declined to consider whether an assignment of claims from a participant or beneficiary to a hospital could confer standing to sue because it found nothing in the record establishing that an assignment had occurred, the district court noted.

The facts in the present case, the district court said, amounted to an “even clearer situation because not only is there no evidence of an assignment, the [c]omplaint does not even allege that [CHUMC] is a third-party beneficiary entitled to payment from Seafarers.” Finding the record to be “completely devoid of any evidence of an assignment,” the district court concluded that CHUMC lacked standing to sue under 29 U.S.C. § 1332(a). *Cooper Hosp. Univ. Med. Ctr. v. Seafarers Health and Benefits Plan*, No. 05-5941 (D.N.J. Aug. 17, 2007).

**Sixth Circuit Finds Participants In Self-Funded Health Plans Have Standing To Bring ERISA Claims Against Blue Cross**

Two participants in self-funded health plans have standing to seek injunctive and other equitable relief against Blue Cross and Blue Shield of Michigan (BCBSM) under the Employee Retirement Income Security Act (ERISA) for allegedly breaching its fiduciary duties even though neither plaintiff is covered under the BCBSM-administered coverage options offered by their employers, the Sixth Circuit ruled September 20, 2007.

BCBSM is the parent company of Blue Care Network (BCN), a state-licensed health maintenance organization that issues its own insurance policies to groups and individuals. In addition, BCBSM acts as a third-party administrator and claims processor for various ERISA welfare benefit plans, including self-funded health plans sponsored by Ford Motor Co. (Ford) and American Axle & Manufacturing (Axle). Eugene Loren and Danielle Hagemann (collectively, plaintiffs) are participants in self-funded health plans sponsored by Axle and Ford, respectively.

Pursuant to §§ 502(a)(2) and 502(a)(3) of ERISA, plaintiffs brought a class action against BCBSM, alleging BCBSM violated its fiduciary duties under ERISA when it negotiated rates more favorable to BCN than to the Ford and Axle self-insured plans. Plaintiffs sought injunctive and other equitable relief, including reimbursement to themselves as well as the self-funded plans for the alleged excess charges resulting from BCBSM’s conduct. Even though they were not covered by a BCBSM-administered option offered by their employers, plaintiffs argued that because the employers operate under a single ERISA plan, the alleged increases affected the plans as a whole, and that, in turn, plaintiffs had to pay excessive contributions, deductibles, and co-payments.

BCBSM moved to dismiss, and the U.S. District Court for the Eastern District of Michigan granted the motion, finding neither plaintiff was a participant in BCBSM-
administered options, and therefore neither had standing under ERISA to sue BCBSM for fiduciary breach.

The Sixth Circuit began its analysis by noting that the question of whether multiple coverage options constitute one plan under ERISA was an issue of first impression. The appeals court noted the only guidance on this issue was a proposed regulation governing the group health plan portability provisions of the Health Insurance Portability and Accountability Act, which clarified that “all medical care benefits made available by an employer . . . are generally considered to constitute one group health plan.” In addition, the appeals court emphasized the fact that an employer intending to create multiple plans has the ability to do so by filing multiple plan documents. Thus, “we start with the strong presumption that the filing of only one ERISA plan document indicates that the employer intended to create only one ERISA plan,” the appeals court said.

The appeals court concluded that BCBSM had failed to overcome this presumption because they did not show, through the relevant plan documents, that the multiple coverage options at issue were intended to operate as separate plans. To the contrary, Ford and Axle “each registered only one plan document with one ERISA identification number,” the appeals court said.

Turning to the question of standing, the appeals court noted plaintiffs were permitted to bring a lawsuit on behalf of their respective plans under ERISA § 502(a)(2), but failed to show individualized harm. The appeals court did find, however, that plaintiffs had standing to bring a lawsuit seeking injunctive or other appropriate equitable relief under ERISA § 502(a)(3) for BCBSM’s alleged breach of fiduciary duties. The appeals court highlighted case precedent holding that “a plan participant or beneficiary may have Article III standing to obtain injunctive relief, pursuant to [§ 502(a)(3)], related to ERISA’s disclosure and fiduciary duty requirements without a showing of individual harm.” Loren v. Blue Cross & Blue Shield of Mich., No. 06-2090 (6th Cir. Sept. 20, 2007).

Second Circuit Vacates Class Action Settlement Against PBM, Orders Subclass Of Self-Funded Plans
The Second Circuit vacated October 4, 2007 the approval of a $42.5 million settlement of a class action against a pharmacy benefits manager (PBM) for alleged breaches of its fiduciary duty to employee benefit plans under the Employee Retirement Income Security Act (ERISA). The appeals court found the district court should have certified self-funded plans as a separate subclass and specified the basis for a 55% allocation discount in the settlement proceeds for insured or capitated plans.

The consolidated case arose as putative class actions that were filed against PBM Merck-Medco Managed Care, L.L.C., Merck & Co., Inc., and Medco Health Solutions (collectively Medco) for alleged breaches of its fiduciary duties to various employee benefit plans (Plans) that had contracted with the PBM. The named plaintiffs were four individual Plan beneficiaries and three Plan trustees. Plaintiffs included insured and capitated Plans, which contracted for full payment of their beneficiaries’ prescription
According to plaintiffs, Medco, among other things, managed formularies and drug-switching programs to favor its parent company Merck and entered into price and rebate agreements with pharmaceutical manufacturers that benefited Merck but were more costly for Plans. The parties reached a settlement agreement under which Medco would modify certain business practices and pay $42.5 million into a fund for class members. Under the settlement, proceeds would be allocated primarily based on the amount of each settling plan’s proportionate share of the total drug spending of all settling class members. Because class members had different relationships with Medco, however, the settlement also provided that insured or capitated plans’ allocation would be reduced by 55% to reflect the fact that they were more insulated from Medco’s alleged improper conduct.

The U.S. District Court for the Southern District of New York approved the settlement in May 2004. Central States Southeast and Southwest Areas Health and Welfare Fund, Iron Workers Tri-State Welfare Fund, and Sweetheart Cup Company, Inc. (collectively, self-funded Plans) objected to the settlement and to the certification of the class, arguing among other things that the self-funded Plans should be certified as a subclass because their interests were not adequately represented and that the settlement was unfair.

In an earlier decision, the Second Circuit vacated the district court's approval of the settlement, holding the named plaintiffs' Article III standing had to be resolved before it could consider the other issues on appeal. On remand, the district court found the named plaintiffs had adequately established standing.

Resuming jurisdiction over the case, the Second Circuit agreed that plaintiffs had established constitutional standing but vacated the district court’s judgment in so far as it failed to establish a subclass of the self-funded Plans and approved the settlement agreement without explaining how the 55% allocation discount was calculated.

The self-funded Plans argued they should have been represented by independent counsel because they had a different relationship with Medco and were more damaged by the PBM’s conduct. According to the self-funded Plans, the insured and capitated Plans avoided the risk of prescription drug cost increases by paying set premiums; therefore, such Plans were not damaged and should receive no part of the settlement fund. The insured and capitated Plans contended, however, that Medco’s failure to pass on savings damaged them financially.

The appeals court viewed this conflict arising from the different relationships the Plans had with Medco as a matter affecting “the very heart of the litigation.” Thus, the appeals court remanded to the district court for “certification of a subclass encompassing the self-funded Plans in order to better protect their claims in the litigation.”
As to the settlement agreement, the appeals court determined its description for calculating each class member’s proportionate share was unambiguous, but found the failure to explain the allocation discount provided to the insured or capitated Plans problematic. *Central States Southeast and Southwest Areas Health and Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, Nos. 04-3300-cv(L), 04-3464-cv(CON), 04-3545-cv(CON), 04-3871-cv(CON) (2d Cir. Oct. 4, 2007).

**U.S. Court In Tennessee Holds PBM Was Not ERISA Fiduciary**

A pharmaceutical benefits manager (PBM) was not a fiduciary under the Employee Retirement Income Security Act of 1974 (ERISA) by virtue of the services it provided pursuant to its contract with the sponsor of an employee benefits plan, a federal trial court in Tennessee ruled November 13, 2007. Plaintiff Robert E. Moeckel, an employee of John Morrell & Co. (Morrell & Co.), brought a putative class action against PBM Caremark, Inc. (Caremark) for breach of fiduciary duties under ERISA. Morrell & Co. had entered into contracts with Caremark from 1997 to 2006 for PBM services to its self-funded ERISA plan. The contracts expressly stated that Caremark was not an ERISA fiduciary and that Morrell & Co. had the sole authority to control and administer the plan. Plaintiff, a participant in the Morrell & Co.’s employee benefits plan, alleged Caremark created hidden “pricing spreads” that yielded significant revenue that it failed to pass on to its plan-customers.

Plaintiff alleged Caremark acted as an ERISA fiduciary in that it had sole discretion to (1) set the price the plan paid for generic prescriptions; (2) select the benchmark average wholesale price reporting source used to set the price the plan paid for brand-name prescriptions; (3) determine whether a particular prescription would be adjudicated and priced as a brand-name or generic prescription; (4) decide when to dispense a brand-name drug as a generic prescription at its mail order facilities; and (5) manage the plan’s formulary.

The U.S. District Court for the Middle District of Tennessee found these activities related to the basic administration of Caremark’s own business and that Morrell & Co. retained exclusive control over the management and administration of the plan at all times. Thus, the court held Caremark did not exercise discretionary control over the plan and the PBM was not a fiduciary under ERISA.

In its extensive analysis of plaintiff’s claims, the court emphasized that many of the activities at issue applied across Caremark’s business as a PBM or were industry standards that were separate and distinct from its contracts with particular plans. The court also stressed that the conduct at issue stemmed from adherence to the contractual terms negotiated by Morrell & Co. at arms’ length. “As with all of Moeckel’s various allegations concerning pricing components of the agreements, if Morrell & Co. believed it was improperly charged, it could have taken whatever action it deemed necessary, including filing a lawsuit against Caremark,” the court remarked.

Ultimately, the court concluded that Caremark lacked final decision-making authority concerning the plan’s management and administration and therefore the services it
provided were not fiduciary in nature. Throughout its analysis, the court cited extensively to a recent Seventh Circuit decision that found PBM Caremark was not acting as an ERISA fiduciary in a case making similar allegations to those in the instant action. See Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc. No. 05-3476 (7th Cir. Jan. 19, 2006). Moeckel v. Caremark, Inc., No. 3:04-0633 (M.D. Tenn. Nov. 13, 2007).

U.S. Court In Missouri Says Health Plan Failed To Establish Fiduciary Status In ERISA Action Against PBM
A health fund failed to establish that it was a fiduciary empowered to bring an action under the Employee Retirement Income Security Act (ERISA) against a pharmacy benefits manager, a federal trial court ruled December 7, 2007. The court granted the plan leave to amend its complaint to plead its fiduciary status.

The lawsuit was brought as a class action by plaintiff Local 153 Health Fund against Express Scripts, Inc. (ESI) and ESI Mail Pharmacy Services, Inc. (ESI Mail), which are defendants in several interrelated cases that were consolidated for coordinated pre-trial proceedings. Plaintiff, an employee welfare benefit plan, alleged it was injured by defendants’ pharmacy benefits management of rebates and discounts, asserting a cause of action under ERISA, 29 U.S.C. § 1132(a)(2), which allows “a participant in, beneficiary of, or fiduciary for, an ERISA plan” to bring a civil action asserting a claim for breach of fiduciary duty. ESI and ESI Mail (collectively, defendants) moved for summary judgment for lack of subject matter jurisdiction, arguing plaintiff was not one of the parties empowered under § 1132(a)(2) to bring an ERISA action.

The U.S. District Court for the Eastern District of Missouri granted the motion but allowed plaintiff the opportunity to amend its complaint to establish its fiduciary status. Acknowledging “much discord” on the issue, the court ultimately followed the majority view and held plans, acting on their own behalf, could not originate actions under ERISA’s § 1132(a)(2). The court went on to find, however, that a plan could bring such an action if it established its status as a fiduciary. Here, aside from its unsubstantiated claim that it was a trustee, plaintiff failed to make such a showing, the court said.

The court also refused to consider the issue of complete preemption since plaintiff had not established its status as a fiduciary, and ability to bring the action under ERISA, in the first place. The court granted plaintiff leave to amend its complaint to establish its fiduciary status, noting that plaintiff had a potentially viable claim against ESI and ESI Mail for breach of fiduciary duty and unjust enrichment. In re Express Scripts, Inc., No. 4:05-CV-00862 SNL (E.D. Mo. Dec. 7, 2007).

Ninth Circuit Stays District Court Decision Finding ERISA Preempts San Francisco Ordinance Mandating Employer Healthcare Expenditures
The Ninth Circuit in a January 9, 2008 order agreed to stay a federal trial court decision that the Employee Retirement Income Security Act (ERISA) preempts a San Francisco ordinance setting new healthcare spending mandates for employers, which were set to go
The San Francisco Health Care Security Ordinance, passed in 2006, requires medium and large employers (those with over 20 employees) and nonprofits with over 50 employees to make certain levels of healthcare expenditures for individuals employed for more than 90 days who work over 10 hours per week. Qualifying healthcare expenditures include contributions to health savings accounts, direct reimbursement to employees for healthcare expenses, payments to third parties for healthcare services, costs incurred in the direct delivery of healthcare services, or payments to the City “to be used on behalf of covered employees.” Covered employers would have to maintain “accurate records of health care expenditures” and “proof of such expenditures” and allow “reasonable access” by City officials. Violations would be subject to penalties and presumptions against employers. The Ordinance also establishes a Health Access Program for uninsured residents funded through contributions from private employers, individuals, and the City.

Golden Gate Restaurant Association (GGRA), representing the interests of the restaurant industry, sought declaratory and injunctive relief that ERISA preempted the Ordinance’s spending requirement. The U.S. District Court for the Northern District of California granted December 26, 2007 summary judgment in GGRA’s favor. Citing ERISA § 514(a), the court found the federal statute preempted the Ordinance’s healthcare expenditure requirements because they had an impermissible "connection with" employee welfare benefit plans. In addition, the court held the Ordinance’s provisions makes "unlawful reference to benefit plans because they refer to, are designed to act immediately upon, and cannot operate successfully without the existence of employee welfare benefit plans."

Following the ruling, the City of San Francisco appealed to the Ninth Circuit and sought an emergency stay of the order in both the district and appeals courts so it could proceed with the Ordinance's implementation as scheduled. "Without this stay, tens of thousands of San Francisco residents and workers will be deprived of critically necessary healthcare services--and will suffer the health-related and financial consequences--during the pendency of this appeal," the City argued. But GGRA said “[i]f granted, the stay would immediately create a patchwork of local regulation and impose serious ongoing administrative and financial hardships for employers.” The district court issued an order December 28 denying the ex parte application for stay pending appeal, saying to hold otherwise would modify the status quo by allowing what the court considered a preempted Ordinance to go into effect.

A three-judge panel of the Ninth Circuit disagreed that maintaining the status quo is a requirement for granting a stay. Instead, the appeals court held there was both a "probability," even a "strong likelihood," that the City would prevail on its argument that ERISA did not preempt the Ordinance. Moreover, the appeals said "the balance of hardships tips sharply in . . . favor" of the City and the public interest supported granting a stay. Golden Gate Restaurant Ass’n v. City and County of San Francisco, No. C 06-
In further developments on this case, the GGRA asked Supreme Court Justice Anthony Kennedy to overturn the Ninth Circuit’s unanimous panel decision allowing the San Francisco ordinance to go into effect during the appeal process. “This implementation immediately disrupted the status quo and eliminated the national uniformity Congress intended to preserve when enacting ERISA,” GGRA argued in its application to Kennedy, in his capacity as a Circuit Justice for the Ninth Circuit. The group said it decided not to petition the full Ninth Circuit to overturn the panel decision because of the “minimal opportunity for success.”

In its application to Kennedy, GGRA said the panel’s decision “was based on an interpretation of ERISA preemption at odds with Supreme Court precedent and recent cases invalidating similar mandates.” According to GGRA, “[i]nterim relief from an individual Circuit Justice is appropriate where the Justice concludes there is a reasonable probability that four members of the Court would vote to grant certiorari to resolve the issues raised in the case,” the application said. GGRA argued the issues raised in the case “strongly suggest” that four Justices would elect to exercise jurisdiction if the Ninth Circuit reversed the district court’s judgment given the national significance of the federal questions at issue; a likelihood of conflicting decisions between circuits courts; and the need to correct the erroneous presumption that the employer benefit mandate was not preempted. Justice Kennedy rejected GGRA’s application February 21, 2008 without opinion.

The Department of Labor (DOL) also has submitted an amicus curiae brief to the Ninth Circuit arguing the lower court correctly found the Employee Retirement Income Security Act (ERISA) preempts a San Francisco ordinance setting new healthcare spending mandates for employers. According to the brief, ERISA preempts the employer spending requirements in the Ordinance because “they mandate employee benefit structures or their administration” and “interfere with uniform plan administration.”

According to DOL, the City attempts to avoid preemption by providing a “City-payment” option as a “non-ERISA” way for employers to comply with the Ordinance. This option in fact “requires an employer to establish and maintain an ERISA plan,” the brief contends. Moreover, the brief continues, the spending requirements should be preempted because they interfere with uniform plan administration.

Eleventh Circuit Finds Health Plan Can Bring ERISA Suit Seeking Reimbursement From Beneficiary’s Conservator
An employer benefit plan may sue under the Employee Retirement Income Security Act (ERISA) to recover from a plan beneficiary’s conservator medical expenses it paid on behalf of the plan beneficiary who later received a tort settlement that was deposited into a special needs trust on behalf of the beneficiary, the Eleventh Circuit ruled January 15, 2008. Reversing the grant of summary judgment in favor of the plan beneficiary and the conservator, who was the plan beneficiary’s mother, the appeals court rejected the lower
court's conclusion that the plan’s reimbursement request did not qualify as “appropriate equitable relief” under ERISA § 502(a)(3).

The plan beneficiary in this case, Joshua Horton, was 14 years old when he was struck by a car and suffered permanent injuries. At that time, Joshua’s mother, Denica Jayne Werber, was a Wal-Mart employee and a participant in the Wal-Mart Stores Inc. Associates’ Health and Welfare Plan (plan). Following the accident, the plan paid $51,446 in medical benefits on Joshua’s behalf. Horton and his mother subsequently filed a personal injury lawsuit against the driver of the car and ultimately reached a $99,000 settlement. After approximately $34,000 was deducted from that amount for attorney’s fees, the remaining $65,000 was deposited into a state probate court account for the benefit of Joshua. The probate court appointed Werber as Joshua’s conservator, and she took possession of the settlement funds and deposited them in a special needs trust.

Pursuant to the terms of the benefit plan, the plan’s administrative committee sought to obtain reimbursement of the medical expenses it paid on Joshua's behalf from the $65,000 settlement. Werber refused and the administrative committee sued Horton and Werber in federal court under ERISA. The administrative committee, as fiduciary of the plan, sought “equitable relief” under ERISA § 502(a)(3), which provides that a civil action may be brought by “a participant, beneficiary, or fiduciary. . .to obtain other appropriate equitable relief.” The U.S. District Court for the Northern District of Georgia granted summary judgment in favor of Horton and Werber, ruling that the administrative committee’s requested reimbursement did not qualify as "appropriate equitable relief."

The appeals court reversed and remanded, relying primarily on Sereboff v. Mid Atlantic Med. Servs., Inc., 126 S. Ct. 1869 (2006), in which the U.S. Supreme Court considered an ERISA plan’s lawsuit against a plan beneficiary to recover medical benefits paid on the beneficiary’s behalf from a tort settlement. As in the present case, the appeals court explained, the plan in Sereboff sought to recover the medical benefit paid in accordance with the plan’s subrogation and reimbursement clause, and sued for restitution under ERISA § 502(a)(3). The Court in Sereboff “held that when a plan seeks restitution from a beneficiary who is in possession of particular, identifiable funds, such a suit sounds in equity and is cognizable under § 502(a)(3),” the appeals court said. Unlike Sereboff, however, the present case involves a benefit plan using § 502(a)(3) to recover a specifically identified fund in the possession of a third party, such as a trustee or conservator, by suing the third party directly, the appeals court explained.

Turning to this question, the appeals court found that the administrative committee’s claim was not defeated simply because Werber holds the requested funds as a third party. Under Sereboff and other authorities, “the most important consideration is not the identity of the defendant, but rather that the settlement proceeds are still intact, and thus constitute an identifiable res that can be restored to its rightful recipient,” the appeals court said. In this case, the appeals court noted, the money Werber holds in trust was identified “as belonging in good conscience to the Administrative Committee by virtue of the Plan’s terms, and the money can clearly be traced to a particular fund in the defendant’s possession.” The appeals court further explained that, if the administrative committee had
sued only Horton, who is not in possession of the disputed funds, the claim would have failed because “it merely would have sought to impose personal liability” on Horton. *Administrative Committee for the Wal-Mart Stores Inc. Assocs. ’ Health and Welfare Plan v. Horton*, No. 07-10012 (11th Cir. Jan. 15, 2008).

**DOL Advisory Opinion Says ERISA Does Not Preempt State Recovery Of Medicaid Payments From Health Plans**

The Employee Retirement Income Security Act of 1974 (ERISA) does not preempt a state Medicaid agency’s action to recover Medicaid benefit payments made on behalf of individuals who also are participants in ERISA-covered private health insurance plans that require prior authorization for covered healthcare items or services, the Department of Labor (DOL) said in an advisory opinion. The opinion, issued by DOL's Employee Benefits Security Administration, was addressed to Ginni Hain, Director, Division of Eligibility, Enrollment & Outreach, Centers for Medicare and Medicaid Services (CMS).

When an ERISA-covered plan participant or beneficiary, who is also a state Medicaid beneficiary, fails to inform the provider at the point of service that he or she has private health coverage, the provider may bill and Medicaid may pay for healthcare items or services received by the participant or beneficiary. However, when the state Medicaid agency discovers that the participant or beneficiary had dual coverage and seeks reimbursement, the plan may reject the state's claim on the ground that the beneficiary failed to obtain the required prior authorization. Thus, the plan may assert that, without prior authorization, the plan does not cover the items or services, and that any state law entitling the state to obtain reimbursement in this situation is preempted by ERISA, CMS explained in its request for the opinion.

According to the opinion, “ERISA would not preempt a State cause of action to recoup Medicaid payments made for covered expenses to the extent that the private plan would have been liable for those expenses if the participant had followed the appropriate prior authorization procedures under the plan before the State made the payment for the items or services.” The opinion explained that ERISA § 514(b)(8) specifically saves from preemption state causes of action to obtain reimbursement for state Medicaid programs from ERISA plans. In addition, the opinion said, “[i]n the Department’s view, a plan that requires participants and beneficiaries to obtain prior authorization for health care items or services, but that makes no provision for reimbursing a State Medicaid Agency for payment of those items or services in cases where prior authorization was not requested, would not be in compliance with ERISA section 609(b)(3).”

The opinion noted however, “that the State cannot compel the plan to reimburse it for items or services to which the participant was not entitled for procedural reasons,” nor “could a plan be required to reimburse the full amount of the State's payment for a particular item or service if, under the terms of the plan, the plan would have paid a lesser amount or would have required the participant to seek an alternative treatment.”
U.S. Court In New Jersey Finds ERISA Preempts Claims Under State Parity Law
A federal court in New Jersey found February 25, 2008 that the Employee Retirement Income Security Act (ERISA) preempted certain insureds’ claims under the state’s mental health parity law. However, the court refused to dismiss the case based on failure to exhaust administrative remedies, agreeing with plaintiffs that it would be futile to have pursued Aetna’s internal appeals.

Plaintiff class sued Aetna and others (collectively, Aetna) alleging that Aetna wrongfully denied coverage for treatment sought for eating disorders by improperly classifying eating disorders as “non-Biologically Based Mental Illnesses.” The two named plaintiffs in the suit are both residents of New Jersey and have daughters who were denied coverage for their eating disorders under ERISA-governed insurance policies issued by Aetna. Aetna moved to dismiss, arguing ERISA preempted plaintiffs’ state law claims under New Jersey’s Mental Health Parity Law and that all counts should be dismissed for failure to exhaust administrative remedies and for failure to state a claim upon which relief can be granted.

At the outset, the U.S. District Court for the District of New Jersey clarified that the claims before the court concerned Aetna’s interpretation of the contractual language contained in the insurance policies as applied to each plaintiff. In finding ERISA preempted plaintiffs’ claims under the Parity Law, the court noted that “Plaintiffs would have no private cause of action under the Parity Law that they do not already have under the terms of their respective policies.” According to the court, “because Plaintiffs can bring their claims under ERISA § 502(a)(1)(B), and because there is no other independent legal duty implicated by Defendants’ actions, any individual cause of action under the Parity Law would be completely pre-empted by ERISA § 502(a)(1)(B)” and the Supreme Court’s preemption analysis in *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004). The court also found preempted plaintiffs’ state law claims for punitive damages.

Turning to defendants’ exhaustion of administrative remedies argument, the court agreed with plaintiffs that resorting to Aetna’s internal appeals process would have been futile. The court noted, however, that plaintiff DiVito “must demonstrate—either at trial or in a subsequent motion to dismiss—the connection between those claims denied as ‘not medically necessary’ and Defendants’ allegedly improper treatment of eating disorders as non-Biologically Based Mental Illnesses.” The court then noted that defendants may properly raise their failure to exhaust argument in a motion for summary judgment “where Plaintiffs must provide evidence to support their assertions.”

The court also refused to dismiss plaintiffs’ fiduciary duty claim pursuant to ERISA § 502(a)(3), finding a split among circuits as to whether such claims are duplicative of claims for benefits under ERISA § 502(a)(1)(B). The court once again noted that defendants’ motion “may be renewed in a summary judgment motion after full discovery.” *DeVito v. Aetna*, No. 07-0418 (FSH) (D.N.J. Feb. 25, 2008).
FOOD AND DRUG LAW/LIFE SCIENCES

Pharmaceutical/Medical Device Settlements

Jazz Pharmaceuticals To Pay $20 Million To Resolve “Off-Label” Marketing Charges
Jazz Pharmaceuticals has agreed to pay $20 million to settle criminal and civil allegations that its wholly owned subsidiary Orphan Medical, Inc. illegally marketed the prescription drug Xyrem, also known as a “date rape” drug, for off-label uses, the U.S. Attorney’s Office for the Eastern District of New York announced July 13. Under the settlement, Orphan has pled guilty to felony misbranding in violation of the Food, Drug, and Cosmetic Act for inducing physicians to prescribe Xyrem, or gamma-hydroxybutyrate (GHB), for uses that were not approved by the Food and Drug Administration (FDA) and not reimbursable by public or private insurers. Xyrem was approved for only two medical uses related to the treatment of patients with the sleeping disorder narcolepsy. According to the release, Orphan admitted that through sales representatives and at least one medical professional it promoted the drug to physicians for uses including fatigue, insomnia, chronic pain, weight loss, and depression. Orphan also paid a psychiatrist “tens of thousands of dollars” for speaking engagements to promote off-label uses of Xyrem, the release said. A federal grand jury indicted the psychiatrist last year on criminal charges for his involvement in promoting Xyrem.

In connection with the case, Jazz has entered into a non-prosecution agreement with the federal government under which it agreed to guarantee Orphan’s obligation to pay criminal restitution to public and private insurers of approximately $12.2 million and a criminal fine of $5 million. To resolve the civil action brought against them under the False Claims Act, Jazz and Orphan will pay $3.75 million plus interest, the release said. The whistleblower action was initiated by a former Orphan sales representative, Shelley Lauterbach, in 2005. In a separate Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General, Jazz agreed to take certain proactive and remedial measures, including implementing a Code of Conduct prohibiting promoting drugs for unapproved uses, requiring compliance training for promotional speakers and sales representatives, and replacing certain Orphan sales managers.

Boston Scientific Announces Settlement To Resolve Allegations Of Faulty ICDs
Boston Scientific Corporation announced August 30, 2007 that three of its Guidant Corporation subsidiaries will pay a total of $16.75 million to settle allegations that they continued to sell implantable heart defibrillators (ICDs) despite the need for potential corrective changes. The three subsidiaries—Guidant Corporation, Cardiac Pacemakers Inc., and Guidant Sales Corporation—are now known as Boston Scientific Cardiac Rhythm Management. Boston Scientific acquired Guidant last year in the face of product recalls and regulatory investigations regarding Guidant’s cardiac devices. The settlement agreement resolves allegations with 35 Attorneys General and the District of Columbia about the allegedly faulty ICDs, which deliver a jolt to the heart when necessary to restore a normal heart rhythm. Per the settlement agreement, the Boston
Scientific subsidiaries also will extend the Supplemental Warranty Program for the devices an additional six months. In addition, the companies have agreed to install a patient safety officer and a patient safety advisory board and to enhance product performance communications. The Boston Scientific subsidiaries admitted no liability in agreeing to the settlement.

**Merck Agrees To $4.85 Billion Settlement To Resolve Vioxx Litigation**

Pharmaceutical giant Merck & Co., Inc. announced November 9, 2007 that it has agreed to a $4.85 billion settlement to resolve federal multidistrict litigation over the company’s pain medicine Vioxx. The multi-billion dollar settlement amount will be paid into a settlement fund for qualifying claims that enter into the resolution process. Merck noted in its press release announcing the settlement that claims by the approximately 47,000 plaintiff groups “will be evaluated on an individual basis.”

The agreement, which also applies to tolled claims, was signed by Merck and the Plaintiffs' Steering Committee of the Vioxx litigation after they met with three of the four judges overseeing the coordination of more than 95% of the current Vioxx claims. Merck voluntarily withdrew Vioxx from the marketplace on September 30, 2004 after a monitoring board overseeing a long term study of the painkiller recommended that the study be halted because of an increased risk of heart attacks and strokes.

According to Merck, in order to qualify for the settlement, claimants will have to pass three gates: an injury gate requiring objective, medical proof of myocardial infarction (MI) or ischemic stroke (as defined in the agreement); a duration gate based on documented receipt of at least 30 Vioxx pills; and a proximity gate requiring receipt of pills in sufficient number and proximity to the event to support a presumption of ingestion of Vioxx within 14 days before the claimed injury. The settlement agreement provides that Merck does not admit causation or fault.

**Aventis Pays Over $190 Million To Settle FCA Claims Alleging Fraudulent Drug Pricing And Marketing**

Aventis Pharmaceuticals Inc. (Aventis) has paid the United States and a number of states, as well as the District of Columbia, over $190 million to resolve allegations that the company caused false claims to be filed with Medicare and other federal healthcare programs as a result of its alleged fraudulent pricing and marketing of drugs, according to a press release issued by the U.S. Department of Justice (DOJ) September 10, 2007. The investigation in the case commenced in June 1995, after Ven-A-Care of the Florida Keys Inc. (Ven-A-Care), a home infusion therapy company, filed a False Claims Act (FCA) qui tam complaint in the U.S. District Court for the Southern District of Florida against Aventis.

Aventis, currently known as sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC, agreed to settle FCA allegations concerning its pricing and marketing of Anzemet, an antiemetic drug used primarily in conjunction with oncology and radiation treatment to prevent nausea and vomiting. Aventis allegedly engaged in a scheme to set and maintain fraudulent and inflated prices for Anzemet knowing they were the basis of federal
healthcare program reimbursement rates. The federal government alleged Aventis used the “spread,” i.e., the difference between the inflated prices that it reported—which were used by federal programs to set reimbursement rates for healthcare providers—and the actual prices for the drugs charged to its customers, to promote and sell Anzemet to existing and potential customers.

Of the more than $190 million settlement, the federal government will recover $179.8 million, while the states and the District of Columbia will recover $10.6 million for their share of Medicaid losses. The Ven-A-Care whistleblowers will receive approximately $32 million as their share of the settlement. Aventis also agreed to enter into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (OIG).

In a separate statement issued by Aventis, the company said the settlement covers the time period September 1, 1997 through June 30, 2004—prior to the formation of sanofi-aventis, and that it “decided to resolve this legacy matter through [the] settlement, without admitting any wrongdoing.”

**Implant Manufacturers Enter Agreements With DOJ To Escape Prosecution For Alleged Fraud**

Five companies that manufacture hip and knee surgical implants have entered into agreements with the Department of Justice (DOJ) that require new corporate compliance procedures and federal monitoring, U.S. Attorney for the District of New Jersey Christopher J. Christie announced September 27, 2007. The 18-month deferred prosecution agreements (DPAs) allow four of the five companies—Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet Inc., and Smith & Nephew, Inc.—to avoid criminal prosecution if they meet all the requirements for reform under the agreements. The fifth company, Stryker Orthopedics, Inc., voluntarily cooperated with the U.S. Attorney’s Office before any other company and therefore executed a Non-Prosecution Agreement under which Stryker is required to implement all the reforms imposed on the other companies under the DPAs, according to Christie.

The companies—which together account for nearly 95% of the market in hip and knee surgical implants—were accused of using consulting agreements with orthopedic surgeons as inducements to use a particular company’s artificial hip and knee reconstruction and replacement products, Christie said. The four companies that agreed to DPAs have also reached civil settlements with the DOJ and the Department of Health and Human Services Office of Inspector General (OIG) in which they have agreed to pay a total of $311 million to settle claims under the Anti-Kickback Statute and the False Claims Act. They have also entered into five-year Corporate Integrity Agreements (CIAs) with the OIG. In addition all five companies have agreed to accept the appointment of federal monitors to review compliance with the corporate reforms required under their agreements, Christie said.

In further developments, two orthopaedic device companies, Wright Medical Group Inc. (Arlington, TN) and Exactech Inc. (Gainesville, FL), announced in December 2007 that
they received subpoenas from Christie’s office. The subpoenas, according to the companies, requested documents for the period January 1998 through the present related to any consulting and professional service agreements between each company and orthopaedic surgeons in connection with hip or knee replacement procedures or products. Both companies said they intended to fully cooperate with DOJ’s request.

**Bristol-Myers Squibb Agrees To $515 Million Global Settlement To Resolve Healthcare Fraud Allegations**

Bristol-Myers Squibb Company (BMS) has agreed to pay more than $515 million to resolve numerous federal and state civil allegations involving its drug marketing and pricing practices, U.S. Attorney for the District of Massachusetts Michael J. Sullivan announced September 28, 2007. The government had alleged that BMS "knowingly and willfully paid illegal remuneration to physicians and other healthcare providers to induce them to purchase BMS drugs from approximately 2000 through mid-2003." Although BMS paid the physicians the remuneration in the form of consulting fees and expenses in exchange for the providers' participation in various consulting programs, advisory boards, and preceptorships, the government alleged that one purpose of the programs, some of which involved travel to luxurious resorts, was to influence the providers' prescribing habits.

The government also alleged that, from 1994 to 2001, Apothecon, a BMS subsidiary, knowingly and willfully paid illegal remuneration such as stocking allowances, prebates, and free goods in order to induce its retail pharmacy and wholesaler customers to purchase its products. The government contended BMS promoted certain drugs for off-label uses and that both BMS and Apothecon set and maintained fraudulent and inflated prices for a wide assortment of oncology and generic drug products with the knowledge that federal healthcare programs established reimbursement rates based on those prices. In addition, the government claimed BMS knowingly misreported to Medicaid its best price for an anti-depression drug.

Under the settlement agreement, BMS agreed to pay $499,000,000 plus interest to resolve the federal and state civil claims. The interest as of the settlement date was $16,483,660.27, Sullivan said, bringing the total payment owing to $515,483,660.27. BMS also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General that, among other things, requires the company to report accurate average sales prices and average manufacturer prices for its drugs covered by Medicare and other federal healthcare programs.

BMS noted in its press release announcing the settlement that "[t]here are no criminal charges against the company," and stated that the "agreement will not affect the company's ongoing business with any customers, including the government."
Merck To Pay More Than $650 Million To Resolve Allegations Of Illegal Price Reporting, Kickbacks

Merck & Co. has agreed to pay more than $650 million to settle allegations of illegal price reporting practices and paying kickbacks to physicians for prescribing the company’s drugs, the Department of Justice announced February 7, 2008. The healthcare fraud settlement, one of the largest ever according to Attorney General Michael B. Mukasey, stems from two whistleblower cases filed under the False Claims Act by H. Dean Steinke, a former Merck employee, and physician William St. John LaCorte. As a result of the settlement, the federal government will receive more than $360 million and 49 states and the District of Columbia will divvy up over $290 million, DOJ said. Steinke will receive about $68 million as his relator’s share in the settlement. LaCorte’s share of the proceeds was not specified in DOJ’s press release. Merck, which did not admit to any liability in agreeing to the settlement, said in a statement the company “believes its pricing and sales and marketing policies and practices were consistent with all applicable regulations and contracts during the relevant time.”

Steinke, who filed his case in the Eastern District of Pennsylvania, alleged Merck offered deep discounts to hospitals that used large amounts of it cholesterol-lowering drug Zocor and pain medication Vioxx, which was used to treat arthritis and is now off the market, but failed to report these discounts to the government. Under the Medicaid Rebate Statute, drug manufacturers must report their “best prices” to the government so that Medicaid can benefit from the same discounts the companies provide to other purchasers. According to DOJ, Merck attempted to exploit an exception to the law by improperly designating the discounted prices offered to hospitals as “nominal.” Steinke also alleged Merck from 1997-2001 used questionable sales tactics and paid kickbacks to physicians, in the form of excess fees for “training,” “consultation,” or “market research,” so they would prescribe Merck’s drugs. Merck agreed to pay $399 million plus interest to settle the allegations.

LaCorte, who filed his case in the Eastern District of Louisiana, alleged Merck would offer hospitals substantially lower prices on Pepcid, which is used to treat heart burn and acid reflux, if they agreed to use its drug over competitors' products. According to the allegations, Merck was motivated by the prospect that patients would continue using Pepcid once discharged from the hospital, and the company again failed to report these discounts to Medicaid. To settle this action, Merck agreed to pay $250 million plus interest. In addition, Merck has entered into a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General.

Caremark Reaches Settlement With States In Prescription Drug “Switching” Case

Caremark LLC (Caremark), one of largest pharmacy benefit management companies in the United States, has reached a $41 million settlement with 28 states and the District of Columbia to resolve prescription “switching” claims, according to a press release issued by Illinois Attorney General Lisa Madigan and several other state attorney general offices. Madigan, along with Maryland Attorney General Douglas Gansler, led the multi-state investigation into Caremark’s drug switching practices. Caremark is a subsidiary of CVS Caremark Corporation. In a February 14, 2008 statement, CVS Caremark said it
expressly denied any and all allegations, and emphasized there had been no finding of wrongdoing or inappropriate business conduct on their part.

Based on the four-year investigation, the complaint filed in the case alleged that Caremark (and its subsidiaries) engaged in deceptive business practices by encouraging physicians to switch patients to different brand-name prescription drugs to save money. In doing so, however, Caremark failed to disclose its own financial motivations for drug switching, or “inform physicians of the effect this switch would have on costs to patients and health plans,” the release said.

As part of the settlement, Caremark must make significant changes to its process for switching patients from the drugs originally prescribed by their physicians. In addition, Caremark has agreed to pay $38.5 million to the states, including $22 million for making drugs more affordable for low-income, disabled, or elderly consumers and educating all consumers about the cost differences among medications and $16.5 million for investigative costs, fees, and consumer education. An additional $2.5 million will be used to reimburse patients who incurred expenses related to certain drug switches.

The settlement also prohibits Caremark from soliciting drug switches when the cost to the patient for the proposed drug is greater than the cost to the patients for the originally prescribed drug; the proposed drug does not have a generic equivalent and the originally prescribed drug does; the patient was switched from a similar drug within the past two years; or the originally prescribed drug’s patent is expected to expire within six months.

The settlement imposes a number of other requirements on Caremark. For example, Caremark will be required to inform patients and prescribers of what effect a drug switch will have on a patient’s copayment, and also inform prescribers of any financial incentives Caremark may have for encouraging certain drug switches. Further, Caremark must reimburse patients for out-of-pocket expenses for drug switch-related healthcare costs, and notify patients and prescribers that such reimbursement is available.

**Eleven Drug Makers Agree To $125 Million Settlement Of AWP Litigation**

Eleven major pharmaceutical companies have agreed to a $125 million nationwide settlement in connection with average wholesale price (AWP) litigation filed in 2002 by consumers and insurance companies, according to a press release issued March 7, 2008 by Seattle-based law firm Hagens Berman, co-lead counsel in the case. The plaintiffs in the case claimed the drug makers intentionally inflated AWPs on certain prescription drugs resulting in consumers and third-party payors paying more than they should for those drugs.

The consolidated class action complaint was filed against 23 pharmaceutical companies in the U.S. District Court for the District of Massachusetts on September 6, 2002. Under the terms of the settlement, 82.5% of the settlement fund is designated for third-party payors' claims and the remaining 17.5% is designated for consumer claims, the release said.
The eleven defendants who agreed to the settlement are Abbott Laboratories, Amgen Inc., Aventis Pharmaceuticals Inc., Hoechst Marion Roussel, Baxter Healthcare Corp., Baxter International Inc., Bayer Corporation, Dey, Inc., Fujisawa Healthcare, Inc., Fujisawa USA, Inc., Immunex Corporation, Pharmacia Corporation, Pharmacia & Upjohn LLC, Sicor, Inc., Gensia, Inc., Gensia Sicor Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., and ZLB Behring, L.L.C. The drugs covered by the settlement include Aranesp, Epogen, Neupogen, Neulasta, Anzemet, Ferrlecit, and Infed, the release said. The district court is expected to set a trial date for the remaining claims against AstraZeneca and Bristol-Myers Squibb on behalf of insurance companies and consumers outside of Massachusetts, according to the release.

**Connecticut AG Sues Eli Lilly Alleging Illegal Marketing Of Zyprexa For Off-Label Uses**

Connecticut Attorney General Richard Blumenthal filed suit March 11, 2008 in the U.S. District Court for the Eastern District of New York against Eli Lilly and Company, Inc. alleging the drug maker illegally marketed its antipsychotic drug Zyprexa for unapproved uses and concealed the drug’s serious side effects. "The illegal marketing campaign exploited children and senior citizens—causing severe weight gain, diabetes and cardiovascular problems," Blumenthal said in a press release. "This scheme involved payments to public officials, bogus educational events and ghostwritten promotional articles summarizing suspect studies. The drug was marketed for anxiety, depression and Attention Deficit Disorder in children when it was never approved for any use in children and caused serious side effects," Blumenthal added.

The lawsuit makes claims under the Connecticut Unfair Trade Practices Act (CUTPA) and the federal Racketeer Influenced and Corrupt Organizations Act (RICO). According to Blumenthal, Zyprexa (olanzapine) has only been approved by the Food and Drug Administration (FDA) for use in treating schizophrenia and bipolar mania. However, in furtherance of the scheme, doctors at "educational" forums urged peers to prescribe Zyprexa; ghostwriters published articles that promoted off-label prescribing, while omitting details about serious side effects; and public officials in various states promoted Zyprexa for unapproved uses in adolescents at detention centers and nursing homes, the release said.

Meanwhile, Eli Lilly paid such physicians and authors generously and concealed the financial arrangements by funneling compensation through its illegal enterprises and third parties. According to Blumenthal, the Connecticut Medical Assistance Programs (CMAP) spent more than $190 million on Zyprexa between 1996 and 2006. The lawsuit seeks restitution, civil penalties, and attorneys' fees.

**CVS Caremark To Pay $37.5 Million To Settle “Drug Switching” Claims**

CVS Caremark Corporation has agreed to pay $37.5 million to resolve claims that it improperly switched patients to a more expensive version of a prescription drug used to treat heartburn and ulcers to increase its Medicaid reimbursements, the Department of Justice (DOJ) announced March 18, 2008. According to DOJ, from 2000 to 2006, CVS Caremark, one of the nation’s leading pharmacy retailers, routinely dispensed the capsule
version of Ranitidine (generic Zantac) instead of the cheaper tablets because of a substantial price difference in Medicaid payment rates.

The lawsuit was initiated in 2003 by whistleblower Bernard Lisitza, a licensed pharmacist. Lisitza also served as one of the relators in an unrelated action against Omnicare Inc., the nation’s largest provider of pharmacy services to the elderly. Omnicare Inc. in November 2007 agreed to pay $49.5 million to the federal government and 43 states to resolve allegations that it defrauded Medicaid by improperly switching patients from cheaper to more expensive versions of certain drugs.

Under the settlement with CVS Caremark, the federal government will receive roughly $21.1 million, with 23 states and the District of Columbia sharing about $15.6 million pursuant to separate settlement agreements. Lisitza will receive over $4.3 million as his relator share. CVS Caremark also has entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

CVS Caremark expressly denied engaging in any wrongful conduct in agreeing to the settlement. In a statement, CVS Caremark explained that for many years it purchased and stocked the capsule form of Ranitidine across its retail chains because “the acquisition cost of capsules was lower than the cost of tablets.” The company denied that this practice was motivated by a desire to increase Medicaid reimbursement.

**InterMune CEO Indicted For Role In Alleged Off-Label Drug Marketing**

The former CEO of biopharmaceutical firm InterMune Inc. was indicted March 18, 2008 for his alleged role in illegally promoting one of the company’s drugs for uses not approved by the Food and Drug Administration (FDA), the Department of Justice (DOJ) announced.

The indictment charges W. Scott Harkonen, M.D., also a former member of InterMune’s board of directors, with wire fraud and felony Food, Drug and Cosmetic Act violations for allegedly directing the marketing and sale of Actimmune, which the FDA has approved to treat certain immune system disorders, for idiopathic pulmonary fibrosis (IPF), an unapproved use.

In October 2006, InterMune agreed to pay the U.S. over $36.9 million and entered into a deferred prosecution agreement to resolve civil and criminal allegations that it illegally promoted Actimmune for off-label uses and caused the submission of false claims.

Actimmune for one IPF patient costs about $50,000 in one year and most of the drug’s sales resulted from prescriptions for the unapproved use, the release said. According to the allegations, Harkonen also caused the issuance and distribution of a false and misleading press release to portray that the results of a clinical trial established that Actimmune helped IPF patients live longer, although this was not in fact the case. This misleading information, DOJ said, was distributed to over 2,000 pulmonologists and patients taking Actimmune.
Eli Lilly Agrees To Pay Alaska $15 Million To Settle Zyprexa Case
Eli Lilly has agreed to pay the state of Alaska $15 million to settle litigation over the use of the drug Zyprexa (olanzapine) by the state's Medicaid program. The lawsuit claimed the state and healthcare providers were insufficiently warned about possible side effects of the drug—used to treat schizophrenia and bipolar disorder—relating to weight gain, high blood sugar, and diabetes, causing harm to Medicaid recipients and resulting in increased costs to the state. The settlement agreement also includes a "term that will ensure that Alaska is treated as favorably as any other state that may settle with Lilly in the future over similar claims," Eli Lilly said in a press release. The agreement "involves no admission of wrongdoing on Lilly's part," the company noted.

Otsuka Pharmaceutical Will Pay $4 Million To Resolve Off-Label Marketing Allegations
Otsuka American Pharmaceutical Inc. will pay over $4 million to settle allegations that it marketed its atypical antipsychotic drug Abilify for off-label uses, the Department of Justice (DOJ) announced March 27, 2008. According to DOJ, Otsuka American, the U.S. subsidiary of Japanese pharmaceutical manufacturer Otsuka Pharmaceutical Co., Ltd., working under an agreement with Bristol-Myers Squibb (BMS) co-promoted sales of Abilify for pediatric use and to treat dementia-related psychosis in seniors. The Food and Drug Administration has approved Abilify only to treat adult schizophrenia and bi-polar disorder and has mandated the drug’s package carry a “black box” warning concerning its use in the treatment of dementia-related psychosis. The government alleged that, from 2002 through 2005, Otsuka knowingly promoted the sale of Abilify for these off-label uses by directing its sales force to call on providers of pediatric or long term care. The federal government will recover roughly $2.3 million from the settlement, with the remaining $1.7 million going to certain state Medicaid programs. DOJ said the settlement resolves the remainder of the allegations made in a whistleblower action under the False Claims Act brought by physician Joseph Piacentile. BMS settled claims based on the same allegations in September 2007. Otsuka also has agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

Merck May Have Manipulated Vioxx Trial Data In Ghostwritten Manuscripts, Selective Presentation To FDA, JAMA Says
Clinical trial manuscripts related to rofecoxib (Vioxx) were authored by Merck & Co. Inc. employees but often attributed first authorship to academically affiliated investigators who did not always disclose industry financial support, according to an article published April 16, 2008 in the Journal of the American Medical Association (JAMA). The JAMA article looked at documents that have become public in the course of litigation against Merck over injuries associated with the use of Vioxx. According to the article, for the publication of clinical trials, "documents were found describing Merck employees working either independently or in collaboration with medical publishing companies to prepare manuscripts and subsequently recruiting external, academically affiliated investigators to be authors."
"For the publication of scientific review papers, documents were found describing Merck marketing employees developing plans for manuscripts, contracting with medical publishing companies to ghostwrite manuscripts, and recruiting external, academically affiliated investigators to be authors," the article found. In addition, recruited authors commonly were the sole author on the manuscript and offered honoraria for their participation. Among 96 relevant published articles reviewed by JAMA, 92% (22 of 24) of clinical trial articles published a disclosure of Merck's financial support, but only 50% (36 of 72) of review articles published either a disclosure of Merck sponsorship or a disclosure of whether the author had received any financial compensation from the company, the article said. The article concluded that "case-study review of industry documents related to rofecoxib demonstrates that Merck used a systematic strategy to facilitate the publication of guest authored and ghost written medical literature."

A second case study looked at how Merck represented mortality findings associated with Vioxx in clinical trials of patients with Alzheimer’s disease or cognitive impairment. The study found that in April 2001, Merck conducted intention-to-treat analyses that clearly identified an increased risk of mortality associated with rofecoxib among patients in the Alzheimer’s disease trials. However, these combined intention-to-treat analyses were not submitted to the Food and Drug Administration (FDA) until 2003, the study said. "The data submitted to the FDA in 2001 used a variety of counting methods, including on-treatment rather than intention-to-treat analyses, an approach that minimized the appearance of the mortality risk," the article said. The study noted that certain trials had no active data and safety monitoring board (DSMB). In looking at the results of the trials, the JAMA article concluded the "mortality findings and the Alzheimer disease findings would, in our judgment, have prompted a DSMB, if it had existed, to stop the trial early."

**Legislative Action**

**Senate HELP Committee Passes Follow-On Biologics Legislation**

On June 27, 2007 the Senate Health, Education, Labor and Pensions (HELP) Committee approved the Biologics Price Competition and Innovation Act of 2007 (BPCIA), S. 1695, which includes standards for the Food and Drug Administration (FDA) to approve follow-on biologics. At the same time, the measure provides incentives, most notably 12 years of data exclusivity for original drug makers, to encourage innovation and development of new therapies.

Supporters of the legislation, including Committee Chairman Edward M. Kennedy (D-MA) and ranking member Mike Enzi (R-WY), and Senators Orrin Hatch (R-UT), Hillary Clinton (D-NY), and Charles Schumer (D-NY), believe follow-on biologics can generate federal savings by introducing competition into the market and enabling patient access to potentially life-saving medications for conditions such as Hepatitis C, multiple sclerosis, cancer, and diabetes. Follow-on biologics are protein products manufactured using biotechnology or derived from natural sources intended to be similar to a product or products already approved in the U.S. They permit the follow-on applicant to rely on scientific knowledge about the approved products to demonstrate safety and effectiveness in a marketing application. Current law, however, does not provide a clear regulatory
pathway for approval of generic versions of these complex and expensive drugs after a patent expires.

**House, Senate Pass FDA User Fee Bill**
The Senate passed by unanimous consent September 20, 2007 the Food and Drug Administration Amendments Act of 2007 (H.R. 3580), which reauthorizes the prescription drug user fee program through 2012. The bill passed the House September 19, 2007 on a motion to suspend the rules. President Bush signed the measure September 27, 2007.

The compromise bill includes the administration's request for an increase in the total annual user fees collected to $392.8 million for fiscal year 2008, an $87.4 million increase over the current base, according to a bill summary. In addition, the legislation contains an additional $225 million in user fees that will be collected over five years to be used for drug safety activities and "are intended to supplement and not supplant any other drug safety resources." The legislation also reauthorizes the medical device user fee program and includes enhancements to ensure sound financial footing for the device review program and to the process for pre-market review of device applications. Under the new bill, medical device companies will pay 31% more in fees in 2008 and 8.5% more each subsequent year through 2012, the summary said. Two new types of fees are set forth in the bill—an annual establishment registration fee and an annual fee for filing periodic reports—which will generate about 50% of the total fee revenue.

In addition, according to Senator Barbara A. Mikulski (D-MD), the bill will save 2,000 Food and Drug Administration (FDA) jobs at risk. The legislation, which Mikulski calls "the most important drug safety bill of the decade," will fundamentally improve drug safety standards at the FDA, she said.

The legislation also reauthorizes the Pediatric Research Equity Act of 2007 and the Best Pharmaceuticals for Children Act of 2007 and establishes the Pediatric Medical Device Safety and Improvement Act of 2007.

FDA's authority over post-market drug safety will be enhanced under the bill. The legislation provides FDA with the authority to require labeling changes and to impose civil monetary penalties for certain violations of the federal Food, Drug, and Cosmetic Act with respect to drugs.

The provision sets forth an administrative procedure and civil monetary penalties for violations. The compromise bill's penalties are somewhat lighter than what was contained in the original House bill, H.R. 2900. Both bills would subject an applicant who violates a Risk Evaluation and Mitigation Strategy (REMS) requirement to a civil monetary penalty of $250,000 per violation, not to exceed $1 million for all such violations adjudicated in a single proceeding. However, the compromise bill provides that for a continuing violation, "the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof), and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1
H.R. 2900, on the other hand, would have allowed the Secretary to impose a civil penalty of not more than $10 million per violation, not to exceed $50 million for all such violations adjudicated in a single proceeding.

**Senate, Senate Approve Genetic Information Non-Discrimination Bill**

By a unanimous vote of 95-0, the Senate approved April 24, 2008 the Genetic Information Nondiscrimination Act (GINA), which prohibits health insurers and employers from discriminating against individuals on the basis of genetic information. The House followed suit on May 1, 2008, approving the measure by a vote of 414-1. GINA prohibits genetic discrimination in health insurance and the workplace by barring health insurers and employers from requesting or using genetic information to take any action that would affect an employee’s health or employment benefits, including health insurance premiums, contribution amounts, and eligibility, according to a bill summary. In addition, the bill prohibits discrimination on the basis of genetic information in hiring, firing, job assignments, and promotions. It also requires that genetic information possessed by employers be confidentially maintained and disclosed only to the employee or under other tightly controlled circumstances. The President is expected to sign the measure.

**Litigation Developments**

**U.S. Court In New York Upholds Plavix Patent, Enjoins Marketing Of Generic**

The U.S. District Court for the Southern District of New York upheld June 19, 2007 a patent on the popular blood thinner Plavix, which is marketed by Bristol-Myers Squibb (BMS) and its product partner Sanofi Aventis. The court found Apotex, Inc., which sought to market the generic equivalent of the drug, failed to prove by clear and convincing evidence that the patent was invalid or unenforceable. The court permanently enjoined Apotex from engaging in any activity that infringes the Plavix patent, saying damages would be set after further proceedings.

The previous month, BMS agreed to plead guilty to criminal charges of making false statements to a federal agency in connection with a proposed settlement agreement of the patent litigation with Apotex. According to the Department of Justice (DOJ), BMS at the time of the negotiations was subject to a separate, unrelated consent decree with the Federal Trade Commission (FTC) that required it to submit any proposed patent settlements to the agency for approval. FTC specifically warned BMS that it would not approve a settlement of the Plavix litigation if it involved BMS agreeing to refrain from launching its own generic version of the drug, DOJ said. BMS nevertheless entered into such an agreement and lied about its existence to the FTC, DOJ contended. BMS will plead guilty to two violations of the federal False Statements Act and pay a $1 million fine, DOJ said.
U.S. Court In New York Allows Claims Against Zyprexa Manufacturer To Go Forward
A federal court in New York allowed claims by a group of pension funds, labor unions, insurance companies, and one individual (plaintiffs) against the makers of the drug Zyprexa to go forward. The court found genuine issues of fact regarding plaintiffs’ claims that they overpaid for the drug given the manufacturer's fraudulent marketing activities. Plaintiffs sued Eli Lilly & Company (Lilly) claiming that it withheld information and disseminated misinformation about the safety of its drug Zyprexa and marketed the drug for off-label uses. Plaintiffs asserted claims under the Racketeer Influenced and Corrupt Organizations Act (RICO), various state consumer protection statutes, common law fraud, and unjust enrichment. Plaintiffs also sought class certification for "[a]ll individuals and entities in the United States and its territories who, for purposes other than resale, purchased, reimbursed, and/or paid for Zyprexa."

The court found that, as purchasers of Zyprexa, consumers and third-party payors had standing to sue for economic damages. By bringing an overpricing suit, "plaintiffs here allege a direct injury to themselves that is not dependant on any physician's decision or injury suffered by those who ultimately ingested Zyprexa," the court said. In allowing plaintiffs’ claims to proceed, the court said such suits furnish "backstop protection against under-regulated potentially dangerous activity by a market where caveat emptor largely rules." In re Zyprexa Prods. Liability Litig. (E.D.N.Y. June 28, 2007).

U.S. Court In Pennsylvania Remands Commonwealth’s Action Against Drug Makers To State Court
The U.S. District Court for the Eastern District of Pennsylvania remanded June 27, 2007 to state court the Commonwealth of Pennsylvania’s action against various pharmaceutical companies alleging they caused the submission of fraudulent claims for prescription medications to Medicaid and the Pennsylvania Assistance Contract for the Elderly (PACE) program. According to the Commonwealth, defendants illegally promoted their respective drugs for “off-label” uses and “non-medically necessary uses” for which reimbursement under Medicaid and PACE was not available. In addition, the state sought recovery as parens patriae of treatment costs for Medicaid and PACE participants allegedly injured by defendants’ drugs due to a failure to warn, negligence, breach of warranty, fraud and misrepresentation, and unjust enrichment. Defendant drug makers removed the case to federal district court and then sought to stay all proceedings pending transfer to ongoing multidistrict litigation involving similar claims. The Commonwealth sought remand to state court.

The U.S. District Court for the Eastern District of Pennsylvania granted remand, holding the state law claims did not raise a disputed and substantial question of federal law and that exercising jurisdiction would contravene principles of federalism and comity. The court found that, while federal law defines a “medically accepted indication,” this was not the basis of liability asserted in the Commonwealth’s complaint. “Here, the central question is whether the Defendants’ advertising and promotion methods violate Pennsylvania tort law, not what is or is not a medically accepted indication or medically necessary use,” the court noted.
Although defendants raised federal defenses, including the Food and Drug Administration’s extensive control over drug labeling, these did not rise to the level of “complete preemption” necessary to confer federal question jurisdiction. “There is no meaningful indication that Congress intended to confer federal jurisdiction over state law causes of actions implicating the federal statutes involved here,” namely the Food Drug and Cosmetic Act and Medicaid, the court said. The court also found that allowing the Commonwealth’s claims to proceed in state court would not conflict with or otherwise hamper federal uniformity in the oversight of prescription medications and Medicaid. On the contrary, the court added, the exercise of federal jurisdiction would “upset the balance between state and federal courts” where “such claims are fact-specific and wholly based on state law.” Pennsylvania v. Eli Lilly & Co., Inc., No. 07-1083 (E.D. Pa. June 27, 2007).

D.C. Circuit Says Terminally Ill Do Not Have Constitutional Right To Experimental Drugs

Terminally ill patients do not have a constitutionally protected right to access experimental drugs that have passed early safety trials but have not yet been cleared by the Food and Drug Administration (FDA) as safe and effective, the D.C. Circuit held August 7, 2007 in an 8-2 ruling. The opinion reverses a 2-1 panel decision by the D.C. Circuit in May 2006 that ruled in favor of the Abigail Alliance for Better Access to Developmental Drugs (Alliance) and the Washington Legal Foundation (WLF), which filed the lawsuit to enjoin the FDA from enforcing a policy barring sales of post-Phase I experimental drugs that have been deemed “sufficiently safe for substantial human testing” but are not approved for commercial sale.

The Alliance and WLF contended that mentally competent, terminally ill adults who are not part of Phase II clinical trials should have access, with the advice of their physicians, to potentially life-saving investigational new drugs without FDA interference. The panel found the access sought by the Alliance to post-Phase I trial drugs involved a fundamental right of self preservation under the Due Process Clause that required strict scrutiny review.

On rehearing en banc, the majority of the D.C. Circuit disagreed with the panel and affirmed a lower court decision, which found “no constitutional right of access to unapproved drugs.” Beginning its due process analysis under the parameters set forth by the U.S. Supreme Court in Washington v. Glucksberg, 521 U.S. 702 (1997), the majority found the nation “has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both drug safety and efficacy.” According to the majority, the Alliance’s argument that efficacy regulation is of relatively recent advent—with the 1962 amendments to the Food, Drug, and Cosmetic Act (FDCA)—overlooks the nation’s long history of drug safety regulation. “FDA regulation of post Phase I drugs is entirely consistent with our historical tradition of prohibiting the sale of unsafe drugs,” the majority said. The majority also characterized the Alliance's argument in terms of a potential slippery slope effect, noting that a history
of non-regulation as a basis for finding a constitutionally protected right would undermine “much of the modern administrative state.”

The majority rejected the Alliance’s contention that a right to self-preservation gave the terminally ill a constitutionally protected right of access to experimental drugs based on the doctrines of necessity, the tort of intentional interference with lifesaving efforts, and traditional self-defense principles. According to the majority, the common law doctrine of necessity did little to support the Alliance’s argument given Supreme Court precedent that the doctrine as a defense could not override a value judgment made by the legislature—i.e. the prohibition on general access to experimental drugs found in the FDCA. The majority also found the tort of intentional interference with lifesaving efforts to be inapplicable since the drugs sought were experimental and not shown as safe or effective to prolong life. Finally, contrary to other cases invoking self-defense principles, “this case involves risk from drugs with no proven therapeutic effect,” the majority noted.

Accordingly, because no fundamental right was at stake, only rational basis review was warranted, the majority held. Applying this standard, the majority concluded “the FDA’s policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.”

A dissenting opinion argued the majority opinion “reflects a flawed conception of the right claimed” by the Alliance and “a stunning misunderstanding of the stakes.” The court fails to come to grips with the Nation’s history and traditions, which reflect deep respect and protection for the right to preserve life, a corollary to the right to life enshrined in the Constitution,” the dissent wrote. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, No. 04-5350 (D.C. Cir. Aug. 7, 2007).


A panel of the Federal Circuit found August 1, 2007 a D.C. law targeting “excessive prices” in the sale of patented prescription drugs conflicted with U.S. patent law and therefore affirmed the grant of injunctive relief to plaintiffs, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). The law, the Prescription Drug Excessive Pricing Act of 2005 (Act), unanimously passed the D.C. Council on September 20, 2007, making it “unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.”

Under the law, a prima facie case of excessive pricing is established when the wholesale price is “over 30 percent higher than the comparable price of any high income country
where the drug is protected by patents or other exclusive marketing rights.” Four foreign countries—United Kingdom, Germany, Canada, or Australia—are then designated as high-income countries for purposes of the Act. The law also provides that “any person directly or indirectly affected by excessive prices of prescription drugs” may bring suit against a “drug manufacturer, or licensee thereof” for violating the law.

PhRMA and BIO challenged the law soon after it passed, claiming the Act was preempted by federal patent laws and violated the Commerce Clause. The district court found the Act unconstitutional, holding it was preempted by the U.S. patent laws and was a per se invalid extraterritorial reach in violation of the Commerce Clause.

Affirming, the Federal Circuit agreed that the Act conflicted with federal patent law. With respect to preemption, the appeals court noted federal patent law attempts to balance two often competing objectives: to reward innovators with higher profits by allowing a limited period of exclusivity and to keep prices reasonable for consumers once those patents expire. “The Act’s operation stands largely—indeed exclusively—within the scope of the patent laws, and its effect is to shift the benefits of a patented invention from inventors to consumers,” the Federal Circuit said. According to the appeals court, the Act essentially “re-balance[s] the statutory framework of rewards and incentives” contrary to the goals set out by Congress in the patent laws. Thus, federal law preempted the Act. *Biotechnology Ind. Org. v. District of Columbia*, No. 2006-1593 (Fed. Cir. Aug. 1, 2007).

On October 30, 2007, the Federal Circuit denied a petition for a rehearing en banc of the panel decision.

A dissenting opinion agreed that the Act was invalid, but argued that the panel’s decision rested on an incorrect basis. “While the D.C. statute in this case appears to be invalid because of its poor drafting, the panel’s opinion suggests that even legitimate price regulation is invalid,” the dissent noted. The dissent said the D.C. Act was subject to field preemption because it sought to establish patent policy, but the panel instead based its decision on conflict preemption. “In my view, a price discrimination provision presents no conflict with the purpose of the federal patent law,” the dissent contended. Thus, the dissent said the decision “warranted our en banc attention.”

A concurring opinion argued, however, that the dissent incorrectly focused only on “price discrimination” in its analysis, rather than the Act “as a cohesive whole.” According to the concurrence, “the direct conflict between the D.C. Act and the objects and purposes of the federal laws regarding pharmaceutical patents makes clear Congress’ intention to preempt the D.C. law.” *Biotechnology Ind. Org. v. District of Columbia*, No. 2006-1593 (Fed. Cir. Oct. 30, 2007).

**Third Circuit Holds Federal Law Preempts State Consumer Fraud Claims Alleging Misleading Drug Ads**

Federal law preempts state consumer protection claims alleging a drug maker deceptively marketed one of its drugs, the Third Circuit ruled August 17, 2007. According to the opinion, the Food and Drug Administration’s (FDA's) exclusive authority and extensive
regulation of drug advertising would be thwarted if general state law claims like the ones at issue were allowed to proceed. The proposed class action alleged Zeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. (collectively Zeneca) engaged in deceptive conduct by misleadingly advertising the acid reflux drug Nexium as an improvement on Prilosec, whose patent was set to expire. The complaint alleged, among other things, unlawful advertising under the Delaware Consumer Fraud Act (DCFA), violations of all 50 states’ consumer protection statutes, and unjust enrichment. The district court dismissed the complaint with prejudice, finding the DCFA exemption for advertising regulated by the Federal Trade Commission (FTC) applied and that federal law preempted the state consumer protection claims.

Although the Third Circuit found the DCFA exemption inapplicable, it affirmed the district court’s dismissal on preemption grounds. The DCFA exempts from its reach claims involving “any advertising or merchandising practice” that is compliant with FTC regulations. The appeals court concluded the exemption did not prevent plaintiffs’ claims here because the FDA’s regulation of prescription drug advertising is independent of the FTC. “We will not rewrite the text of the exemption to include regulation of activities that are not within the FTC’s authority,” the appeals court said.

The appeals court did agree, however, that federal law impliedly conflict preempted plaintiffs’ deceptive advertising claims under state consumer protection laws. While neither the language of the Food, Drug, and Cosmetic Act (FDCA) nor the FDA’s regulations explicitly preempt state consumer fraud laws, the appeals court found allowing such claims to go forward would unnecessarily conflict with the agency’s extensive and specific involvement in regulating prescription drug advertising. In the appeals court’s view, the “high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising.” Moreover, “the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA,” the appeals court said.

A dissenting opinion argued the state law claims at issue did not conflict with federal law because they alleged only that Zeneca misleadingly advertised Nexium as superior to Prilosec and did not question the veracity of any statement in the FDA-approved drug label. With no actual conflict, the dissent questioned how the congressional purpose of protecting prescription drug users would be frustrated by allowing the claims to proceed. Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc., No. 05-5340 (3d Cir. Aug. 17, 2007).

Fourth Circuit Upholds $1 Million Penalties For Performing Mammograms Without Required Certification
A $1 million fine imposed on a radiologist and his radiology group by the Food and Drug Administration (FDA) for performing mammograms without the required certification was not excessive under the Eighth Amendment, a federal appeals court ruled August 17, 2007. The Fourth Circuit found the seriousness of the deficiency—i.e. using
mammography equipment that did not produce quality images—warranted the substantial fine.

The FDA imposed monetary sanctions on Dr. Amile Korangy and Korangy Radiology Associates (KRA) after they performed 192 mammograms despite the expiration of their statutorily required certification. The Mammography Quality Standards Act (MQSA) requires mammography facilities to be certified by the FDA and authorizes the agency to impose civil monetary penalties up to $10,000 for each violation of the requirement. Korangy’s certificate was set to expire on May 6, 2002. The American College of Radiology, an FDA-approved accreditation body, had inspected Korangy’s equipment and informed him that it failed to meet quality standards for clinical image. Korangy nonetheless continued to perform mammograms until July 25, 2002, when he received certification of new mammography equipment. The FDA initially sought to impose the statutory maximum of $10,000 per violation, but later agreed to reduce that amount to $3,000 for a total of over $1 million assessed against both KRA and Korangy.

The Fourth Circuit said even assuming the penalties were at least partially punitive and therefore subject to the Excessive Fines Clause of the Eighth Amendment, it could not conclude the penalties imposed were “grossly disproportionate to the gravity of the offense.” The FDA imposed a per violation fine that was significantly less than the $10,000 statutory maximum authorized by Congress in the MQSA, the appeals court noted. “Moreover, KRA lost its certification not because of a failure to comply with a reporting requirement or some similar ‘technicality,’ . . . but because its equipment did not produce an image of adequate quality,” the appeals court pointed out. According to the appeals court, the “seriousness of that deficiency cannot be over-emphasized” given its potential implications for patients. Korangy v. U.S. Food and Drug Admin., Nos. 05-2300, 06-1860 (4th Cir. Aug. 17, 2007).

**Maine High Court Finds Product Liability, Failure To Warn Claims Time-Barred**

The Maine Supreme Judicial Court held October 18, 2007 that product liability and failure to warn claims brought against the surgeons who implanted a particular device in the plaintiff-patients were barred by the statute of limitations. The high court found that each plaintiff had received notice of the device's risks but failed to bring suit within the applicable limitations period. Nineteen patients who received surgically implanted Vitek devices in their temporomandibular joints to relieve jawbone malfunctions sued Oral Surgery Associates (OSA) and the oral surgeons who implanted the devices claiming product liability, breach of warranty, and negligence. The trial court held the patients' “duty to warn” claims were time-barred and that they failed to raise a genuine issue of material fact as to when they had knowledge of the risks associated with their Vitek implants.

The high court noted that the Vitek implants at issue were the subject of a Food and Drug Administration (FDA) safety alert in 1990 that warned of the “serious problems” associated with the implants, including the risk of “implant perforation, fragmentation, and/or [a] foreign body response which may result in progressive bone degeneration.” The high court observed that the question presented in the appeal was “whether the duty
to warn is fulfilled upon proof that a notice warning of the dangers of an implant was received by the patient, or whether it must also be shown that the patient understood the warning.” The high court found that generally, a “surgeon has fulfilled her duty to warn when she has passed along important information regarding the safety of implants, such as FDA alerts, to affected patients. The duty does not require the surgeon (or courts) to inquire into whether each patient subjectively understood those warnings.” *Farnum v. Oral Surgery Assocs.*, No. CUM-06-691 (Me. Oct. 18, 2007).

**U.S. Court In Massachusetts Awards Damages Against AstraZeneca, Bristol-Myers Squibb In AWP Litigation**

A federal district court in Massachusetts has awarded two classes of third-party payors $12,941,869 in damages against AstraZeneca and $695,594 in damages against Bristol-Myers Squibb (BMS) after finding the drug makers violated Massachusetts law by grossly inflating the average wholesale prices (AWPs) of their drugs. The massive nationwide multi-district class action involves the pricing of pharmaceutical drugs reimbursed by Medicare, private insurers, and patients making coinsurance payments based on AWP between 1991 and 2003.

The instant decision involved two classes in particular—third-party payors (TPPs) in Massachusetts that reimburse Medicare beneficiaries for their statutory 20% coinsurance obligations under Medicare, known as Medigap or supplemental insurance (Class 2); and TPPs that make coinsurance payments and pay for drugs based on AWP (Class 3).

In a decision issued in June 2007, the U.S. District Court for the District of Massachusetts concluded AstraZeneca and BMS violated Mass. Gen. Laws ch. 93A, the state’s deceptive trade practices act, by “[u]nscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup.” The court found the spreads, or the differences between actual acquisition costs and the published AWPs used to set reimbursement levels, “were as high as 1,000%.” While acknowledging that the mega-spreads were widely known by 2001, the court found the pharmaceutical companies’ conduct “was still egregious under the unfairness prong of Chapter 93A because neither the TPPs nor the government could move quickly or effectively to fix the problem.”

At issue in the court’s November 1, 2007 decision was whether AstraZeneca and BMS should be subject to double or treble damages for knowingly or willfully violating Chapter 93A.

With respect to the Class 2 plaintiffs, the court found defendants’ conduct “was both knowing and willful because they knew that Medicare beneficiaries, and thus their insurers, were locked by statute into paying twenty percent of grossly inflated phony AWPs.” Although the court said it was “tempting” to impose treble damages on AstraZeneca, it ultimately decided to assess only double damages, citing certain mitigating factors, including that the company was not the first to start the illegal spread marketing, and that it provided some free drugs to consumers. The court also found BMS’ conduct was willful and knowing as to three specific drugs, but again opted to
impose double rather than treble damages “because there was little evidence that BMS actually marketed the spread, and it also had a program for the poor.” Accordingly, for Class 2, the court ordered double damages against AstraZeneca of $5,557,370 and against BMS of $388,557.

With respect to Class 3, the court found AstraZeneca’s and BMS’ conduct was not knowing and willful because most of the plaintiffs were sophisticated TPPs that were not locked into the AWP benchmark by statute but continued to negotiate their contracts on the basis of AWP even after it became widely understood that these prices were inflated. Thus, the court awarded single damages for Class 3 against AstraZeneca of $7,384,499 and against BMS of $307,037. In re Pharmaceutical Ind. Average Wholesale Price Litig., No. 1456 (D. Mass. Nov. 1, 2007).

U.S. Court In Maine Enjoins Maine Law Restricting Data Mining

A federal district court in Maine agreed to preliminarily enjoin the enforcement of a new state law restricting the collection and disclosure of physician prescribing information for marketing purposes that was set to go into effect January 1, 2008. The court found the Maine law’s (L.D. 4) attempt to regulate the use of prescription drug data violated the First Amendment by impermissibly restricting commercial speech.

The statute is similar to New Hampshire’s Prescription Information Law, which was struck down as unconstitutional by the U.S. District Court for the District of New Hampshire. IMS Health Inc. v. Ayotte, No. 06-cv-280-PB (D.N.H. Apr. 30, 2007). The New Hampshire case currently is under appeal before the First Circuit.

Three prescription drug information intermediaries (PDII)—IMS Health, Wolters Kluwer Health, through its subsidiary Source Healthcare Analytics, Inc., and Verispan LLC—filed suit in federal district court challenging the Maine statute. A similar challenge is pending in Vermont, which also enacted a law restricting the use of prescription drug data. A decision in that case is expected in 2008.

As PDII-s, plaintiffs acquire prescription data from billions of prescription transactions per year throughout the United States. They then de-identify patient information and sell the data to their clients, mostly pharmaceutical companies. The pharmaceutical companies use the information to market to specific prescribers. The laws stem from concerns that pharmaceutical companies use the prescription drug data to try and influence physicians to prescribe higher-priced drugs.

Under the Maine statute, prescribers can demand confidentiality of their individualized prescribing information. In those cases, carriers, pharmacies, or PDII-s would be prohibited from selling or using prescriber-identifiable data for marketing. The “opt out” process in the Maine statute is in contrast to New Hampshire’s law, which adopted a blanket prohibition against the sale or transfer of prescription information containing patient-identifiable or prescriber-identifiable data for any commercial purpose.
The U.S. District Court for the District of Maine framed the “narrow question” here as whether “the opt-out provision in the Maine Law makes a constitutional difference.” While a closer question than the New Hampshire statute, the court ultimately concluded the provisions of the Maine law seeking to restrict the use and disclosure of commercial information violated the free speech guarantee of the First Amendment. Applying intermediate scrutiny as defined in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980), the court examined the Maine legislature’s stated reasons for enacting the legislation—protecting patient and prescriber privacy, decreasing the influence of drug representatives, ending the use of prescriber comparisons for purposes of manufacturer profitability and decreasing unnecessary marketing costs, and enhancing the effectiveness of other laws. The court found while these purposes represented a substantial government interest, the law ultimately did not directly advance those interests and was not narrowly tailored. “We believe that restrictions on the dissemination of information of crucial public interest are neither good healthcare policy nor consistent with our society’s core beliefs in the free flow of information,” said Robert H. Steinfeld, IMS senior vice president and general counsel, following the ruling. *IMS Health Corp. v. G. Steven Rowe*, No. CV-07-127-B-W (D. Me. Dec. 21, 2007).

**California Appeals Court Holds Federal Medical Device Amendments Preempt State Tort Action**

The Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k(a), preempted a wrongful death action against the manufacturer of a heart valve alleging negligence and strict liability under state common law, a California appeals court ruled January 11, 2008. In 1987, Claudia Blanco underwent surgery and received a mitral heart valve manufactured by a wholly owned subsidiary of Baxter-Travenol Laboratories. She died in 2002 and an autopsy revealed “two missing leaflet fragments” of the valve.

Her husband Michael Blanco and their son (plaintiffs) brought a wrongful death action against Baxter Healthcare Corp. in state trial court, alleging negligence, strict liability, breach of express warranty, and breach of implied warranty. The Class III medical device under the MDA had received premarket approval (PMA) from the Food and Drug Administration (FDA) in 1986, but two years later was subject to a “Class I Recall” after reports of possible valve failures involving leaflet fracture and/or escape. Baxter moved for summary judgment, arguing the MDA preempted plaintiffs’ state common law causes of action. The California Court of Appeal, Fourth District, Division 3, affirmed a trial court decision granting Baxter summary judgment.

The MDA’s preemption language, § 360k(a), provides “no state . . . may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device . . . .” Citing the U.S. Supreme Court’s decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the appeals court noted the ambiguous issue of whether § 310k(a) preempts a common law tort action over a medical device. The appeals court distilled two central points from the fractured *Medtronic* Court applicable to the instant case—whether any device-specific
federal requirements exist with respect to the valve and, if so, whether there would be a conflict between that federal requirement and “any of the liability-creating premises of the plaintiffs’ state-law tort suit.”

The appeals court concluded that the FDA’s approval of the PMA for the valve was a device-specific federal requirement that could preempt any conflicting state law requirements. Thus, a jury verdict in plaintiffs’ failure for negligent manufacturing or negligent failure to warn would impose safety and labeling requirements different from those the FDA imposed in the approved PMA or recall process, the appeals court held.

The appeals court also concluded that the FDA’s Class I recall of the valve did not alter its conclusion. “The fact the FDA has implemented a Class I recall does not necessarily mean the FDA has completely removed the device from the marketplace,” the opinion said.

Likewise, the appeals court held plaintiffs’ strict liability claim would impose a state requirement on Baxter concerning the elimination of a defect in its manufacturing process that was different from the FDA requirement imposed in the approved PMA.

As a Class III medical device, the hearing device had to clear FDA’s “premarket approval” (PMA) process as defined in 21 U.S.C. § 360(e). The PMA process “is a rigorous one,” requiring the device manufacturer to submit a detailed application to the FDA, the high court noted. The MDA preempts “any requirement” that is “different from, or in addition to, any requirement applicable under this chapter to the device” and that “relates to the safety or effectiveness of the device . . . ,” 21 U.S.C. § 360k(a). Federal regulations stemming from this provision clarify that state or local requirements “are
preempted only when . . . there are . . . specific requirements applicable to a particular
device. . . .” See 21 C.F.R. § 808.1(d).

According to the Arkansas high court, in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), the Supreme Court stated that the MDA preempts a state law only if the state law constituted a requirement “with respect to a device,” rather than being “of general applicability,” and “there are specific requirements applicable to the device under the act.” According to the high court, Despain’s allegations were general tort claims that the hearing device was defective because of the way it reacted to a strong magnetic field and Soundtec failed to warn him of that danger. Despain did not allege, the high court continued, that any particular part of the device should have been designed in a specific manner.

Moreover, even if a state common law claim constituted a device-specific requirement, MDA preemption would still be inapplicable here, the high court said, because of the lack of device-specific federal regulations from the FDA applicable to the hearing device at issue. According to the high court, the PMA is a “manufacturer-driven process,” not one in which the FDA supplies guidelines for how a device should be designed or manufactured. Although the FDA’s approval of the device was subject to certain “conditions,” they were all general in nature (e.g. requiring the use of approved labeling and the submission of adverse incident reports). Thus, the high court held Soundtec was not entitled to summary judgment on federal preemption grounds.

The high court also rejected the lower court’s application of the learned intermediary doctrine, which provides that the manufacturer may rely on the prescribing physician to warn patients about a product's risks. The high court found an open question as to whether the warnings Soundtec gave to Despain’s prescribing physician were sufficient to fully convey the risks associated with the hearing device. Despain v. Bradburn, No. 07-714 (Ark. Feb. 7, 2008).

In further developments, following the U.S. Supreme Court’s decision in Riegel v. Medtronic, Inc. (discussed below), the Arkansas Supreme Court April 10, 2008 reversed its decision and affirmed the grant of summary judgment in Soundtec’s favor. Given the Court’s ruling, the Arkansas high court said it was compelled to reverse its holding that the MDA did not preempt state tort duties.

A concurring opinion wrote to express “deep concern” about the Riegel decision. According to the concurrence, while the MDA clearly preempts states from setting up regulatory systems that compete with those established by the federal government under the statute, the “state’s common law on tort is no such regulatory system.” “[T]he MDA, which was enacted to protect the public against defective and unsafe medical devices through federal regulation, is now turned on its head and instead grants immunity to the providers of medical devices,” the concurrence argued. Despain v. Bradburn, No. 07-714 (Ark. Apr. 10, 2008).
U.S. Supreme Court Says Federal Medical Device Amendments Preempt State Law Claims Challenging Safety And Effectiveness

In a much-anticipated decision, the U.S. Supreme Court ruled February 20 that the Medical Device Amendments of 1976 (MDA) preempt state common law claims challenging the safety and effectiveness of a medical device that received Food and Drug Administration (FDA) premarket approval (PMA). The majority opinion, written by Justice Antonin Scalia, concluded the “rigorous” PMA process results in federal device-specific requirements and that the state tort claims at issue were preempted because they would allow a jury to impose "different" or "additional" safety and effectiveness standards on the device manufacturer than those mandated under federal law. A dissenting opinion, authored by Justice Ruth Bader Ginsburg, argued Congress in enacting the MDA never intended to preempt consumer actions under state tort law, but rather to prevent potentially conflicting state premarket regulatory systems that had arisen in the absence of a federal regime for overseeing medical devices. Justice John Paul Stevens wrote a separate opinion concurring in the judgment.

At issue in the case was the interpretation of the express preemption provision in the MDA to the federal Food, Drug, and Cosmetic Act, which provides that states may not establish “any requirement” for medical devices that is “different from, or in addition to” those under federal law and that “relates to the safety or effectiveness of the device . . .” 21 U.S.C. § 360k(a).

The case arose when Charles Riegel and his wife sued Medtronic, Inc. in a New York federal district court alleging the company’s Class III medical device, the Evergreen Balloon Catheter, which had been used in an attempt to dilate Charles’ coronary artery, was designed, labeled, and manufactured in a manner that violated the state’s common law, causing him to suffer severe and permanent injuries. The district court held the MDA preempted the Riegels’ claims. The Second Circuit affirmed, finding the Riegels’ common law claims, if successful, would “impose state requirements that differed from, or added to” the device-specific federal requirements.

In finding that the MDA preempted the Riegels’ action, the High Court first determined that the federal government, through the FDA’s PMA process, had established device-specific requirements for the Medtronic catheter at issue. The opinion distinguished the Court’s decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the majority found federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not preempt state common law claims of negligence and strict liability. The *Lohr* case involved a device that entered the market through the “substantial equivalence” § 510(k) process, rather than the “rigorous” PMA process to which Medtronic’s catheter had been subject, the majority said.

Under the MDA, a new device need not undergo premarket approval if the FDA finds it is “substantially equivalent” to another device on the market. The Court in *Lohr* found the federal requirements imposed under the § 510(k) process were not requirements specific to the device in question but reflected “entirely generic concerns about device regulation generally,” Scalia said. “Unlike general labeling duties, premarket approval is
specific to individual devices. And it is in no sense an exemption from federal safety review—it is federal safety review,” Scalia wrote. The 510(k) process is focused on equivalence, not safety, but for PMA, the opposite is true, the opinion observed.

“[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness,” Scalia said.

According to the Court, because safety and effectiveness were the subject of the Riegels’ common law claims, the remaining issue was whether New York’s tort duties constituted “requirements” under the MDA. The issue of whether state tort claims are “requirements” in the context of the MDA was one that fractured the Court in Lohr, with five Justices concluding that they were, Scalia said.

The majority here held that state “requirements,” as contemplated in the MDA, include common law duties. “State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect,” Scalia reasoned. “Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation,” he added.

The majority concluded by noting that a state could still provide a damages remedy for claims premised on a violation of FDA regulations, which in such a scenario would “parallel” rather than add to federal requirements. Although the Riegels argued their lawsuit raised parallel claims, the Court refused to address the argument since it had not been raised before.

In her dissenting opinion, Ginsburg argued that Congress in the MDA did not intend to preempt state tort remedies. According to Ginsburg, the preemption language in the MDA, not found in other statutes regulating drugs and additives, was necessary because states acted to fill the previous void in device regulation by adopting their own regulatory systems. “Congress included [the preemption provisions] to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level,” Ginsburg reasoned. Similar preemption language was not necessary for drugs and additives because states had not developed their own potentially conflicting regulatory regimes. Thus, “Congress did not regard FDA regulation and state tort claims as mutually exclusive;” Ginsburg wrote. Riegel v. Medtronic, Inc., No. 06-179 (U.S. Feb. 20, 2008).

Supreme Court Deadlocks On Whether Michigan “Fraud-On-The-FDA” Exception Is Preempted Under Buckman

“The tie goes to the runner” or in this case to the Michigan plaintiffs who are allowed to advance their products liability claims involving the diabetes drug Rezulin. On March 3, 2008, in a 4-4 split decision, the U.S. Supreme Court affirmed the judgment of the Second Circuit, which found no preemption of plaintiffs’ common law claims based on a
This decision is the second in a trilogy of FDA preemption cases considered by the Court this term. Chief Justice John Roberts’ recusal created the potential for a deadlock. Although the two-sentence *per curiam* opinion (handed down just one week after oral argument) provides no precedential value, it heightens the anticipation of the Court’s decision in the third FDA preemption case that the Court will hear this fall, *Wyeth v. Levine*, U.S. Supreme Court No. 06-1249. The issue in *Levine* is whether FDA approval of prescription drug labeling provides a preemption defense to state law products liability actions.

The issue presented in *Kent* was whether implied preemption of state law fraud-on-the-FDA claims articulated in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (*Buckman*) is limited to express claims of fraud-on-the-FDA or whether *Buckman* extends to traditional tort causes of action that require the fact-finder to determine whether the manufacturer withheld material information from or misled the FDA.

Under a Michigan statute, FDA approval provides an absolute defense with an important exception. M.C.L. § 600. 2946(5)(a). If the manufacturer or seller intentionally withholds from or misrepresents to the FDA information that is required to be submitted under the federal Food, Drug and Cosmetics Act (FDCA) and the drug would not have been approved or the FDA would have withdrawn approval if the information were accurately submitted, plaintiff may recover under common law. *Id.*

The district court found that the fraud-on-the-FDA exception to immunity for FDA-approved drugs was preempted under *Buckman*. The Second Circuit reversed, limiting implied preemption under *Buckman* to express "fraud-on-the-FDA" theories of liability. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. Oct. 5, 2006).

Applying a presumption against preemption, the Second Circuit held that, absent a clear statement from Congress, the common law claims preserved by the immunity exception are not preempted. The Supreme Court’s split decision in *Kent* leaves intact the Second Circuit’s no preemption ruling. *This summary was prepared by Deborah M. Russell, McGuireWoods LLP.*

**Alabama High Court Says Learned Intermediary Doctrine Applies Even Where Pharmacist Gave Dosing Advice To Patient’s Physician**

The learned intermediary doctrine applied to cut off any liability of a pharmacist, and by extension the hospital where he worked, in a wrongful death action brought by the estate of a patient who apparently died after taking too much medication prescribed by his physician, the Alabama Supreme Court has held. Although the pharmacist provided the patient’s physician with advice for dosing the drug at issue, the physician was the party responsible for prescribing the medication and adequately conveying its risks and benefits to the patient, the high court said.
Plaintiff Sharon Larrimore, as administratrix of her husband Luther’s estate, sued Dr. John M. McMahon Jr. and Springhill Hospitals, Inc., d/b/a Springhill Memorial Hospital (SMH) for wrongful death. Luther went to SMH’s emergency room where McMahon diagnosed him with gout in his knee. McMahon prescribed colchicine and consulted SMH’s pharmacist Gregory Weeks about proper oral dosing of the medication. McMahon did not provide the pharmacist with information regarding Luther’s medical history, which included a number of existing medical problems. McMahon’s prescription did not indicate the maximum number of pills that could be taken and Luther, who suffered from kidney disease, presumably took an excessive amount. Luther died prompting plaintiff’s action.

Plaintiff settled with McMahon, leaving its action against SMH for the alleged negligence of its pharmacist Weeks. A jury awarded plaintiff $4 million in punitive damages. SMH argued it was entitled to a judgment as a matter of law because Weeks could not be liable (nor the hospital vicariously liable) under the learned intermediary doctrine.

Citing its decision in  
*Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881 (Ala. 2004), the high court agreed, holding the learned intermediary doctrine applied and foreclosed any duty of care Weeks owed to Luther. The high court found the learned intermediary doctrine was not limited to product liability cases against drug manufacturers, noting its decision in  
*Walls* that a pharmacist did not have a duty to warn customers of foreseeable injuries from the prescription drugs the pharmacist was dispensing.

The high court acknowledged the fact scenario in  
*Walls*, which dealt with a pharmacist's duty to his or her customers, differed somewhat from the present circumstances, which involved a pharmacist's duty when giving a physician dosing information. But the high court found the same rationale for applying the learned intermediary doctrine in the physician-patient-manufacturer context applied equally to the physician-patient-pharmacist relationship (i.e. that physicians are best positioned to convey the risks and benefits of a particular drug to their patients).

The high court rejected plaintiff’s argument that Weeks voluntarily assumed a duty of care when he answered McMahon’s question about proper dosing of colchicine. The high court distinguished cases plaintiff relied on for applying the “voluntary-undertaking doctrine” to a pharmacist on the ground that they involved the interactions between the pharmacist and the customer. “None of those cases address the voluntary assumption of a duty based on a pharmacist’s interaction with the customer’s physician,” the high court reasoned.  

**U.S. Court In District Of Columbia Says Associations Lacked Standing To Challenge FDA Approval Of Plan B For OTC Use**

Associations representing certain physicians and pharmacists failed to establish standing in their lawsuit challenging the Food and Drug Administration’s (FDA’s) approval of the emergency contraceptive Plan B for over-the-counter (OTC) use in women over 18, a federal trial court in the District of Columbia held. According to the court, the
associations failed to establish a sufficient personal stake in the outcome of the litigation to warrant federal court jurisdiction.

In August 2006, the FDA approved Barr Pharmaceuticals Inc.’s supplemental new drug application (SNDA) for Plan B, which is marked by Barr's wholly owned subsidiary Duramed Research, Inc. Under the SNDA, Plan B could be marketed as an OTC drug for individuals age 18 and older, while those under 18 would still need a prescription.

Several associations, including Association of American Physicians & Surgeons (AAPS) and the Safe Drugs for Women (SDW), brought an action in federal district court alleging FDA’s approval of the SNDA violated the Federal Food, Drug, and Cosmetic Act (FDCA) and the Administrative Procedure Act (APA). Barr and Duramed moved to dismiss, arguing plaintiffs lacked standing to sue and failed to exhaust their administrative remedies.

The U.S. District Court for the District of Columbia agreed that plaintiffs lacked representational standing and granted defendants’ motion. As an initial matter, the court noted that plaintiffs were basing their standing on the claims of AAPS and SDW suing on behalf of physicians and pharmacists.

First, he court rejected plaintiffs’ attempt to demonstrate informational injury—i.e. that their members were deprived of their FDCA-granted right to information. The court found no support for the proposition that the FDCA could support informational standing; therefore, plaintiffs could not show they were deprived of information to which they were legally entitled.

Next, the court discounted plaintiffs’ argument that the FDA’s approval of the SNDA would lead to an increased risk of harm for consumers of Plan B who are older than 18. Specifically, plaintiffs failed to show a “substantially increased risk of harm” and a “substantial probability of harm” as required under D.C. Circuit precedent for a public-safety standing argument to succeed.

Plaintiffs also alleged physicians would suffer competitive and economic injuries by losing patient office visits. But plaintiffs failed to allege that any physician had in fact suffered a loss of revenue. And more importantly, plaintiffs’ alleged competitive and economic injuries did not fall within the FDCA’s zone of interests for prudential standing. In fact, physicians’ “alleged interest in generating fees from unnecessary doctor visits is antithetical to the purposes of the FDCA,” the court noted. The court also rejected plaintiffs’ claims that the FDA’s approval of the SNDA subjected member pharmacists to an increased risk of liability, additional administrative burdens, and compelled speech in violation of conscience-based objections.

As an alternative basis for dismissal, the court also found plaintiffs failed to exhaust their administrative remedies. Specifically, the court said, the FDA allows parties to participate in the regulatory process through the submission of a citizen petition. The FDA is empowered to grant the relief plaintiffs sought, but had not yet had the opportunity to
address all their arguments, the court reasoned in declining to resolve these issues without the benefit of the agency’s expertise and a developed administrative record. *Association of Am. Physicians & Surgeons, Inc. v. Food and Drug Admin.*., No. 07-0668 (JDB) (D.D.C. Mar. 4, 2008).

U.S. Court In North Carolina Says Federal Law Preempts State Inadequate Labeling Claims Against Drug Maker

A federal district court in North Carolina dismissed March 25, 2008 state law failure-to-warn and inadequate labeling claims against a drug manufacturer finding they conflicted with Food and Drug Administration (FDA) drug labeling regulations. The court refused to dismiss, however, the plaintiff’s negligence claims related to the design, manufacturer, research and development, testing, processing, distribution and sale of the drug at issue because they were not premised on a failure to warn or inadequate labeling.

Plaintiff Health Michelle Horne brought the action against Novartis Pharmaceuticals Corp. in connection with the death of her infant son shortly after his birth. When she became pregnant in 2003, Horne continued taking Novartis’ drug Lotensin HCT®, an ACE inhibitor, to treat her hypertension while in her first trimester. The drug’s FDA-approved label warned about the potential danger to the fetus of pregnant woman taking Lotensin HCT® in the second and third trimesters but noted that “[t]hese adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester.” A subsequent study released in 2006, which prompted an FDA public health advisory, indicated that infants exposed to ACE inhibitors during the first trimester had a significant increased risk of birth defects, including malformations of the cardiovascular system. Horne’s son had been born with several heart and kidney defects and died nineteen days after his birth.

Novartis moved to dismiss Horne’s subsequent state law action, arguing her claims conflicted with the warnings approved and mandated by the FDA for ACE inhibitors. The U.S. District Court for the Western District of North Carolina dismissed Horne’s claims in so far as they stemmed from allegations of inadequate labeling, affording considerable deference to federal regulations issued in January 2006 stating the FDA’s position that its approval of a drug label preempts contrary state law (71 Fed. Reg. 3922).

In so holding, the court noted that conflict preemption “turns on the identification of ‘actual conflict,’ and not on an express statement of preemptive intent” by Congress. According to the court, the FDA-approved label indicated that the agency considered the medical and scientific proof available at the time and concluded the risks of birth defects and fetal injury did not appear to result from using Lotensin HCT® in the first trimester. To hold Novartis liable for plaintiff’s inadequate warning claims would place the drug company “in an impossible situation whereby the Defendant could not comply with federal law and state law at the same time,” the court observed. Thus, the court found a direct and positive conflict between federal law and plaintiff’s state law claims for inadequate labeling and/or failure to warn.
The court refused to dismiss, however, plaintiff’s claims that Novartis was negligent in manufacturing, designing, testing, and researching the drug, finding these allegations were not premised on the inadequate warning claims. Horne v. Novartis Pharmaceuticals Corp., No. 3:06cv368 (W.D.N.C. Mar. 25, 2008).

Third Circuit Finds FDA Regulatory Actions Preempt State Failure-To-Warn Claims Against Drug Makers

In a 2-1 opinion, the Third Circuit held April 8, 2009 that state law tort claims against the makers of the anti-depressants Paxil and Zoloft were conflict preempted by Food and Drug Administration (FDA) regulatory action that specifically rejected adding a warning to the drugs' labels about an increased risk of suicidality in adults taking these medications. The appeals court decision in the consolidated action ultimately concluded the actions the FDA took pursuant to its regulatory authority under the Food, Drug, and Cosmetic Act (FDCA) preempted plaintiffs’ claims. Specifically, the appeals court emphasized the FDA had publicly, and on numerous occasions, rejected adding a warning to the drug labels of these types of anti-depressants concerning an increased risk of suicidality in adults.

In one case, Joseph Colacicco sued drug manufacturers SmithKline Beecham, d/b/a 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 version. The U.S. District Court for the Eastern District of Pennsylvania granted defendant drug manufacturers’ motion to dismiss on a finding of federal preemption. In the other case, Beth Ann McNellis sued Pfizer Inc. alleging it violated New Jersey products liability and consumer fraud statutes by selling Zoloft without warning that it increased the risk of suicidality. McNellis’ father, Theodore DeAngelis, took Zoloft before committing suicide. The U.S. District Court for the District of New Jersey denied Pfizer’s motion for summary judgment, but certified its order on the federal preemption issue for interlocutory appeal.

After an extensive review of the relevant regulations and Supreme Court precedent concerning federal preemption, the Third Circuit concluded that plaintiffs' actions in this case conflicted with federal law and therefore should be dismissed. The appeals court noted that state tort actions, to the same extent as state statutes, may stand as obstacles to achieving federal objectives. “Absent a determination that the FDA-approved labeling and the FDA’s refusal to require the warnings suggested by plaintiffs in this case preempt state tort actions, the manufacturers may be subjected to considerable liability based on varying standards, with no benchmarks that they should follow,” the appeals court observed.

Plaintiffs in the two cases argued that under FDA regulations, specifically 21 C.F.R. § 314.70(c), manufacturers may strengthen and augment warnings on drug labeling without prior FDA approval. Thus, state law failure-to-warn claims should be viewed as complimentary to FDA regulations, plaintiffs contended. Under the FDCA, the FDA has authority to prohibit false or misleading labeling. Therefore, a state law obligation to include a warning about the existence of an association between taking the anti-
depressants and suicidality in adults would directly conflict “with the FDA’s oft-repeated conclusion” to the contrary. The appeals court made clear, however, that it was not deciding whether the FDA’s mere approval of drug labeling was sufficient to preempt state law failure-to-warn claims. “Our holding is limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.”

A dissenting opinion argued the majority gave short shrift to the presumption against preemption given that Congress in the FDCA set forth no statutory preemption provision related to drug labeling. In the dissent’s view, clear congressional intent should be required to preempt “failure-to-warn claims [that] stand near the heart of the states’ police powers over matters of health and safety.” “Informed by the presumption against preemption,” the dissent viewed “the federal and state constructs as complementary.”

Colacico v. Apotex, No. 06-3107 (3d Cir. Apr. 8, 2008).

D.C. Circuit Finds PCMA May Pursue Claims Challenging D.C. Pharmacy Benefits Law

The D.C. Circuit held April 18, 2008 that collateral estoppel does not bar an association representing pharmacy benefit managers (PBMs) from suing the District of Columbia over a law imposing requirements on PBMs. This newest development in the long-running case overturns the lower court’s grant of summary judgment to D.C. and remands to that court for a decision on the merits.

At issue is D.C.’s AccessRx Act of 2004 (Act), D.C. Code § 48-831.01 et seq. Title II of the Act requires, among other things, PBMs to act as fiduciaries, to disclose the content of their contracts with pharmacies and manufacturers, and to pass on any payments or discounts they receive from pharmacies or manufacturers. The Pharmaceutical Care Management Association (PCMA) sued seeking to block the law’s implementation, claiming that the Employee Retirement Income Security Act of 1974 (ERISA) preempted Title II and that Title II was otherwise unconstitutional.

The U.S. District Court for the District of Columbia granted PCMA a preliminary injunction against the enforcement of the statute. However, while D.C. was appealing the injunction, the First Circuit upheld a Maine statute that is similar to Title II. Pharmaceutical Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 297 (1st Cir. 2005). D.C. amended its AccessRx Act of 2004 to conform to the Maine law. The district court then reversed course and granted summary judgment against PCMA, holding the amended AccessRx Act was nearly identical to the Maine law, that PCMA had a full and fair opportunity to litigate its claims in Rowe, and that its loss in Rowe precluded it from relitigating those claims in the instant case.

Here, the appeals court held collateral estoppel did not bar PCMA’s claims because the issues presented were legal in nature. In support of its reasoning, the appeals court noted that a “trade association could readily avoid the estoppel consequence of a loss by having one or more of its members bring the lawsuit.” In addition, “[a]pplying collateral estoppel here would also freeze the development of the law in an area of substantial public interest,” the appeals court said. Accordingly, the appeals court vacated the district
court’s grant of summary judgment and remanded for further consideration. 


**Other Developments**

**FDA Announces Revised Boxed Warning For Avandia**

The Food and Drug Administration (FDA) announced November 14, 2007 a revised boxed warning for the diabetes drug Avandia about the potential increased risk for heart attacks associated with the drug. According to a press release posted by the agency, the drug’s manufacturer, GlaxoSmithKline, agreed to add this information to the drug’s existing boxed warning in Avandia’s labeling.

The drug (rosiglitazone), which was approved in 1999, came under scrutiny after the New England Journal of Medicine published a study that indicated Avandia could increase the risk of having a heart attack. About 1 million Type II diabetics take the drug. FDA is advising healthcare providers to closely monitor patients who take Avandia for cardiovascular risks. At this time, the agency said it has not found sufficient evidence to indicate the risks of heart attacks or deaths are different between Avandia and some other oral type 2 diabetes treatments.

Senator Finance Committee Ranking Member Charles Grassley (R-IA), who has questioned the FDA’s handling of information about emerging safety questions with Avandia, said the “case is a clear example of the problem within the FDA, where the views of the office that reviews drugs after they’re on the market must play second fiddle to the position of the FDA office that approved a drug for the market in the first place. The system is off balance, and that’s not good for public safety.” GSK has agreed to conduct a long term study to evaluate potential cardiovascular risks associated with Avandia. However, Grassley noted that “2014 is a long time to wait for a more definitive review of the drug’s risks and benefits.”

**OIG Takes Back Power To Investigate Employee Criminal Conduct From FDA**

The Department of Health and Human Services Office of Inspector General (OIG) will no longer share responsibility with the Food and Drug Administration (FDA) for investigating potential criminal misconduct by FDA employees, Inspector General Daniel Levinson said in a September letter to FDA Commissioner Andrew C. von Eschenbach. Effective November 30, OIG will withdraw from the memorandum of understanding (MOU) that was negotiated with FDA in 1998.

“To ensure integrity in the process of conducting sensitive employee misconduct investigations and based on our experience operating under the MOU, this function is more appropriately placed in an investigative office with statutory independence,” Levinson said in his letter to von Eschenbach. In his response, von Eschenbach noted that to the best of his knowledge, FDA “has worked within the letter and the spirit of the MOU during the 9 years of its life span and promptly notified HHS/OIG of every FDA
employee misconduct case that developed into a criminal investigation as well as every matter that could create an actual or apparent conflict of interest.”

According to von Eschenbach, FDA was never notified of the difficulties in applying the terms of the MOU consistently as Levinson alleged in his letter. Von Eschenbach also expressed confidence that OIG “will thoroughly and promptly investigate and resolve all cases of alleged criminal conduct by FDA employees and notify FDA in writing when such resolutions occur.”

**FDA Proposes Amendment To Rules On Label Changes**

The Food and Drug Administration (FDA) issued a proposed rule (73 Fed. Reg. 2848) January 16, 2008 amending its regulations to codify "the agency’s longstanding view" on when a pharmaceutical manufacturer may change the labeling of an approved drug, biologic, or medical device in advance of FDA review of such changes. Under the rule, a supplemental application submitted under certain provisions would be appropriate to amend the labeling for an approved product only to reflect newly acquired information. In addition, the rule would clarify that such a supplemental application may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug, biologic, or device.

American Association for Justice (AAJ) the same day released a statement demanding FDA's withdrawal of the proposed rule saying it "directly contradicts congressional intent that the duty to warn people of a drug’s hazards rests with the drug company, who is in the best position to warn about problems associated with the drug." According to AAJ, an association of trial lawyers, under the Food and Drug Administration Amendments Act of 2007, drug companies must update prescription drug labels to warn consumers of drug hazards at the earliest sign of a problem. However, under the new proposal, drug companies would only have to update a label after they establish a "causal association" between the drug and the hazard, which could take years, AAJ said.

**FDA Says It Will Not Implement User Fee Program For Review Of DTC Televised Drug Advertisements**

The user fee program for the Food and Drug Administration’s (FDA’s) review of certain direct-to-consumer (DTC) televised drug advertisements will not be implemented, according to an agency notice published in the January 16, 2008 Federal Register (73 Fed. Reg. 2924). In December 2007, FDA issued a notice (72 Fed. Reg. 70334) establishing user fee rates for the program in fiscal year 2008, but the agency withdrew that notice. The notice explained that the FDA had to nix the new user fee program because the necessary user fees were not “provided in advance in appropriations Acts” as required by the Food and Drug Administration Amendments Act (FDAAA).

The FDAAA, which President Bush signed into law in September 2007, authorized the user fee program for FDA’s advisory review of DTC televised drug advertisements. The program was available, according to the notice, to companies interested in submitting to the FDA for advisory review a DTC television advertisement. The FDAAA provided, however, that the fees authorized for the DTC program “shall be collected and available
for obligation only to the extent and in the amount provided in advance in appropriations Acts.” The Consolidated Appropriations Act of 2008 (Pub. L. No. 110-161), signed by President Bush on December 26, 2007, did not appropriate user fee funds for the voluntary review of DTC televised drug advertisement, FDA explained.

“As a result, under [the FDAAA], FDA does not have the authority to collect and spend user fees for this purpose,” the notice said. FDA also noted that, under the FDAAA, if the agency failed to receive sufficient funding from companies (i.e., at least $11.25 million in advisory review fees and operating reserve fees) by 120 days after the legislation's enactment (January 25, 2008), the program “shall not commence.” Finally, FDA said that no invoices would be sent to companies, and that any advertisements voluntarily submitted would be reviewed “in as timely a manner as resources permit.”

NY AG Serves Subpoenas On Merck And Schering-Plough
New York Attorney General Andrew M. Cuomo announced January 28, 2008 that he has served subpoenas on Merck & Co. and Schering-Plough Corp. seeking information regarding the cholesterol-lowering drug Vytorin and the ENHANCE drug trial. On January 14, Merck and Schering-Plough announced the long-awaited results of the ENHANCE trial, which found no statistically significant difference between treatment groups taking Ezetimibe (Zetia) and high-dose simvastatin (also known as brand-name drug Vytorin) versus simvastatin alone (a generic drug). John Dingell (D-MI), Chairman of the House Energy and Commerce Committee, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, also have been investigating the matter.

According to Cuomo, he is “seeking to determine whether the companies deliberately concealed the negative results” of the ENHANCE trial. The first prong of Cuomo’s investigation is brought under New York’s False Claims Act and consumer protection laws, and focuses on the aggressive marketing of Vytorin to unsuspecting patients and doctors. The second prong of the investigation, brought under New York’s Martin Act, concerns the sale of the companies’ stocks to investors before the negative study results were disclosed, Cuomo said. Meanwhile, the Food and Drug Administration (FDA) issued an Early Communication January 25 noting the agency's "ongoing review" of Vytorin. The agency said it will conduct a review of the trial as soon as it receives the results.

Grassley Seeks To Pinpoint When GSK Knew About Paxil’s Suicide Risk
Senate Finance Committee Ranking Member Charles Grassley (R-IA) is trying to establish when GlaxoSmithKline (GSK) knew about the risks of suicidal behavior associated with the anti-depressant Paxil and at what point the drug maker shared this information with federal regulators and the public. In a February 6, 2008 letter to GSK President Christopher Viehbacher, Grassley cited a recent report in New Scientist suggesting GSK knew Paxil was associated with an increase risk of suicide as early as 1989, but only widely published this link in May 2006 with a “Dear Healthcare Professional” letter.
Grassley said the *New Scientist* report was based on several documents unsealed on January 18, 2008 in the case of *O’Neal v. SmithKline Beecham d/b/a GlaxoSmithKline*. In particular, Grassley pointed to an expert report prepared by Dr. Joseph Glenmullen, an instructor with Harvard Medical School, which concluded that analyses of GSK data “demonstrate a causal link between the anti-depressant and suicidal behavior. This has been true since 1989 although the 'bad' Paxil numbers obscured the risk for a decade-and-a-half.” Grassley said nine pages of Glenmullen’s report are not available publicly and asked GSK to provide his committee with an unredacted version. In addition, Grassley asked GSK to indicate when it first learned Paxil was associated with an increased risk of suicide and when GSK first communicated this finding to the Food and Drug Administration and the public. Grassley asked for a response by February 14.

**Lawmakers Told Aventis Knew Of Ketek Clinical Trial Fraud**

Aventis (now known as Sanofi-Aventis U.S. Inc.) knew of fraud involved in its large safety study of the antibiotic Ketek (telithromycin), Ann Marie Cisneros, former Senior Clinical Research Associate, PPD, Inc., told the House Energy and Commerce Subcommittee on Oversight and Investigations in a February 12, 2008 hearing. PPD monitored a number of protocols that included the large Ketek study, Study 3014. In her testimony, Cisneros detailed many study irregularities she discovered and noted her concerns when no actions were taken in response to her consistent warnings about the study. "In my eight years in clinical research work, this is the only instance I've come across of such abysmal behavior by a drug sponsor," Cisneros told the lawmakers.

Once information came out about the dangers of Ketek, the Food and Drug Administration (FDA) announced labeling changes for the antibiotic that narrowed the usage of the drug from three to one approved indication following recommendations of a joint advisory committee that met in December 2006. According to the FDA, the advisory panel concluded the risks of Ketek outweighed the benefits for treatment of acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis—two previously approved indications.

Paul Herbert Chew, M.D., President, Research and Development, Sanofi-Aventis U.S. Inc. told lawmakers that “the safety and efficacy of Ketek” are “well-supported by clinical data.” Chew said that allegations of impropriety during Study 3014 “were actively investigated by Aventis.” According to Chew, Aventis submitted the study results in good faith believing that any deviations had been addressed. Chew pointed the finger solely at Dr. Anne Kirkman-Campbell who ran one study site at which fraud was discovered. Dr. Kirkman-Campbell is currently serving a 57-month prison sentence for fraud associated with Study 3014.

**FDA Issues Draft Guidance On Distribution Of Articles Discussing Unapproved Uses Of Drugs And Devices**

The Food and Drug Administration (FDA) issued a notice in the February 20, 2008 *Federal Register* (73 Fed. Reg. 9342) announcing the availability of draft guidance on "Good Reprint Practices" for industry in the distribution of medical or scientific journal articles and reference publications that involve unapproved uses of FDA-approved drugs.
and medical devices. "Articles that discuss unapproved uses of FDA-approved drugs and devices can contribute to the practice of medicine and may even constitute a medically recognized standard of care," said Randall Lutter, FDA deputy commissioner for policy. Lutter also noted that the guidance safeguards against off-label promotion.

Some of the principles recommended by the draft guidance include ensuring that the article or reference be published by an organization that has an editorial board and that the organization should fully disclose any conflicts of interest or biases for all authors, contributors, or editors associated with the journal article. The guidance also states that articles should be peer-reviewed and published in accordance with specific procedures. In addition, the draft guidance recommends against distribution of special supplements or publications that have been funded by one or more of the manufacturers of the product in the article, and articles that are not supported by credible medical evidence are considered false and misleading and should not be distributed. The FDA also noted that it "retains legal authority to determine whether distribution of an article or publication constitutes promotion of an unapproved ‘new use,’ or whether such activities cause a product to be considered misbranded or adulterated under The Federal Food, Drug and Cosmetic Act."

Consumer group Public Citizen said in a statement that FDA's decision "to once again permit the promotion of off-label uses of drugs contrasts the current recklessness of the agency with the more consumer-protective FDA of 10 years ago." According to Public Citizen, § 401 of the Food and Drug Administration Modernization Act, which was passed in 1997 and was in place until October 2006, required companies to submit medical journal articles in advance to the FDA and agree to file within three years a supplemental new drug application for the off-label use it wanted to promote. However, "[t]hese safeguards will no longer be required under today’s proposal," the group said. The "proposal, if finalized, constitutes a health threat because it encourages drug companies, who have no reason to fear FDA sanctions, to promote drugs for purposes not proven to be safe and effective," according to Public Citizen.

FDA Advisors Detail Funding Levels Agency Needs For Core Programs
The Food and Drug Administration (FDA) needs a substantial infusion of resources to address deficiencies in its many responsibilities as overseer of the nation’s food and drug supply, according to the members of a former FDA Science Board panel. Responding to an earlier request by Democratic leaders from two House committees, the group estimated FDA’s budget needs to increase by $375 million in fiscal year (FY) 2009, an additional $450 million in FY 2010, and an additional $460 million in each of FYs 2011, 2012, and 2013.

The administration’s FY 2009 budget proposed an increase of $130 million in FDA funding levels, $51 million of which represents non-user fee resources. House Energy and Commerce Committee Chairman John Dingell (D-MI), one of the lawmakers who asked the former Subcommittee on Science and Technology of the FDA Science Advisory Board to quantify the agency’s resource needs, said the estimates show the President’s budget "has completely missed the mark."
The Subcommittee reported in earlier 2008 that a year-long study of the agency revealed the FDA is not positioned to “fulfill its mission without substantial and sustained additional appropriations.” Although the Subcommittee was disbanded after completing its analysis, Dingell, along with several other Democratic lawmakers, asked the panel for a more detailed accounting of adequate appropriations levels. In a February 25, 2008 letter responding to the lawmakers, Gail H. Cassell, Ph.D, Vice President for Scientific Affairs for Eli Lilly Company who was part of the Subcommittee, said the estimates cover a five-year span because the "years of neglect cannot be wiped away instantly."

Cassell said all but four of the former Subcommittee members (two who were unavailable and two who were government employees) had a chance to review and sign off on the estimates provided to the lawmakers. According to Cassell, the Subcommittee did not do a program-by-program analysis, with specific needs down to the lowest operational levels, but did conduct a thorough review of the FDA’s major programs and capabilities. “[W]hether the Subcommittee has reached a proposed number that is accurate to the dollar is not the issue; it is that FDA needs a very substantial increase in resources if it is to protect us as the public expects and Congress demands,” Cassell said.

**Patent Office Upholds Key Stem Cell Patent**

The U.S. Patent and Trademark Office has upheld the validity of a key stem cell patent held by the Wisconsin Alumni Research Foundation (WARF), according to a press release posted by WARF February 28, 2008. In 2006, consumer groups the Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights challenged three related patents held by WARF. The patents are based on work done by University of Wisconsin researcher Dr. James Thomson. “We’re extremely pleased with this decision. It affirms what WARF has believed all along, that Dr. Thomson’s breakthrough discoveries are patentable inventions,” said WARF Managing Director Carl Gulbrandsen.

Geron Corporation, which develops biopharmaceuticals for the treatment of cancer and chronic degenerative diseases, holds an exclusive license under the patents to develop and commercialize therapies based on cells derived from human embryonic stem cells. “In the course of the reexamination proceeding, the Patent Office conducted a thorough evaluation of relevant scientific and patent publications, considered extensive legal arguments and reviewed several expert declarations. The decision explains in precise detail why this pioneering technology is entitled to patent protection. We are, of course, pleased with the holding,” said Geron’s chief patent counsel and senior vice president of business development David J. Earp, J.D., Ph.D..

The Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights said in a February 28, 2008 statement that they would “continue their challenge of [the] three overreaching patents,” including eventual appeals in court if necessary. "WARF has won the second round with respect to just one of the patents, but the battle is hardly over. We're in this for the long haul," the groups said. The challenges to the other two patents are still pending.
FRAUD AND ABUSE

Settlements and Enforcement Action

Sixteen Individuals Charged With Defrauding Medicare Of $101 Million In DME Billing Scheme
U.S. Attorney for the Southern District of Florida R. Alexander Acosta announced May 25, 2007 that 16 defendants have been charged for their alleged involvement in a durable medical equipment (DME) billing scheme that defrauded Medicare of approximately $101 million. According to the press release, prosecutors have filed in the U.S. District Court for the Southern District of Florida seven separate cases involving fraudulent Medicare billing through a total of 34 DME companies. Of the estimated $101 million in fraudulent claims submitted, Medicare paid out approximately $62.3 million.

In the case from which the largest share of these fraudulent claims is derived, a Miami federal grand jury returned May 22, 2007 a 46-count indictment against eight defendants, including the married couple, Abner and Mabel Diaz. The indictment charged the Diazes with operating All-Med Billing Corp. (All-Med), a Miami medical billing company, through which they executed a scheme to submit tens of millions in fraudulent claims to Medicare from 1998 to 2004 for reimbursement for DME and related services. According to the indictment, All-Med submitted approximately $80 million in false claims on behalf of 29 DME companies, and Medicaid paid the DME companies approximately $56 million, the release said. The claims submitted were allegedly fraudulent in that the equipment had not been ordered by a physician and/or had never been delivered to a Medicare patient. Also charged in this indictment were five other individuals who operated three DME companies involved in the fraudulent scheme, as well as one individual who was an All-Med employee.

U.S., Texas Reach $15 Million Settlement With Hospital District To Resolve FCA Claims
U.S. Attorney for the Southern District of Texas Don DeGabrielle announced June 5, 2007 that the federal government and the state of Texas reached a $15 million settlement with the Harris County Hospital District in connection with a qui tam False Claims Act suit. Whistleblower Robert E. McCaslin, Jr., an employee in the hospital district’s billing department, alleged the hospital district was making claims to Medicare and Medicaid without first submitting them to primary carriers. “[T]he result of this practice,” the government contended, “was that Medicare and Medicaid paid claims that should have been paid by other responsible third party insurers and not the Medicare and Medicaid programs.” McCaslin also claimed the hospital district improperly submitted claims to Medicare and Medicaid for services provided to incarcerated individuals. According to the release, Medicare and Medicaid only rarely pay for such services, which instead must be billed to the individual first.

The settlement calls for the federal government to recover nearly $12.1 million and Texas to recover over $3.3 million. The hospital district also entered into a compliance
agreement with the Department of Health and Human Services Office of Counsel to the Inspector General.

U.S. Intervenes In Suit Alleging False Billings Under Medicare For Home Care Renal Dialysis
The United States has intervened in a whistleblower suit alleging Renal Care Group Inc. (RCG) and Renal Care Group Supply Company (RCGSC) fraudulently billed for supplies and equipment provided to End Stage Renal Disease (ESRD) patients who received dialysis treatments at home, the Department of Justice (DOJ) announced July 17, 2007. According to the complaint, between January 1999 and December 2005, RCGSC submitted claims to Medicare for home dialysis supplies provided to ESRD patients. However, all of these claims—as well as related claims for support services rendered by RCG dialysis clinics—are allegedly false because the defendants were prohibited from billing, and not qualified to bill Medicare for these home dialysis patients, DOJ said. Medicare only pays companies that provide dialysis supplies to ESRD patients when they are independent from dialysis facilities. Here, an alleged sham supply company, RCGSC, was set up that was not independent from RCG, and that did little more than submit bills to Medicare.

Consultant To Pay $30.5 Million To Resolve Charges It Caused False Medicaid Claims
Consulting firm Maximus Inc. agreed to pay $30.5 million to settle an action under the civil False Claims Act (FCA) alleging it caused the District of Columbia’s Child and Family Services Agency (CFSA) to submit false claims to Medicaid for undocumented target case management services provided to foster children, the Department of Justice (DOJ) announced July 23, 2007. Maximus also entered into a deferred prosecution agreement (DPA) with the U.S. Attorney’s Office for the District of Columbia and DOJ’s Civil Division, as well as a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.

Maximus was under contract with CFSA to provide consulting services on Medicaid reimbursement claims for children in the District’s foster care program. The investigation stemmed from a whistleblower action instituted by a former Maximus division manager who contended the firm was causing CFSA to submit claims to Medicaid for services that had not in fact been provided. CFSA already has repaid the federal government $12.15 million following a Centers for Medicare and Medicaid Services review that found CFSA could not support 35% of the targeted case management claims it submitted.

HealthSouth Agrees To Pay Over $14 Million To Settle False Claims, Kickback Allegations
HealthSouth Corporation and two physicians have agreed to pay the United States a total of $14.9 million to settle allegations of false claims and illegal kickbacks, the Department of Justice (DOJ) announced December 14, 2007. The settlement resulted from disclosures made by HealthSouth in 2004 and 2005 to the U.S. Attorney for the Northern District of Alabama, Alice Martin, and the Department of Health and Human Services Office of Inspector General (OIG). The disclosures were made after an internal investigation
revealed HealthSouth submitted claims to Medicare and Medicaid for services provided to patients referred by orthopedic surgeons Dr. James Andrews and Dr. Lawrence Lemak, when HealthSouth had improper financial relationships with the physicians, DOJ said. The financial relationships violated the Anti-Kickback Statute and the Stark Law, DOJ noted.

According to DOJ, HealthSouth will pay $14.2 million, and the physicians will pay a total of $700,000 under separate settlement agreements. In addition, HealthSouth will be required to amend its existing Corporate Integrity Agreement with the OIG to address kickback issues.

**Federal Monitor’s Oversight Of UMDNJ Comes To An End**

The University of Medicine and Dentistry of New Jersey (UMDNJ) is a “much changed institution” that no longer requires the oversight of a federal monitor put in place pursuant to a deferred prosecution agreement (DPA), according to a final report issued January 3, 2008. In his final report, federal monitor Herbert J. Stern said “[f]rom the top down, UMDNJ has undergone major personnel, policy, and cultural changes.” Stern emphasized that UMDNJ still faces “significant challenges going forward,” including completing 42 investigations of alleged misconduct.

UMDNJ in December 2005 entered into the DPA with U.S. Attorney for the District of New Jersey Christopher J. Christie to avoid prosecution for Medicaid fraud related to charges of double-billing for procedures. Under the DPA, the federal monitor was given far-reaching authority to oversee the university’s activities and, in exchange, enforcement of the criminal charges against UMDNJ was held in abeyance. “This work, as detailed in our previous reports, has lead to the end of systems and lax policies that caused us to uncover over $400 million of fraudulent, wasteful, and/or abusive practices,” the final report said.

The DPA could have been extended an additional year past its December 31, 2007 expiration date, but the monitor concluded such a move would not be necessary. According to the report, U.S. Attorney Christie has agreed to seek dismissal of the criminal complaint against UMDNJ. The final report highlights a number of improvements at UMDNJ, including an expansion of the Board of Trustees from six to 18 members and an overhaul of the university’s administrative leadership, including expanding the Internal Audit and Compliance offices.

The final report also makes several recommendations where continued improvement is needed. For example, the final report says UMDNJ must do more to strengthen its Office of Ethics and Compliance, including a nation-wide search for a new Compliance leader and periodic reports to the Board concerning investigations. In addition, UMDNJ "must continue to implement reforms in the purchasing/materials management area," the report concluded.
DOJ Reaches $26 Million Settlement With St. Joseph’s Hospital Of Atlanta To Resolve FCA Allegations

The U.S. Department of Justice (DOJ) has reached a $26 million settlement with St. Joseph’s Hospital of Atlanta Inc. (St. Joseph’s) and Saint Joseph’s Health System Inc. to resolve False Claims Act (FCA) allegations in connection with the hospital’s billing practices for inpatient admissions and other services, according to a DOJ press release issued December 21, 2007. DOJ’s investigation in the case focused on St. Joseph’s submission of Medicare claims over a five-year period (2000-2005) charging services at “inpatient admissions” rates when they should have been charged at a lower “outpatient visit” rate.

Tami Ramsey, a registered nurse and former St. Joseph’s employee, initiated the case by filing a qui tam suit in federal district court. Ramsey will receive $4.94 million as her share of the settlement. The federal government subsequently intervened in the case. “The settlement covers claims submitted by St. Joseph’s . . . for short inpatient admissions, usually of one day or less but sometimes longer, where the services were such that they should have been billed on an outpatient ‘observation’ basis or as an emergency room visit,” the release said. In addition, St. Joseph’s allegedly admitted patients for three days, even though the patient’s medical condition did not fully meet specific criteria for a covered admission. According to the release, this practice was apparently directed at ensuring that the patient would qualify under Medicare payment rules for subsequent coverage for skilled nursing facility services. The settlement also covers certain claims submitted by St. Joseph's for inpatient admissions relating to placement of carotid artery stents, which were not covered under Medicare benefits.

As a result of the settlement, DOJ will dismiss the lawsuit against St. Joseph’s. In order to continue participating in federal healthcare programs, St. Joseph’s Hospital and Health System also must enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

Nine Florida Defendants Sentenced For Roles In $56.5 Million Medicare Fraud Involving DME, Infusion Therapy

The Department of Justice (DOJ) announced January 23, 2008 the sentencing of nine individuals who collectively filed fraudulent claims with Medicare for over $56.5 million of unnecessary durable medical equipment (DME) and infusion therapy. The sentences for the nine individuals were handed down over the last two weeks and range from 87 to 19 months in prison, a DOJ press release said.

The individuals owned separate Miami-based healthcare corporations that fraudulently billed for various items of DME including oxygen concentrators, wheelchairs, hospital beds and pressure reducing mattresses, wound therapy pumps, or for infusion therapy services. The announcement comes as part of a broad-based effort to crack down on fraud in South Florida, where statistics show billing data for DME that are out of line with the rest of the nation. According to data from the Centers for Medicare and Medicaid Services, Miami-Dade County alone accounted for more paid DME claims than 44 other states. On average, a Medicare patient in Miami-Dade County allegedly receives $6,200
worth of DME every year based on paid amounts, compared to $1,200 per year on average for patients in the rest of the country.

**New Antifraud Efforts Aimed At Infusion Therapy Providers In South Florida; Miami Medical Biller Charged In $170 Million Medicare Fraud Scheme**

The Department of Health and Human Services (DHHS) is launching a two-year demonstration project targeting fraudulent practices of infusion therapy providers in South Florida where Medicare charges for these services are “disproportionately high.” The latest move is part of a broad-based effort by DHHS and the Department of Justice (DOJ) to fight fraud in the infusion therapy industry. According to a DHHS fact sheet, the scams involved clinics billing Medicare for infusion therapy services provided to HIV/AIDS patients that were never rendered or were not medically necessary. The infusion therapy services often were billed to Medicare at “clinically unbelievable frequencies and toxic dosages,” DHHS said.

The latest demonstration to crack down on Medicare fraud focuses on South Florida, which in 2004 had Medicare submitted charges for HIV/AIDS infusion services that were three times higher than in California and nearly five times higher than New York despite having fewer AIDS cases overall. Under the demonstration, clinics or solo practitioners in South Florida providing intravenous infusion therapy and/or intramuscular and subcutaneous injections in the office setting will be required to reapply for Medicare provider status within 30 days of receiving notice from the Centers for Medicare and Medicaid Services (CMS). Those who fail to reapply; fail to report a change in ownership; have owners, directors, partners, or managers who have committed a felony; or no longer meet provider enrollment requirements will have their Medicare billing privileges revoked, DHHS said. In addition, infusion providers who successfully complete the reapplication process may be subject to enhanced review, including site visits, based on a risk assessment, the agency added. CMS also plans to send Medicare Summary Notices to beneficiaries in South Florida on a monthly rather than quarterly basis and to establish a new toll-free Part B Florida beneficiary infusion fraud hotline to step-up scrutiny of infusion providers. DHHS announced a similar demonstration in July involving home health agencies in Los Angeles and Houston.

Meanwhile, U.S. Attorney for the Southern District of Florida R. Alexander Acosta announced August 20, 2007 that Rita Campos Ramirez, owner of a Medicare billing company in Miami, was criminally charged in connection with an alleged scheme to defraud Medicare of $170 million. Campos, owner of R and I Medical Billing Inc., provided billing services from October 2002 to April 2006 for roughly 75 Miami-based health clinics that purported to provide HIV infusion services to Medicare beneficiaries, according to a DOJ press release. DOJ said clinic owners provided Campos with bills stating infusion amounts she knew were medically impossible but she submitted the charges anyway. Campos received a fee of approximately 5% of all claims Medicare paid, DOJ said. Campos is charged with conspiracy to commit healthcare fraud and submission of false claims to Medicare. According to the release, she agreed to plead guilty to the charges.
**New Antifraud Efforts Target DME Suppliers In Florida, California**

The Centers for Medicare and Medicaid Services (CMS) is launching a new two-year pilot project to root out Medicare fraud involving durable medical equipment, prosthetics and orthotics suppliers (DMEPOS) in South Florida and Southern California, calling these areas a “hotbed of fraudulent activity.” Under the demonstration, DMEPOS suppliers in these areas must reapply for participation in Medicare to maintain their billing privileges. CMS plans to send letters to suppliers asking them to resubmit Medicare applications. Those that fail to reapply within 30 days of receiving the letter, fail to report a change in ownership or address, or fail to report having owners/managers who have committed a felony within the past 10 years will have their billing privileges revoked, CMS said.

**DHHS Announces Antifraud Efforts Targeting HHAs In Houston And Los Angeles**

The Department of Health and Human Service (DHHS) plans to implement a two-year demonstration project that will require home health agencies (HHAs) in Houston and Los Angeles to reapply for enrollment into the Medicare program, according to a DHHS fact sheet released July 17, 2007. The demonstration will focus on HHA providers in Harris County, Texas (including Houston), and four counties in California—Los Angeles, Orange, Riverside, and San Bernadino—areas that have had “rapid and unexplained increases in the number of HHAs,” the agency said. For example, in California, the number of HHAs has jumped by “well over” 50% since October 2002. Moreover, HHA billings to Medicare between fiscal years 2003 and 2006 “rose by almost 62 percent in Los Angeles County, almost 61 percent in Riverside and San Bernadino Counties (combined), and by 19 percent in the State of California.” In Texas, the number of HHAs has doubled in the past four years, according to DHHS, while increasing by 150% in Harris County during the same time period.

Each HHA in the “demonstration locales” will be required to submit a CMS-855A form (the Medicare enrollment application for home health providers) to the applicable Medicare contractor within 60 days after the contractor requests such data. An HHA will face revocation of its Medicare billing privileges if it does not meet this and other requirements. As part of its evaluation of the effectiveness of the demonstration, CMS will consider whether the enrollment process used in the demonstration should be implemented in other parts of the country as a means of deterring fraudulent activities.

**New York AG Issues Subpoenas To Home Health Agencies In Fraud Crackdown**

In connection with an ongoing investigation by New York’s Medicaid Fraud Control Unit, Attorney General Andrew M. Cuomo has subpoenaed more than 50 New York home health agencies over concerns about widespread fraud. “From unqualified aides to deceptive billing practices, the operations we’ve uncovered threaten patient care while bilking taxpayers out of millions,” Cuomo said in an August 20, 2007 statement. Cuomo also said he asked ten of the state’s largest home health agencies to make additional self-disclosures, with an eye toward putting together “a global picture of the extent of the problem and a roadmap for repair.”
According to Cuomo’s statement, the Operation "Home Alone" investigation has revealed several home health aides operating with falsified certifications, some issued by schools lacking state accreditation. Cuomo subsequently announced that ten home health aides, two registered nurses, and a Medicaid recipient were convicted of felony grand larceny as part of the Operation "Home Alone" ongoing probe of the home healthcare industry. The investigation revealed the aides were in possession of falsified certification documents and lied about the hours they worked. The nurses both worked for multiple certified home health agencies and would submit bills to the agencies for multiple patients during concurrent periods of time, Cuomo said. Also as a result of the investigation, two home health aide certification school operators pled guilty to grand larceny. The schools provided false credentials to hundreds of home health aides as part of a widespread and elaborate scheme to defraud Medicaid of millions of dollars, Cuomo said.

In further developments, Cuomo announced August 27, 2007 the convictions of a Brooklyn-based home healthcare services agency (HHA) and its principals on charges of defrauding the Medicaid program of over $12 million. Under the fraudulent scheme, Immediate Home Care, Inc. and its owner-operators, Nachem Singer and Ervin Rubenstein, employed unqualified, uncertified home health aides and billed Medicaid for services never rendered, according to the press release. Immediate Home Care pled guilty to felony grand larceny and agreed to pay $12.5 million in restitution. Singer and Rubenstein also pled guilty to felony grand larceny.

The Office of New York State Comptroller Thomas P. DiNapoli said the results of two audits examining the period of 2001 through April 2006 confirmed widespread fraud in New York's market for home healthcare services. The audits revealed Medicaid payments over the five-year audit period of $5.7 million for claims home care services providers inappropriately billed for services provided to Medicaid recipients who were hospitalized. In addition, auditors discovered eight cases where Medicaid paid for home care services totaling $13,928 after the Medicaid recipient had already died.

DOJ Brings FCA Action Against Tenet’s Former General Counsel
The Department of Justice (DOJ) filed a lawsuit September 18, 2007 against Tenet Healthcare Corporation’s former General Counsel (defendant) under the False Claims Act (FCA) alleging she submitted false certifications about Tenet’s compliance with federal requirements to the Department of Health and Human Services (DHHS). As a result, the complaint alleges Tenet unlawfully obtained over 70,000 individual payments from Medicare, totaling roughly $18 million.

According to the complaint, which was filed in the U.S. District Court for the Southern District of Florida, defendant learned in 1997 that North Ridge Medical Center, a Tenet-owned hospital, was illegally billing Medicare for referrals from certain physicians whose employment contracts violated the Stark Law. The government contends defendant submitted declarations in June 1997 and June 1998 to DHHS stating that, to the best of her knowledge and belief, Tenet was in material compliance with all federal program legal requirements. Before making the certifications, the complaint alleges, the defendant
had received an internal memorandum raising concerns about the North Ridge employment contracts at issue as well as confirmation from outside counsel that the arrangements were illegal. At the time of the alleged false certifications, defendant was the Associate General Counsel and Corporate Integrity Program Director for Tenet. In that capacity, the complaint says, she was personally responsible for investigating and reporting alleged violations of federal program legal requirements by Tenet employees.

In 2004, Tenet paid the government $22.5 million to resolve claims initiated in a whistleblower action of improper billing under the FCA for referrals provided by physicians with whom North Ridge allegedly had prohibited financial arrangements. As part of a subsequent $920 million settlement in 2006 involving claims of Medicare fraud and overcharges, Tenet agreed to produce a number of documents, including the internal memo and report concerning the North Ridge physician employment contracts. According to the complaint, these documents established defendant knew the declarations were false at the time they were made. These actions, the complaint alleged, allowed Tenet to receive payments it was not entitled to and obstructed the government’s efforts to recover past improper payments.

New York Attorney General Announces Fraud Investigation Into Health Insurers’ Reimbursement Scheme

New York Attorney General Andrew M. Cuomo announced February 13, 2008 that his office is conducting an industry-wide investigation into health insurers’ alleged scheme to defraud consumers by manipulating reimbursement rates through use of a faulty billing information database that determine reasonable and customary fees. Cuomo said he intends to file a lawsuit against UnitedHealth Group (and its New York health plan subsidiaries), as well as Ingenix, Inc. (Ingenix), which is UnitedHealth Group’s healthcare billing information unit.

The ongoing investigation has thus far revealed that Ingenix operates a “defective and manipulated” health billing information database, and this database is used by most major health insurance companies to set reimbursement rates for out-of-network medical expenses, the release said. Cuomo said his office has issued 16 subpoenas to the nation’s largest health insurance companies, including Aetna, CIGNA, and Empire BlueCross BlueShield. “The subpoenas . . . request documents showing how the insurer computes ‘reasonable and customary’ rates, copies of member complaints and appeals, and communications with members and between Ingenix and the insurer on the issue,” the release said.

The investigation also has found that two of UnitedHealth Group’s subsidiaries have been “dramatically under-reimburs[ing] their members for out-of-network medical expenses by using data provided by Ingenix,” Cuomo said. Under these subsidiaries’ health plans, members pay a higher premium for the right to use out-of-network physicians. The subsidiaries will cover up to 80% of either the doctor’s full bill or of the “reasonable and customary” rate depending upon which is cheaper, according to the release. These subsidiaries, as well as many other health insurance companies, relied on Ingenix’s database to determine their “reasonable and customary” rates, the release explained. The
investigation revealed, however, that the rates produced by the database were “remarkably lower than the actual cost of typical medical expenses.” Cuomo said that, “by distorting the ‘reasonable and customary’ rate,” these UnitedHealth Group subsidiaries’ were able “to keep their reimbursements artificially low and force patients to absorb a higher share of the costs.”

In a statement, UnitedHealth Group said "[w]e are in the midst of on-going discussions with the Attorney General’s office and we will continue to cooperate fully."

**Georgia Hospital To Pay Over $5 Million To Settle FCA Lawsuit**
Memorial Health University Medical Center, Georgia Eye Institute, and Provident Eye Physicians (collectively, Memorial) have agreed to pay the government $5.08 million to settle a whistleblower lawsuit alleging violations of the False Claims Act (FCA) and Stark Law. According to the allegations, employed ophthalmologists had an unlawful financial relationship with Memorial and were compensated at levels above commercially reasonable rates in excess of fair market value. The lawsuit was initiated in the U.S. District Court for the Southern District of Georgia by whistleblower Dr. Ryan F. Boland, who was formerly employed by the Georgia Eye Institute. Memorial, which did not admit any wrongdoing, also will enter into a Certification of Compliance Agreement with the Department of Health and Human Services Office of Inspector General.

**False Claims Cases**

**Third Circuit Holds Attorneys’ Fees Not Available To Qui Tam Plaintiff In States With No FCA Statute**
In 2003, Edward Bogart, a former employee of King Pharmaceuticals, commenced a qui tam action against the company under the federal False Claims Act (FCA) for misrepresenting Medicaid pricing information on behalf of 10 states and the District of Columbia, which all had statutes similar to the FCA. King settled with these qui tam actions through a committee of the National Association of Medicaid Fraud Control Units (NAMFCU). Bogart was paid counsel fees and expenses of $800,000 and relator fees of over $9 million. King also settled with the other 40 states that did not have qui tam legislation and that were not parties to the case.

Although Bogart did not participate in the negotiation of the settlements nor was he a party to any of the settlement agreements for the non-qui tam states, he claimed he was entitled to be paid up to one-third of their settlements, which totaled $30 million, under a common fund theory of recovery. Bogart failed to specify whether this percentage constituted a relator’s share or counsel fees. The common fund doctrine “provides that a private plaintiff, or plaintiff’s attorney, whose efforts create, discover, increase, or preserve a fund to which others also have a claim, is entitled to recover from the fund the costs of his litigation, including attorney’s fees.” Application of the common fund doctrine requires court “control over a fund or jurisdiction over the parties . . .”

The Third Circuit denied Bogart’s claim for relief for three reasons. First, the appeals court found the district court lacked control over the non-qui tam states’ settlements, and
therefore the purported “common fund.” The Federal Settlement Agreement expressly stated that “King’s obligation to pay . . . shall arise only under the NAMFCU Agreement and the State Settlement Agreements.” Second, the district court lacked jurisdiction over the non-qui tam states, the appeals court said. Since it lacked jurisdiction over the fund and the non-qui tam states, it lacked the authority to award common fund relief from the non-qui tam states’ settlement proceeds, the court reasoned. Third, even if the district court had authority, the appeals court found “an award to Bogart would be inappropriate.” According to the appeals court, the “mere fact that a large number of parties has reached such settlements does not mean that the sum of the settlement amounts . . . constitutes a common fund.” Finally, the appeals court commented that Bogart’s request for litigation costs under the common fund doctrine was “but a thinly-veiled attempt to obtain a reward for providing information about King from states that ha[d] declined to enact qui tam laws providing for such a reward.” United States ex rel. Bogart v. King Pharmaceuticals, No. 06-2098 (3d Cir. July 16, 2007).

U.S. Court In Massachusetts Says Government’s “Complaint-In-Intervention” Relates Back To Initial Qui Tam Action

The federal government’s claims against pharmaceutical manufacturer Dey, Inc. under the False Claims Act (FCA) were not time-barred because they related back to the time the whistleblower initiated the underlying qui tam action, the U.S. District Court for the District of Massachusetts ruled July 17, 2007 in denying Dey’s motion to dismiss. The case was initially filed in August 1997 as a qui tam action under the FCA in the U.S. District Court for the Southern District of Florida by Ven-A-Care of the Florida Keys against 39 pharmaceutical companies, alleging they defrauded Medicare and Medicaid by reporting inflated drug prices used to set the programs’ reimbursement rates. Nine years later, on August 24, 2006, the federal government filed a “complaint-in-intervention” and the action was transferred to the federal trial court in Massachusetts as part of a multidistrict litigation. The complaint was unsealed on September 7, 2006.

Defendant Dey (Dey Inc., Dey L.P., Inc., and Dey L.P.) argued that all causes of action accruing in connection with claims for payment more that six years before the government intervened were barred under the FCA’s statute of limitations. Citing the Second Circuit’s decision in United States v. The Baylor Univ. Med. Ctr., 469 F.3d 263 (2d Cir. 2006), Dey argued the action was commenced for purposes of the statute of limitations when the government filed its complaint-in-intervention. The government argued the FCA action commenced when the relator filed its complaint against Dey in August 1997. According to the government, under the FCA, the limitations period starts when the action is “brought,” not when it is unsealed. The court agreed with the government, holding the action was commenced for purposes of the statute of limitations when the relator filed its sealed complaint.

Next, the court addressed whether the “complaint-in-intervention” should be treated as an amended complaint that related back to the relator’s initial complaint under Fed. R. Civ. P. 15(c). In Baylor, the Second Circuit held the government’s complaint-in-intervention could not relate back to the date of the initial complaint pursuant to Rule 15(c)(2) because the qui tam complaint was under seal thus depriving the defendant of notice. But the
court here noted that unlike Rule 15(c)(2), whose “touchstone” is notice, Rule 15(c)(1) allows relation back when “permitted by the law that provides the statute of limitations applicable to the action.”

The court found the “unique structure of the FCA” supported the government’s position that its complaint should be treated as an amended complaint that related back to the relator’s complaint under Rule 15(c)(1). The court did note some limits to relation back under this theory, including if the government’s complaint asserted unrelated, new claims. While acknowledging the many extensions sought by the government here were “worrisome,” the court found no evidence they were improper, in bad faith, or prejudicial. Thus, the court refused to dismiss the government’s claims under the FCA, although it did dismiss its common law claims of unjust enrichment and fraud that accrued before August 23, 2000 since there was no legal basis for applying Rule 15(c)(1) to those claims. In re Pharmaceutical Ind. Average Wholesale Price Litig., No. 1456 (D. Mass. July 17, 2007).

Third Circuit Says Relator With Invalid Qui Tam Claims Not Entitled To Share Of Alternate Remedy

A relator whose qui tam claims are proven invalid is not entitled to any share of the proceeds of an alternate remedy pursued by the government under the False Claims Act (FCA) that are attributable to those claims, the Third Circuit ruled July 17, 2007. “The [FCA] evinces no intent to compensate relators who bring unfounded § 3729 claims, whether the claims are legally or factually unfounded,” the appeals court held.

Hackensack University Medical Center (HUMC) hired Health Systems Management Network (HSMN), a consulting firm, in 2000 to improve HUMC’s compliance with documentation and billing regulations. Around that time, Marilyn Capek, an administrator for the Center for Infectious Diseases (CID), discovered HUMC had been billing the same claims to both Medicare and a National Institutes of Health (NIH) grant. Phil Hefner was hired by HSMN to work on the case, but was fired after showing up late and performing poorly in two meetings. Before he was terminated, Capek told Hefner she had found paperwork that suggested double billing and referred to it as “fraud.” That same year, HUMC returned the wrongful charges to Medicare in the amount of $5298.97. The double billing occurred because a staff member responsible for entering the code to the NIH grant was not doing so, causing the bills to go out to Medicare, the opinion said. Hefner filed a qui tam suit against HUMC and CID.

The Third Circuit held Hefner failed to show defendants' conduct satisfied the FCA’s scienter requirement, i.e. that HUMC either had actual knowledge of or reckless disregarded for its billing errors. While HUMC’s compliance department was not concerned with invoices sent to the NIH grant, the “mere failure of a system to catch an error does not establish recklessness,” the appeals court said.

The appeals court also rejected Hefner's argument that CID should not have been granted summary judgment because it operated as an integrated enterprise with HUMC.
The Third Circuit concluded CID could not be held liable under an integrated enterprise or agency theory because HUMC itself was not liable.

Next, the appeals court struck Hefner’s retaliation claim, finding no evidence that Hefner’s employer knew he was acting in furtherance of an FCA claim when it fired him. Thus, Hefner was not engaging in “protected conduct” under the FCA, in fact he was “removed almost immediately after he met with Capek and before he talked to anyone from HUMC about what he had learned.”

Finally, the appeals court rejected Hefner's claim to a share of the money HUMC repaid to the government. Under the FCA, the U.S. may pursue claims through any alternate remedies available so long as “the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section.” 31 U.S.C. § 3730(c)(5). Hefner argued that when the government accepted HUMC’s repayment, it pursued an alternate remedy under § 3730(c)(5); therefore, he was entitled to a share of the proceeds. The court disagreed, setting precedent that a relator does not have a legal right to recover a share of the proceeds of an alternate remedy when his qui tam action is invalid. United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., No. 06-2287 (3d Cir. July 17, 2007).

U.S. Court In Illinois Rejects Whistleblower’s FCA Action Against Drug Maker Alleging Off-Label Promotion
A whistleblower failed to plead with the required particularity his claims that Ortho-McNeil Pharmaceutical, Inc. violated the False Claims Act (FCA) by causing the submission of false claims to Medicaid for off-label uses of its drugs, a federal court in Illinois ruled July 20, 2007. The court found the relator failed to set forth the “who, what, when, where and how” of the alleged fraud and therefore did not meet the Rule 9(b) pleading requirements.

Relator Edward West, a former sales representative of Ortho-McNeil, brought a qui tam action against the company and its corporate parent Johnson & Johnson on behalf of the United States and California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia, and the District of Columbia. The United States, the various states, and the District of Columbia declined to intervene.

Part of West’s action alleging Ortho-McNeil used kickbacks and unlawful remuneration to increase sales of its drugs Levaquin and Ultram was transferred to the District of Massachusetts as part of multi-district litigation (MDL) (discussed further below). Before the court here were West’s allegations that Ortho-McNeil knowingly caused the submission of false claims to Medicaid by marketing Levaquin and Ultram for uses not approved by the Food and Drug Administration (FDA). Specifically, West contended Ortho-McNeil sales representatives instructed physicians that Levaquin should be used to treat prostatitis, a non-FDA approved use and disseminated articles to physicians promoting Ultram for non-FDA approved conditions such as osteoarthritis and diabetic neuropath and at non-approved dosage levels.
The U.S. District Court for the Northern District of Illinois granted defendants’ motion to dismiss, finding West’s “generalized allegations” did not meet the heightened pleading standards of Rule 9(b). The court noted that West did not identify which sales representatives were involved in the alleged actions, when the alleged events took place, to which physicians the statements were made or articles distributed, or how the alleged statements or articles were communicated. The court also refused to relax the pleading requirements based on West’s argument that he lacked access to all the facts needed to detail his claims. *United States ex rel. West v. Ortho-McNeil Pharmaceutical, Inc.*, No. 03 C 8239 (N.D. Ill. July 20, 2007).

In a February 19, 2008 decision, a federal district court in Massachusetts ruled West could proceed with some of the claims he asserted against Ortho-McNeil that had been transferred to the court as part of the MDL. The instant action before the Massachusetts federal district court alleged Ortho-McNeil resorted to illegal kickback schemes designed to gain and maintain a competitive edge for Levaquin after a cheaper competitor drug entered the market.

Specifically, West alleged Ortho-McNeil provided rebates “into the tens of thousands of dollars” to hospitals to increase the “spread” between Medicare and Medicaid reimbursement levels and the actual cost to the provider; provided price discounts to hospitals that agreed not to carry competing drugs on their formularies; made cash payments to hospitals; encouraged hospitals to divide single use premix bags of Levaquin to create a secret discount and increase hospital profits; offered kickbacks under the guise of “speaker fees” and “research grants”; and give improper gifts to physicians.

The U.S. District Court for the District of Massachusetts refused to dismiss West’s allegations related to discounts, cash bribes, dividing single use premix to increase profits, and improper speaker fees, grants, and gifts, but dismissed his allegations regarding rebates. The court noted that West’s case was a “tag-along” action because it involved allegations similar to others transferred in the MDL that drug makers used fraudulent marketing and billing schemes to inflate the average wholesale prices (AWPs) used by Medicare and Medicaid to set reimbursement levels.

While the court found relator’s rebate allegations were publicly disclosed in previous litigation, it concluded West, as a former Ortho-McNeil salesman, was an “original source” of the AWP-based claims under the FCA. The court nonetheless dismissed, with leave to amend, West’s AWP-based allegations, finding he failed to plead fraud with the required particularity. The court also found West was not an original source of his allegations that Ortho-McNeil did not fully incorporate rebates into its “best price” reports for Medicaid purposes. “Unlike the AWP fraud allegation, it is not self-evident that a sales representative would know whether a company accounted for such rebates in its ‘best price’ reports,” the court noted.

Next, the court held West’s allegations that Ortho-McNeil sales representatives gave discounts to hospitals that agreed not to carry drugs that competed with Levaquin on their formularies was not “substantially similar” to the claims in the other publicly disclosed
complaints, which specifically alleged the discounts were used to increase the spread. The court also doubted West’s allegations that Ortho-McNeil paid (or planned to pay) specific bribes to two hospitals to persuade them not to drop Levaquin from the formulary would trigger the public disclosure bar. Even assuming the cash bribe allegations were publicly disclosed, West was an “original source” because he had “direct and independent” knowledge of the bribery scheme.

The court also concluded that there was no public disclosure of relator’s single use premix allegation. In addition, the court ruled West’s claims that Ortho-McNeil improperly provided speaker fees, research grants, and gifts to physicians had been publicly disclosed, but that West qualified as an “original source” of those claims. Finally, the court dismissed West’s claims against defendant Johnson & Johnson, finding he failed to plead facts that the corporate parent could be liable under a “piercing the corporate veil” theory for Ortho-McNeil’s alleged conduct. United States ex rel. West v. Ortho-McNeil Pharmaceutical, Inc., No. 1456 (D. Mass. Feb. 19, 2008).

U.S. Court In District of Columbia Dismisses Some Of Relator's Claims Against Health System Alleging Widespread Medicare Fraud
A federal district court in the District of Columbia found July 17, 2007 that it lacked subject matter jurisdiction over a relator’s claims alleging a scheme to defraud Medicare extended beyond the hospital named in the original complaint to other facilities owned by its parent company Columbia/HCA Healthcare Corp. According to the court, the allegations in the relator’s amended complaint were based on information publicly disclosed in a newspaper article and the relator did not show any “direct and independent” knowledge of the information underlying her claims to support original source status under the False Claims Act (FCA).

The long-running case was initiated by relator Chryissa Staley, a nurse at Indiana Path Hospital (IPH) in Tennessee, and two physicians, who are no longer parties to the litigation, under the qui tam provisions of the FCA. The original complaint named Columbia/HCA Healthcare, its former indirect subsidiary IPH, Summit Home Health, and Horizon Mental Health Management, for allegedly inflating costs at IPH to defraud Medicare. IPH opened a new unit dedicated to the treatment of geriatric patients with mental and physical illnesses (called the GP unit). The GP unit was to be funded by Medicare under a special program instituted under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). According to the allegations, IPH and its management services company Horizon decided to improperly inflate the GP’s expenses on its year-end cost report to maximize the TEFRA base payment rate by among other things keeping patients in the unit longer than was medically necessary, recruiting sicker patients to the unit to increase the average length of stay, and ordering supplies and equipment for use in other hospital units while billing them to the GP unit. The cost report was then used to set a “base” rate at which IPH would be reimbursed, per-day and per-patient in future years. After the initial cost report, IPH allegedly moved to cut expenses in the GP unit so it would be eligible for year-end bonuses by accruing costs well below the inflated TEFRA rate. Staley later amended the original qui tam complaint
to add claims of similar fraudulent schemes at other GP units in hospitals owned by Columbia/HCA.

Relying extensively on the U.S. Supreme Court’ decision in *Rockwell Int’l Corp. v. United States*, 127 S. Ct. 1397, the U.S. District Court for the District of Columbia held the claims against the other Columbia/HCA hospitals were based on publicly disclosed information (i.e. a *New York Times* article) and Staley was not an original source of the information underlying the claims in her amended complaint. Although the newspaper article, which detailed potential Medicare fraud at Columbia/HCA hospitals following a *Times* investigation, was issued six-months after Staley filed her original complaint, it pre-dated the amended qui tam complaint that broadened the fraud allegations beyond IPH, the court noted. The court found Staley’s subsequent claims were “based upon” this prior “public disclosure” even where she modified or added further detail to the general fraudulent scheme alleged in the article.

Also citing *Rockwell*, which focused specifically on the parameters necessary to qualify as an “original source” to avoid the FCA public disclosure bar, the court found no evidence that Staley “had any direct or independent knowledge of anything that happened at any other Columbia/HCA hospital.” Staley, and the other relators, never worked at other Columbia facilities and provided no evidence that they worked with other Columbia employees or had contact with “corporate” officials.

The court did refuse, however, to grant Horizon and Columbia/HCA summary judgment as to Staley’s FCA claims based on the allegedly fraudulent cost report. As to Horizon, the court found evidence that one of its executives participated in developing goals and strategies for raising the TEFRA rate and that this knowledge could be attributed to Horizon based on communications between the executive and her superiors. While it refused to “pierce the corporate veil” as a basis for holding Columbia/HCA liable, the court found other evidence that the corporation was “directly involved” in the fraudulent scheme, including the process of finalizing the cost report and billing the government. Moreover, a reasonable jury could conclude that if Columbia/HCA reviewed IPH’s cost reports, it at least acted with “reckless disregard” given the marked drop-off in costs after the TEFRA period ended. *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, No. 01-50 (D.D.C. July 17, 2007).

**U.S. Court In New York Dismisses Relator’s Claims That Hospital Inappropriately Billed Technological Component Of Radiological Studies**  

The U.S. District Court for the Southern District of New York dismissed with prejudice a relator’s claims alleging a hospital and medical school violated the False Claims Act (FCA) by billing the federal government for the technical component of radiological studies before physicians had completed the professional component. The court did allow, however, the relator to move forward with his FCA retaliation claim against the medical school and hospital.

Relator Robert C. Smith was a medical doctor licensed in New York and Connecticut. He was a member of the faculty of Cornell University’s medical school and an attending
radiologist at New York Presbyterian Hospital (NYPH). Smith brought a qui tam action against Cornell and NYPH alleging they engaged in a scheme to defraud Medicare and Medicaid when NYPH billed for the technical component of radiological studies before physicians at Cornell completed the corresponding professional component. He also asserted that NYPH and Cornell retaliated against him in response to his investigation of FCA fraud.

Smith had previously brought a similar action in Connecticut against the Yale School of Medicine, where he worked as a professor, and Yale-New Haven Hospital. With respect to that action, the federal district court in Connecticut found it lacked jurisdiction under the FCA’s public disclosure bar; Smith failed to plead fraud with particularity; and Smith failed to state a cognizable legal claim because there was no basis for his argument that the technical and professional component of a radiology study could not be billed separately.

In the instant case, the U.S. District Court for the Southern District of New York found it had subject matter jurisdiction, distinguishing the present matter from the Connecticut case where public disclosures had been made in a previous state court action. Next, the court concluded that while Smith’s complaint provided a “rough sketch” of his theory of FCA fraud, he failed to provide the detail and specificity required by Federal Rule of Evidence 9(b). Notably, the court said, he failed to allege a single NYPH employee or hospital technician involved in making false submissions or provide any specific amounts, dates, or other details for any fraudulent claims. Thus, the court dismissed his FCA fraud claims with prejudice, noting Smith had been provided numerous opportunities to argue his case. Moreover, the court held any further amendment would be futile because his theory of fraud—namely, billing for the technical component of radiological studies without ensuring the studies were “medically necessary” (i.e. that the professional component was completed by a Cornell physician)—lacked merit.

The court did conclude, however, that Smith could continue with his FCA retaliation claim, finding he sufficiently alleged he was an NYPH employee (even if he was also employed by Cornell); the claim was not untimely under New York’s residual three-year statute of limitations for personal injury lawsuits; and that Smith adequately stated the elements of an FCA retaliation claim. United States ex rel. Smith v. New York Presbyterian Hosp., No. 06 Civ. 4056 (NRB) (S.D.N.Y. July 18, 2007).
Seventh Circuit Upholds Dismissal Of FCA Qui Tam Action Against Caremark Rx For Failure To Plead Fraud With Particularity

The Seventh Circuit affirmed July 27, 2007 the dismissal of a False Claims Act (FCA) qui tam action against Caremark Rx, LLC (Caremark) after finding the relators’ third amended complaint failed to plead fraud with sufficient particularity as required by Federal Rule of Civil Procedure 9(b).

The relators, Michael Fowler, Peppi Fowler, Victor Cortes, and Danny Nevarez, were employed at two of Caremark’s distribution facilities. Relators original and two amended complaints alleged various fraudulently schemes by Caremark, including restocking returned drugs but continuing to bill the government and misrepresenting savings from its “intervention services” aimed at replacing a prescribed drug with a less expensive alternative in appropriate cases. While the third amended complaint was more detailed, the district court found it again failed to link relators’ allegations to specific false claims. The court also noted the complaint contained few allegations identifying false invoices or bills actually submitted by Caremark to the government.

Affirming the district court's ruling on the merits, the appeals court noted the relators failed to provide any information addressing whether Caremark knowingly took any improper actions sufficient to implicate the FCA. Further, in their third amended complaint, the relators erred “by assuming, without any support, that once a prescription was returned, Caremark automatically either kept the money or continued to bill without providing an appropriate credit to the government or replacement prescription to federal employees,” the appeals court said. Likewise, the relators' allegations relating to Caremark’s “intervention services” did not meet Rule 9(b) requirements because they failed to satisfy the FCA's scienter requirement, i.e., that Caremark knowingly presented false claims to the government in relation to these services. United States ex rel. Fowler v. Caremark Rx, LLC, No. 06-4419 (7th Cir. July 27, 2007).

U.S. Court In Texas Declines To Dismiss FCA Suit Alleging Medicaid Funding Fraud

A federal district court in Texas refused to dismiss a False Claims Act (FCA) qui tam action alleging a health system was involved in a fraud scheme that illegally abused the intergovernmental transfers (IGTs) procedure for the Medicaid Upper Payment Limits (UPL) program. In denying that motion, the U.S. District Court for the Eastern District of Texas accepted the defendant-healthcare system’s contention that the fraudulent activity alleged by the whistleblower was partially based on public proceedings of the Henderson County Hospital Authority (HCHA), but rejected the argument that the proceedings amounted to an “administrative hearing” triggering the FCA’s public disclosure bar, codified at 31 U.S.C. § 3730(e)(4)(A).

The whistleblower in the case, Linnea Rose, filed a FCA qui tam action in June 2005, alleging that East Texas Medical Center Regional Healthcare System, a hospital conglomerate that owns and operates private hospital facilities in East Texas, and one of its hospitals, East Texas Medical Center Athens, (collectively, defendants) devised and implemented a scheme to fraudulently receive, via IGTs, additional Medicaid matching
funds from the federal government under the UPL program. The UPL program allows states to reimburse public rural hospitals for certain uncompensated care provided under Medicaid at an amount equal to what Medicaid would have paid for the same service. The district court also noted that federal regulations require states to separate UPLs by facility type because public hospitals are reimbursed at a higher rate than private nonprofit hospitals.

According to Rose’s qui tam complaint, defendants’ scheme began with HCHA opening a bank account with funds provided by defendants, which was followed by an IGT from the bank account to the state. The federal government then matched the funds, based on the state’s federal matching rate, and transferred the money back to the bank account, which in turn was transferred back to defendants. Under this scheme, Rose alleged, defendants were allowed to receive matching funds as if they were public entities. After the federal government declined to intervene in the action, the district court ordered the complaint unsealed in February 2007. Defendants moved to dismiss, asserting the court lacked jurisdiction based on the FCA’s public disclosure bar.

The district court first noted the parties did not dispute that the transactions described in Rose’s complaint were based on 2002 proceedings of the HCHA that were open to the public. The evidence, however, did not indicate these proceedings were extensive or that the subject matter discussed was part of other ongoing proceedings conducted by the HCHA, the district court found. “Furthermore, there is no evidence that the meetings invited or received public comment or that relevant documents were openly distributed,” the court said. The district court therefore concluded that it could not find as a matter of law that the HCHA proceedings fell within the category of “administrative hearings” as specified in the public disclosure bar of the FCA. United States ex rel. Rose v. East Texas Med. Ctr. Reg’l Healthcare Sys., No. 2:05-cv-00216-TJW (E.D. Tex. Aug. 14, 2007).

Eighth Circuit Upholds CMPs And Assessments Against Former Owner/CEO Of Home Health Agency
The Eighth Circuit upheld August 7, 2007 a $711,212 civil monetary penalty and assessment and seven-year exclusion from federal healthcare programs imposed on the former owner and chief executive officer of Iowa’s largest home health agency for submitting fraudulent claims to Medicare and Medicaid. The Department of Health and Human Services (DHHS) Office of Inspector General (OIG) said the ruling is the first reported decision by a federal appeals court upholding the OIG’s administrative sanctions under the Civil Monetary Penalties Law (CMPL) against corporate owners and executives who are responsible for Medicare and Medicaid fraud.

The OIG imposed the penalty and assessment against Thomas M. Horras, the founder and former CEO of Hawkeye Health Services, Inc., after an investigation of the home health agency’s Medicare cost reports for the 1995 to 1997 revealed a host of “items or services that were not related to patient care,” including costs associated with divorce proceedings, luxury automobiles, and personal membership dues. The OIG also imposed a separate penalty and assessment, as well as a five-year exclusion, against Hawkeye’s former Director of Finance Christine Richards. Auxi Health Inc., Hawkeye’s current
owner, settled with the OIG for $125,000. An administrative law judge (ALJ) affirmed the exclusion and CMP as to Horras, although it reduced his initial assessment to $673,212 to take into account the Auxi Health settlement. Acknowledging Richards’ “different quanta of management responsibilities,” as well as the settlement, the ALJ reduced Richards’ exclusion to one year, with a $2,500 CMP and a $2,146 assessment.

The Eighth Circuit affirmed the sanctions imposed on Horras and Richards. The appeals court rejected Horras’ argument that the settlement with Auxi Health precluded further action against him. Under the CMPL and associated regulations, an assessment may be imposed against any person responsible for the false claims submission provided the assessments in the aggregate do “not exceed the amount that could be assessed if only one person was responsible.” See 42 C.F.R. 1003.102(d)(1). Here, the ALJ did reduce Horras’ assessment in consideration of the settlement, the appeals court noted.

The appeals court also rejected Horras’ contention that the allegedly false claims must be “material” to the payment made by Medicare. Unlike the False Claims Act, the CMPL focuses on the amount falsely or fraudulently claimed; thus, proof of loss by the government is not an element of the statute. The appeals court also noted the relevant legal standard as whether the costs are “related to patient care,” not whether the items or services were disclosed on the cost reports. “To claim an item or service unrelated to patient care is to file a false or fraudulent claim under the CMPL,” the appeals court wrote.

With respect to Richards, the appeals court said the CMPL contains no exception for non-principal employees. Moreover, “[n]either the recovery from Horras, nor the settlement with Hawkeye/Auxi, protects Richards from liability.” The appeals court agreed with the ALJ’s determination that “Richards acted in reckless disregard” of her knowledge that certain automobile costs, monthly club dues, charitable donations, and fees related to Hawkeye’s sale were unallowable expenses. Horras v. Leavitt, No. 06-2115 (8th Cir. Aug. 7, 2007).

### Sixth Circuit Rules Relator Not Entitled To Share Of Government’s Settlement Proceeds Absent Valid FCA Claim

A relator was not entitled to a share of the settlement proceeds recovered by the government after it declined to intervene in a qui tam action because he failed to any show valid overlapping allegations in his False Claims Act (FCA) complaint, the Sixth Circuit ruled September 6, 2007.

Relator Sean Bledsoe, a respiratory staff therapist, brought a qui tam action under the FCA against his former employer, White County Community Hospital, its owner, Community Health Systems, Inc. (CHS), and other entities (collectively defendants) in federal district court, alleging they defrauded Medicare and Medicaid by unbundling services and miscoding and upcoding billed items. Bledsoe reported the billing irregularities to the government before filing his qui tam action. As required by the FCA, 31 U.S.C. § 3730(b)(2), Bledsoe filed a written disclosure statement outlining CHS’ allegedly fraudulent practices. The government declined to intervene in the suit but
pursued a separate investigation of CHS’ billing practices. The government eventually settled with CHS, requiring the company to repay Medicare overpayments totaling nearly $31 million. The settlement covered coding irregularities with respect to certain specific diagnosis-related group (DRG) codes and "reserved and excluded" Bledsoe's claims from its scope.

Meanwhile, Bledsoe amended his complaint to add new substantive allegations, including fraud in White County Hospital's psychiatric unit. Defendants moved to dismiss and Bledsoe moved to recognize the settlement agreement, arguing he was entitled to a percentage of the settlement proceeds as an "alternate remedy" under 31 U.S.C. § 3730(b) and (c). The district court dismissed Bledsoe's action with prejudice. According to the court, Bledsoe failed to state his FCA claims with particularity as required by Fed. R. of Civ. P. 9(b). The district court also concluded that Bledsoe was not entitled to a relator's share of the government's settlement with CHS.

On the initial appeal from this decision, the Sixth Circuit reversed, holding Bledsoe should have been given the opportunity to plead his FCA claims with sufficient particularity and that the government’s settlement could constitute an “alternate remedy.” See United States ex rel. Bledsoe v. Community Health Sys., 342 F.3d 634 (6th Cir. 2003). Subsequently, Bledsoe filed another amended complaint. The district court again dismissed the complaint, finding several allegations failed to comply with Rule 9(b), the remaining allegations were time-barred, and Bledsoe was not entitled to a share of the government’s settlement proceeds. The Sixth Circuit agreed that most of the allegations failed to plead fraud with the required particularity, although it did find Bledsoe sufficiently pled “the time, place and content” with respect to his allegations that defendants “would add other unsupported diagnosis codes to the principal diagnosis code” to increase Medicare and Medicaid reimbursement.

At the outset, the appeals emphasized that, for a relator to proceed on allegations of a generalized “fraudulent scheme,” the claims that are pled with specificity must be “characteristic example[s]” that are “illustrative of [the] class” of claims at issue. Applying this standard, the Sixth Circuit dismissed most of Bledsoe’s allegations, although it did find sufficient particularity with respect to one alleged fraudulent scheme—submitting a fraudulent secondary diagnosis so as to receive greater reimbursement. According to the appeals court, Bledsoe alleged a representative example of one patient who was fraudulently given a secondary diagnosis for Tachycardia and cited a December 9, 1997 bill submitted to Medicaid for the services provided to that patient. In so holding, the appeals court rejected the district court’s conclusion that these allegations should be dismissed because Bledsoe failed to name specific employees who submitted the claim.

The appeals court further determined the district court erroneously concluded all of Bledsoe’s allegations were time-barred under the FCA’s applicable six-year statute of limitations. On an issue not previously addressed, the appeals court ruled that extrinsic evidence, in this case the disclosure statement made to the government, could be considered with respect to the “relation back” inquiry under Fed. R. Civ. P. 15(c)(2).
Thus, the appeals court concluded that those allegations regarding CPT upcoding and miscoding in relator’s complaint, when read in conjunction with Bledsoe’s disclosure statement, arose out of the “same conduct, transaction or occurrence” and therefore related back to prior pleadings and were not time-barred.

Finally, the appeals court held Bledsoe was not entitled to a share of the settlement proceeds recovered by the government. Here, only allegations related to one DRG overlapped under both the settlement agreement and Bledsoe’s complaint. The allegations related to that DRG in Bledsoe’s complaint were dismissed by the district court and affirmed on appeal for lacking sufficient particularity. Because Bledsoe failed to allege a valid claim, nor was there any prospect for him to recover on the claim under any circumstances, he was not entitled to a share of the settlement proceeds, the appeals court concluded. United States ex rel. Bledsoe v. Community Health Sys., Inc., No. 06-5096 (6th Cir. Sept. 6, 2007).

U.S. Court In Illinois Refuses To Dismiss Whistleblowers’ Claims Alleging Off-Label Drug Promotion

The U.S. District Court for the Northern District of Illinois refused September 13, 2007 to dismiss a False Claims Act (FCA) qui tam complaint against a drug maker involving alleged off-label promotion of its anticoagulant drug on the basis of the public disclosure bar or failure to plead the fraud with sufficient particularity. The court found while the complaint relied in part on publicly disclosed information, the jurisdictional bar did not arise because relators included other allegations not in the public domain regarding the information and training provided to the drug company's sales force. In addition, the court applied a relaxed pleading requirement to relators' complaint because their "claims are based on fraud allegedly committed against third parties." The court did dismiss, however, one relator's retaliation claim.

Relators Katy Kennedy and Frank Matos are former Aventis Pharmaceuticals, Inc. (Aventis) sales representatives. Kennedy and Matos brought a qui tam action under the FCA and the Illinois Whistleblower Protection Act against Aventis and PharmaNetics, Inc. (collectively, defendants), alleging they promoted and marketed Aventis’ anticoagulant drug Lovenox for off-label uses, causing healthcare providers to present false reimbursement claims to the U.S. government and the state of Illinois.

Lovenox was approved by the Food and Drug Administration (FDA) for seven indications related to preventing and treating deep vein thrombosis in certain specific instances. According to relators, Aventis had PharmaNetics develop the so-called ENOX test to address physician concerns about performing interventional procedures like cardiac catheterization on patients taking Lovenox, although the FDA had not approved the drug for use with such procedures. Relators further alleged that sales representatives were trained on the off-label uses of the drug; encouraged to provide items of value to physicians and others to induce them to use Lovenox; and paid excessive fees to speakers who promoted the drug’s use. Kennedy also brought a separate retaliation claim against Aventis, contending she was harassed and forced to resign after reporting her concerns to her superiors.
The government did not intervene in the action. Defendants moved to dismiss for lack of subject matter jurisdiction based on the public disclosure bar and failure to plead fraud with particularity. The U.S. District Court for the Northern District of Illinois granted the motion as to Kennedy’s retaliation claim but denied it as to all other claims.

The court acknowledged that many facts regarding the alleged off-label marketing of Lovenox were in the public domain, including press releases about the ENOX test and a suit brought by PharmaNetics against Aventis alleging false advertising and off-label drug promotion. The court also noted that many of relators’ allegations were based on the publicly disclosed information. But the court ultimately concluded the relators’ complaint did not “depend[] essentially upon” the publicly disclosed information and could stand on its own, noting claims concerning internal sales meetings and other instances where Aventis management allegedly instructed employees on off-label uses of Lovenox.

The court also refused to dismiss relators’ complaint for failure to plead fraud with the particularity required under Fed. R. Civ. P. 9(b). In so holding, the court concluded that the Rule 9(b) pleading requirements should be relaxed because, while relators alleged with particularity the facts regarding defendants’ alleged off-label marketing, specific facts about particular false claims were not likely within relators’ reach. “Given the significant proportion of medical care in this country that is financed by Medicare and Medicaid, relators have drawn a reasonable inference that claims for reimbursement regarding off-label uses of Lovenox were submitted to the federal government or the State of Illinois for payment,” the court held. United States ex rel. Kennedy v. Aventis, No. 03 C 2750 (N.D. Ill. Sept. 13, 2007).

**U.S. Court In Utah Dismisses With Prejudice FCA Whistleblower Action, Finds Insufficient Support For False Certification Claim**

A whistleblower failed to show how allegedly improperly coded laboratory services amounted to a False Claims Act (FCA) violation under a theory of improper certification, a federal court in Utah ruled September 12, 2007. In dismissing the whistleblower's complaint with prejudice, the court noted the relator did not identify a statute or regulation conditioning payment on compliance that the defendant medical lab and Medicare carrier allegedly violated.

The case arose when Edyth Sikkenga brought a qui tam action against her former employer Regence Bluecross Blueshield of Utah (Regence), a Medicare carrier, and Associated Regional and University Pathologists (ARUP), a laboratory owned by the University of Utah Medical Center. Sikkenga alleged among other things 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. Specifically, Sikkenga contended that ARUP and Regence billed Medicare using a generic diagnoses code, 796.4, signifying “other abnormal clinical findings,” that did not reflect patients’ true diagnoses.
The U.S. District Court for the District of Utah dismissed the complaint with prejudice for failure to plead fraud with particularity under Fed. R. Civ. P. 9(b). According to the court, in her opposition brief, Sikkenga shifted her focus from allegations of using false diagnostic codes to a theory of false certification. In support of her false certification argument, Sikkenga pointed to 42 U.S.C. § 1320c-5(a), which requires healthcare providers “to assure” the services for which they bill the government “will be supported by evidence of medical necessity.” The requirement to assure, however, is not necessarily the same as the requirement to certify, the court pointed out, refusing to equate the two absent some specific authority to that effect. Moreover, § 1320c-5(a)(3) does not expressly condition payment on compliance with its terms nor does it make use of the 796.4 code non-compliance, the court added.

The court also rejected Sikkenga’s other bases for her false certification theory. According to the court, “Sikkenga’s theories, if adopted, would convert the federal courts into examiners of every aspect of regulatory compliance by any entity paid from Medicare funds because it is possible to imagine undesirable results from (alleged) noncompliance.” Thus, the court concluded, Sikkenga failed to articulate a legal theory explaining why any particular claim was false. The court noted that lack of precision, i.e. using the more generic 796.4, was not necessarily the same as an inaccuracy. United States ex rel. Sikkenga, Regence Bluecross Blueshield of Utah, No. 2:99-CV-00086 (D. Utah Sept. 12, 2007).

U.S. Court In Nevada Denies Physician's Request For Attorneys' Fees In Dismissed FCA Case, But Permits Amended Fee Application

The U.S. District Court for the District of Nevada denied October 23, 2007 a physician’s request for attorneys' fees after he was found to be the "prevailing party" in a False Claims Act (FCA) case brought by the federal government, but gave him the opportunity to amend his fee application to demonstrate net worth using an acceptable accounting method. In its complaint against R.D. Prabhu, a board certified physician in both pulmonary and internal medicine, the federal government claimed that his billing practices violated the FCA. Specifically, the government alleged that, through his medical practice, Prabhu-Lata Shete, M.D.’s, Ltd. (Shete Corp.), Prabhu unlawfully billed for simple pulmonary tests even though he knew that pulmonary rehabilitation was not a covered benefit under Medicare.

The district court granted the physician’s motion for summary judgment, finding the government failed to submit sufficient evidence to establish that Prabhu knowingly submitted any false claims, or that the claims were not medically necessary. Defendant Shete Corp. subsequently filed an application pursuant to the Equal Access to Justice Act (EAJA), seeking an award of costs and attorneys’ fees of approximately $841,337. Shete Corp. argued that it was the “prevailing party,” and therefore was entitled to fees under the EAJA because the federal government acted without substantial justification in pursuing the FCA litigation against Prabhu.

U.S. Magistrate Judge Lawrence Leavitt, on behalf of the district court, first noted that Shete Corp. was a “prevailing party” under the EAJA. But Judge Leavitt concluded Shete
Corp. was financially ineligible to receive a fee award under EAJA, which requires that a corporation’s net worth be less than $7 million at the time the civil action was filed. Leavitt noted that Shete Corp.’s fee application used “cash basis” accounting to establish its net worth, a method that did not comply with generally accepted accounting principles (GAAP). Leavitt said that Shete should, however, be given 30 days to file an amended EAJA fee application in accordance with GAAP. United States v. Prabhu, No. 2:04-CV-0589-RCJ-LRL (D. Nev. Oct. 23, 2007).

In a subsequent development in this case, the Nevada district court awarded Shete Corp $542,494.68 in fees and costs under EAJA, after finding he submitted supplemental information in accordance with GAAP. The court this time found Shete Corp had met the EAJA’s financial eligibility requirements. The court rejected, however, the request for higher attorneys’ fees under the EAJA’s “special factor” exception, the finding although defendant had proven that certain of his attorneys had expertise in Medicare fraud law, he did not prove that such expertise “was essential for competent representation” or that no other “suitable counsel would have taken on its case at the statutory rate.”

The court also rejected the government’s contention that the attorney billing statements were not sufficiently detailed, finding “the billing entries at issue provide sufficiently detailed information to allow the court to determine whether the time the Shete Corporation’s attorneys devoted to various tasks was not excessive or otherwise unreasonable.” After ruling on each contested fee, the court ultimately held the Shete Corporation is entitled to recover attorneys’ fees and costs under the EAJA of $427,536.04 for attorneys’ fees and $114,958.64 in expenses. United States v. Prabhu, No. 2:04-cv-00589-RCJ-LRL (D. Nev. Feb. 25, 2008).

U.S. Court In District Of Columbia Allows Relators To Proceed With FCA Action Against Hospital
A federal district court in the District of Columbia said November 20, 2007 that a False Claims Act (FCA) qui tam action alleging a hospital knowingly submitted hundreds of false claims to Medicare could go to trial, concluding the relators’ secondary evidence of the hospital’s submission of false claims created a sufficient fact issue. Relators in the case are four certified registered nurse anesthesiologists (CRNAs), Sheila El-Amin, Joyce B. Lasley, Katherine Linden, and Robert A. Roubik, who were formerly employed by George Washington University Hospital (GWU). In their qui tam action, the CRNAs contended that, over a six-year period commencing in October 1989, GWU knowingly overcharged Medicare by submitting claims for anesthesia services that falsely represented the services were rendered by physician-anesthesiologists, when in fact the services were provided by CRNAs and residents-in-training.

The government opted not to intervene in the case, but the CRNAs decided to proceed, seeking to recover damages and civil penalties. After a protracted discovery period of nearly a decade, the district court granted GWU’s motion for an order compelling relators to produce any and all Medicare claim records, including all HFCA 1500 claim forms within relators’ possession and control, relating to the claims at issue. In accordance with that order, the CRNAs produced 223 HCFA 1500 claim forms for anesthesia services
during the relevant time period, 50 of which identified one of 15 GWU anesthesiologists as the physician providing the indicated services.

Both GWU and the CRNAs recognized that, over the relevant time period, the hospital submitted hundreds more claims for anesthesia services than were documented in these 223 claim forms, according to the district court. Nonetheless, GWU moved for summary judgment seeking to limit the scope of the CRNAs’ case to the 50 HCFA 1500 claim forms identifying the specified GWU physician-anesthesiologists. In its motion, GWU argued that summary judgment should be granted on all claims other than those for which relators possessed HCFA 1500 claim forms because, “[w]ithout these forms, there is no proof of an actual claim,” leaving no issue of material fact for the jury. The CRNAs argued the HCFA 1500 claim forms were not the sole method by which they could establish a violation of the FCA, noting “an abundance of detailed evidence that [GWU] billed Medicare, including . . . tens of thousands of pages of direct evidence that [GWU] billed Medicare for every one of the anesthesia procedures in issue.”

The district court said the relevant issue was what evidence (or proof) the relators needed to adduce at trial to demonstrate that GWU submitted a false claim to the government in violation of the FCA. The relators argued that secondary evidence (i.e. Explanation of Medicare Benefit (EOMB) forms) was an adequate substitute for an actual HCFA 1500 claim for each alleged violation of the FCA. The district court agreed, concluding the FCA “does not by its language require Relators to present the actual HCFA 1500 claim form to demonstrate a violation” of the Act. In this case, relators collected a variety of billing documentation, including EOMB forms, the district court said, and this “serves as circumstantial evidence that [GWU] submitted claims to Medicare,” which is sufficient to create a genuine issue of material fact as to whether GWU submitted such claims.

The district court also concluded that the best evidence rule, Fed. R. Evid. 1002, does not bar secondary evidence of Medicare claims. That rule generally requires that an original be admitted into evidence to prove the content of a writing. Here, the “Relators are excused from presenting original HCFA 1500 claim forms [under an exception to the best evidence rule] that provides that an original is not required if it cannot be obtained by any available judicial process or procedure,” the district court explained. “Relators have shown that they made a reasonable effort to locate HCFA 1500 claim forms, including serving a subpoena on the HCFA, and that despite their diligent efforts these forms are not obtainable,” the court said. The district court also emphasized that when the relators received no response to their subpoena, they performed a manual search of millions of pages of documents at the Federal Records Center. United States ex rel. El-Amin v. The George Washington Univ., No. 95-2000(CKK) (D.D.C. Nov. 20, 2007).

First Circuit Says Communications With Government Do Not Constitute “Public Disclosure” Under FCA

A pharmaceutical company’s voluntary disclosure of potentially improper marketing practices to the government does not trigger the False Claims Act’s (FCA’s) public disclosure bar, the First Circuit ruled November 15, 2007. The appeals court held the qui tam action was properly dismissed, however, for failing to plead fraud with particularity;
although, it found the relator should have been given the opportunity to amend his complaint.

Peter Rost, who worked for Pharmacia Corp. (Pharmacia) as Vice President of Marketing, initiated a qui tam action in 2003 alleging Pharmacia had knowingly caused the submission of false claims by promoting the human growth hormone Genotropin for off-label uses. The lawsuit against Pfizer, Inc., Pharmacia’s parent company, claimed damages under the FCA and the statutes of ten states and the District of Columbia.

Pfizer had acquired Pharmacia in 2003 and immediately instituted an internal investigation of the questionable marketing practices that occurred before the acquisition. Pfizer also notified federal regulatory agencies, including the Department of Health and Human Services Office of Inspector General through its voluntary disclosure program. Pfizer made its first public announcement regarding the investigation in 2004 Securities and Exchange filings. In April 2007, Pfizer and its Pharmacia subsidiaries reached settlements with the federal government totaling $34.7 million and entered into a deferred prosecution agreement concerning the conduct at issue.

Pfizer argued that its communications with the government constituted “public disclosures” triggering the FCA’s jurisdictional bar at 31 U.S.C. § 3730(e)(4)(A), and that Rost did not qualify as an “original source.” The U.S. District Court for the District of Massachusetts disagreed that the FCA public disclosure bar applied, but dismissed the complaint for failure to plead fraud with the particularity required under Federal Rule of Civil Procedure 9(b). The district court did not rule on Rost’s request to amend his complaint to allege fraud with particularity.

The appeals court noted that the question of whether a self-disclosure made by a private party to government agencies constitutes a “public disclosure” under the FCA was one of first impression in the First Circuit. Based on the plain language of the FCA, the structure of the statute, and its legislative history, the appeals court concluded there was no public disclosure in connection with Pfizer’s communications with the government. To hold otherwise, would render the phrase public disclosure “superfluous” and equating the government with the public would be inconsistent with the rest of the statute. Moreover, the appeals court observed, the effect of Pfizer’s argument would be to reinstate the “government knowledge” bar, which Congress eliminated in the 1986 amendments to the statute. Finally, the appeals court noted that its holding was consistent with the majority view among the circuits, with only the Eighth Circuit concluding that mere disclosure to the government is a public disclosure if made to appropriate investigative officials.

The appeals court went on to find that the complaint was properly dismissed for failing to plead fraud with the required particularity. Here, Rost’s complaint alleged that given more than half of all adult and a quarter of all pediatric sales of Genotropin were for off-label uses, it stood to reason that some physicians were persuaded to write those prescriptions by the improper marketing practices and that some of those claims involved federal healthcare program reimbursements. But the appeals court found the complaint failed to allege any false claims that were presented to the government for
reimbursement. “At most, Rost raises facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility,” the appeals court said. *United States ex rel. Rost v. Pfizer, Inc.*, No. 06-2627 (1st Cir. Nov. 15, 2007).

**U.S. Court In California Says Insurer Not Obligated To Pay Defense And Indemnity Costs In FCA Action Against Nursing Home**

An insurance company did not have to pay defense and indemnity costs under a nursing home's commercial general liability policy in connection with a False Claims Act (FCA) case against the nursing home, a federal district court in California ruled November 27, 2007. According to the U.S. District Court for the Northern District of California, the FCA action did not qualify as a “medical incident” requiring the furnishing of “professional services” under the policy at issue, and therefore the insurance company did not have a duty to defend the underlying FCA action.

In the underlying litigation, the California Advocates for Nursing Home Reform (CANHR) and two individual relators filed a FCA qui tam complaint alleging Lenox Healthcare, Inc. (Lenox) submitted false certifications regarding its compliance with state and federal laws to improperly obtain continued funding under California’s Medicaid program (Medi-Cal) and Medicare. In addition, relators alleged Lenox owned and operated the Mill Valley Healthcare Center (Center), which in October 1997, was found to have approximately 30 deficiencies following a certification survey conducted by California’s Department of Health Services (DHS). From that time through March 1998, according to relators, the Center submitted three plans of correction that DHS found unacceptable, but finally submitted a fourth plan that was approved. In a follow-up survey, however, DHS again found numerous deficiencies.

The court concluded both Lenox and the Center had “acted in reckless disregard of the falsity of their statements” in submitting claims and representing that they complied with federal and state nursing home laws, and in drafting plans of correction for the Center, in order to continue collections of Medi-Cal and Medicare payments. (*United States ex rel. California Advocates for Nursing Home Reform v. Lenox Healthcare Inc.*, No. 99-0651 CRB (N.D. Cal. Sept. 27, 2002)). The district court awarded $1,415,000 in damages under federal and state False Claims Acts, $4,245,000 in trebled damages, and attorneys’ fees and expenses.

After Lenox filed for bankruptcy, CANHR and the other relators (collectively, plaintiffs) filed an action to recover defense and indemnity costs from American International Specialty Lines Insurance Co. (AISLIC), which had issued Lenox an insurance policy providing commercial general liability coverage over the time period at issue. Under the policy, AISLIC “will pay on behalf of the insured all sums which the insured shall become legally obligated to pay as damages because of the injury to which this insurance applies caused by a medical incident which occur during the policy period.” In addition, the policy defined a “medical incident” as “any act or omission . . . in the furnishing of professional health services . . . ."
The court held AISLIC did not have a duty to defend Lenox in the underlying FCA action. The court rejected plaintiffs’ argument that the FCA action alleged a covered “medical incident” because the preparation of Lenox’s plans of correction involved the furnishing of “professional healthcare services.” According to the court, “Lenox’s liability under the FCA was premised on the presentation of false claims and records or statements to the government, not the underlying deficiencies in patient care that was used to establish the falsity of Lenox’s claims and representations.” The district court also noted that the FCA complaint did not allege that Lenox prepared these plans of correction in order to provide a professional healthcare service “separate and apart” from obtaining the Medi-Cal and Medicare payments. “Rather, the underlying complaint alleged that Lenox submitted the plans of correction solely to keep receiving the fraudulently-claimed payments,” the court said. United States ex rel. California Advocates for Nursing Home Reform v. American Int’l Specialty Ins. Co., No. 3:06-cv-03069-JSW (N.D. Cal. Nov. 27, 2007).

U.S. Court In Massachusetts Says Some Government Claims In FCA Action Against Drug Maker May Be Time-Barred

Certain claims asserted by the federal government against pharmaceutical manufacturer Roxane Laboratories, Inc. (Roxane) in a whistleblower action under the False Claims Act (FCA) may be time-barred unless the discovery rule applies, the U.S. District Court for the District of Massachusetts ruled December 6, 2007. Relator Ven-A-Care of the Florida Keys initially filed the qui tam action under the FCA in April 2000, alleging Roxane defrauded Medicaid by reporting inflated drug prices used to set the programs’ reimbursement rates. Ven-A-Care’s first complaint alleged wrongdoing with respect to one drug, Ipratropium Bromide, and one Roxane entity. Relator subsequently amended its complaint three times, adding claims based on numerous other drugs against multiple defendants including four Roxane entities.

Nearly seven years later, on February 9, 2007, the federal government filed a “complaint-in-intervention” as part of a multidistrict litigation. The government’s complaint alleged Roxane defrauded Medicare and Medicaid in connection with nine drugs. Roxane argued that the FCA statute of limitations barred all causes of action accruing in connection with claims for payment more than six years before the government intervened. Citing the Second Circuit’s decision in United States v. The Baylor Univ. Med. Ctr., 469 F.3d 263 (2d Cir. 2006), Roxane said the action was commenced for purposes of the statute of limitations when the government filed its complaint-in-intervention. The government argued that the filing of the relator’s action in April 2000 tolled the statute of limitations as to the FCA claims or, alternatively, that the United States’ claims were timely because they “relate back” to the relator’s claims against Roxane.

Noting its holding in a previous decision addressing a similar issue (United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey, Inc., 498 F. Supp. 2d 389 (D. Mass. 2007)), the court said the action commenced for purposes of the statute of limitations when the relator filed its sealed complaint. Again citing its previous holding, the court said the government’s “complaint-in-intervention” should be treated as an amended complaint that related back to the relator’s initial complaint under Fed. R. Civ. P. 15(c). The court
noted that relation back would not apply, however, to the extent that the government’s complaint asserted new claims unrelated to the original complaint.

Here, Ven-A-Care filed its third amended complaint on February 15, 2005, adding for the first time several new drugs. The government contended that the relator’s third amended complaint should relate back to its first complaint under Fed. R. Civ. P. 15(c) because the allegations involving new drugs were part of the same “broad scheme of price manipulation” on which the original complaint was based. The court disagreed, finding relation back as to these claims would be inappropriate, noting “insufficient allegations that the circumstances of the pricing for each drug are similar.” Thus, the complaint in intervention only related back to the 2005 Ven-A-Care complaint and all claims that accrued before February 15, 1999 were time-barred unless saved by the discovery rule, which the court declined to rule on at this stage of the litigation. *United States of America ex rel. Ven-A-Care of the Fla. Keys, Inc., v. Boehringer Ingelheim Corp.*, No. 1456 (D. Mass. Dec. 6, 2007).

**U.S. Court In Tennessee Rejects FCA Action Against Hospital Alleging Deficient Care**

A federal district court in Tennessee dismissed December 17, 2007 a qui tam action under the False Claims Act (FCA) based on a hospital’s alleged false certifications of compliance with Medicare Conditions of Participation. Plaintiff Anne F. Landers is a registered nurse who was employed as the associate chief nursing officer at Baptist Memorial Hospital, Inc., d/b/a Baptist Memorial Medical Center (Baptist Medical). In 1994 or 1995, Baptist Medical Center underwent a major restructuring that resulted in severe staffing shortages, according to the opinion. Specifically, Baptist Medical increased the nurse/patient ratio to 1:3 in the Intensive Care Unit, used surgical technicians (scrub techs) as nurse circulators in the Operating Room, and failed to meet certain applicable standards of care for cleanliness and sterilization.

The hospital’s chief operating officer asked plaintiff to evaluate these issues. According to the opinion, Landers submitted an unsolicited report to her supervisors outlining her concerns in February 1998. Shortly thereafter, the hospital terminated Landers. Landers initiated a qui tam action under the FCA against Baptist Medical Center and its corporate affiliates (defendants). The federal government declined to intervene. Landers alleged that defendants both expressly and impliedly falsely certified compliance with applicable statutes, regulations, and rules to obtain reimbursement of their medical claims. According to Landers, despite their certifications to the contrary on various CMS forms, defendants failed to satisfy Medicare Conditions of Participation related to adequate nursing staffing; organizing surgical services appropriate to the scope of services offered; having policies governing surgical care aimed at maintaining high standards of care; and providing a sanitary environment.

The U.S. District Court for the Western District of Tennessee granted defendants summary judgment, finding the CMS forms in which defendants agreed to abide by applicable Medicare laws and regulations did not expressly or impliedly condition payment on compliance. “Conditions of participation are not the equivalent of Conditions
of Payment, which are codified in a separate section,” the court said. Instead, “Conditions of Participation are quality of care standards directed towards an entity’s continued ability to participate in the Medicare program rather than a prerequisite to a particular payment,” the court observed.

While defendants’ alleged non-compliance may eventually lead to corrective action or even termination, Landers failed to present any evidence that defendants would have been ineligible to receive payment of its Medicare claims. Moreover, Landers did not present enough evidence that defendants’ alleged false claims were material to the government’s decision to make payments, the court added.

Finally, the court rejected Landers’ “worthless services claim”—i.e., that caring for patients in a manner that did not conform to applicable standards of care amounts to billing the government for care not actually performed. Even assuming Landers established defendants’ non-compliance with the Medicare Conditions of Participation and applicable standards of care, this was not sufficient to demonstrate the services were so deficient that for all practical purposes they amounted to no performance at all. United States ex rel. Landers v. Baptist Mem’l Health Care Corp., No. 2:99-cv-2097 (W.D. Tenn. Dec. 17, 2007).

Seventh Circuit Concludes State’s Action Against Drug Maker Not Removable, But Reverses Attorneys’ Fees Award
The state of Wisconsin’s action challenging a drug company’s alleged unfair pricing methods did not belong in federal court, but attorneys’ fees were not warranted given the company’s “objectively reasonable basis for seeking removal” a third time, the Seventh Circuit ruled February 4, 2008. The state of Wisconsin originally filed its lawsuit in June 2004 in state trial court, alleging Dey, Inc. and other pharmaceutical companies violated state laws and unjustly enriched themselves by inflating the average wholesale price (AWP) of their drugs causing Medicaid overpayments. Dey removed the case three times to federal district court, which remanded on each occasion and sanctioned Dey $14,208 following the last removal.

Dey based the third notice of removal, which was filed more than two years after the state instituted the action, on the unsealing of a complaint in a Massachusetts federal district court charging various pharmaceutical companies, including Dey, with violating the False Claims Act. 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. According to Dey, that action created original federal jurisdiction over Wisconsin’s suit for the first time, so the instant action was removal to federal court under 28 U.S.C. § 1446.

The FCA, 31 U.S.C. § 3732(b), provides that “the district courts shall have jurisdiction over any action brought under the laws of the any State for the recovery of funds paid by a State or local government if the action arises form the same transaction or occurrence as an action brought under [31 U.S.C.] § 3730.” The Seventh Circuit said that § 3732(b) is a
way to confer federal jurisdiction over federal and state claims arising from the same fraudulent scheme, regardless of diversity of citizenship.

The appeals court acknowledged that 31 U.S.C. § 3730(b)(5) implements a “first-to-file” bar, preventing subsequent suits based on the facts underlying a pending action. But this provision would not be implicated here, the appeals court reasoned. “The State of Wisconsin . . . is suing to recover a loss inflicted on it by the defendants’ fraud. Such a suit is not ‘related’ to a qui tam suit,” the appeals court said.

The appeals court rejected Dey’s argument that trying Wisconsin’s suit with the federal action in Massachusetts would promote judicial economies. “On Dey’s submission, a suit that has been proceeding for years in a state court is to be wrenched into federal court” and would have to start over, producing the opposite of judicial economy, the appeals court noted. Moreover, the qui tam complaint in the Massachusetts federal district court is not an “amended pleading, motion, order or other paper” from which removability could first be ascertained under § 1446(b). Thus, the appeals court agreed with the district court that the action was not properly removable to federal court. The appeals court reversed, however, the lower court’s award of attorneys’ fees to the state, finding Dey had a reasonable basis for seeking removal. Wisconsin v. Amgen, Inc., No. 07-1999 (7th Cir. Feb. 4, 2008).

U.S. Court In Massachusetts Dismisses Whistleblowers’ FCA Action Alleging Kickbacks, Off-Label Promotion Involving Procrit

A federal district in Massachusetts dismissed January 25, 2008 a qui tam action under the False Claims Act (FCA) alleging Ortho Biotech Products, L.B. (OBP) paid kickbacks to providers to induce their prescription of the anti-anemia drug Procrit and promoted the drug for off-label uses. The court found the kickback allegations failed to plead fraud with sufficient particularity and the FCA’s first-to-file bar applied to the off-label promotion claims. In November 2003, relator Mark Duxbury filed the whistleblower action under the FCA against OBP. The court in 2006 allowed Duxbury to add Dean McClellan as a co-relator and to file an amended complaint.

Duxbury and McClellan were former OBP employees working in the sales force responsible for Procrit. According to relators, beginning in 1992 OBP engaged in a scheme to give kickbacks to providers, including free samples, off-invoice discounts, rebates, and educational grants, to prescribe Procrit. Relators also alleged OBP, starting in January 1998, promoted off-label dosing of Procrit in violation of the Food, Drug and Cosmetic Act and used “sham drug trials” to falsify eligibility for Medicare reimbursement for off-label uses of the drug. The government declined to intervene. Defendants moved to dismiss, arguing the court lacked jurisdiction under the FCA’s public disclosure bar, certain claims were barred by the “first-to-file rule,” and plaintiffs failed to plead fraud with the required particularity.

The U.S. District Court for the District of Massachusetts granted the motion to dismiss. The court found the kickback allegations were public disclosures, noting pending multi-district litigation, In re Pharmaceutical Industry Average Wholesale Price Litigation.
(AWP Litigation), MDL 1456 (D. Mass), filed more than a year before the instant action. Citing Rockwell Int’l Corp. v. United States, 127 S.Ct. 1397 (2007), the court also concluded the kickback allegations were “based upon” the public disclosure because they were the “same as” those alleged in the AWP Litigation complaint. The court found Duxbury qualified as an “original source” but limited this status to his period of employment with OBP, 1992-1998. McClellan did not qualify as an original source, the court continued, because he joined the action as a co-relator in 2006, did not assert any new claims of his own at that time, and failed to show he provided prior information to the government.

While the court concluded it had subject matter jurisdiction to hear Duxbury’s claims of alleged kickbacks during the 1992-1998 period, it ultimately found his allegations lacked the particularity required under Fed. R. Evid. 9(b). “Although Duxbury identifies providers and approximate amounts of free samples, discounts, ‘off-invoice’ rebates, or educational grants, he fails to identify a single false claim consequently filed by these providers,” the court said.

The court next held the first-to-file bar precluded subject matter jurisdiction over relators’ off-label marketing claim. Although Duxbury filed his original complaint in November 2003, the court determined that a complaint filed in Colorado one month later was the first to assert claims for off-label marketing of Procrit. See United States ex rel. Blair v. Ortho Biotech, Inc., Civ. No. 03-02585 (D. Colo. Dec. 22, 2003). According to the court, Duxbury’s original complaint alleged only that OBP paid physicians to participate in clinical trials and used them “[t]o provide cash payments” to encourage off-label uses. The complaint failed to allege, however, that OBP engaged in a widespread scheme to promote off-label uses of Procrit, the “sine qua non of manufacturer liability,” the court said. Thus, the court dismissed relators’ off-label marketing claims, finding them barred by the Blair complaint. United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., No. 03-12189-RWZ (D. Mass. Jan. 25, 2008).

U.S. Court In Mississippi Declines To Dismiss Whistleblower’s Fraud Allegations Against Blue Cross Blue Shield

The U.S. District Court for the Southern District of Mississippi refused February 5, 2008 to dismiss a whistleblower’s qui tam action against a Medicare Part B carrier under the False Claims Act (FCA). In so holding, the court rejected the carrier’s argument that it was entitled to statutory immunity, regardless of whether it acted with gross negligence or fraudulent intent, under a federal statute (42 U.S.C. §1395u(e)(3)) providing immunity from liability in certain circumstances to certifying officers, disbursing officers, or carriers.

Sherrie Conrad was a former management consultant for a Medicare provider, Mid-South Rehab Companies (Mid-South). During the course of her work for Mid-South, Conrad discovered and then reported alleged fraudulent Medicare claims submitted by Mid-South to Blue Cross Blue Shield of Mississippi, d/b/a Tri-Span Health Services (Blue Cross). Conrad subsequently filed a qui tam action under the FCA alleging that Blue Cross caused certain false claims submitted by Mid-South to be processed for payment through
Medicare, and that such conduct was “grossly negligent and knowing.” The complaint alleged that, in her role as consultant, Conrad came to learn of thousands of false claims submitted for Medicare reimbursement, including multiple billings for a single service, billing for personal items, and illegal related-party transactions. Conrad also asserted in her complaint that Blue Cross failed to audit and/or investigate and failed to recognize, reject, or report the false claims to any supervising authority.

Blue Cross contended that it was entitled to statutory immunity under 42 U.S.C. § 1395u(e)(3), which provides that no individual designated as a certifying officer or disbursing officer shall be liable for any payments made, “in the absence of gross negligence or intent to defraud the United States.” In a separate subsection, the statute provides that carriers shall not be held liable for payments certified and disbursed by the respective officers. The district court agreed with Conrad’s contention that Blue Cross was not entitled to immunity under 42 U.S.C. § 1395u(e)(3) because its conduct amounted to gross negligence or fraud. Relying on legislative history and case precedent from federal appeals courts, the district court concluded that a carrier’s immunity under 42 U.S.C. § 1395u(e)(3) is “co-extensive” with that of its certifying and disbursing officers, and therefore such immunity excludes cases involving gross negligence and fraud. United States ex rel. Conrad v. Blue Cross Blue Shield of Miss., No. 2:99cv72-LG-JMR (S.D. Miss. Feb. 5, 2008).

Seventh Circuit Upholds $64 Million FCA Award

The Seventh Circuit found February 20, 2008 that a False Claims Act (FCA) defendant’s fine of over $64 million was not excessive, though the appeals court did not reach the defendant’s claim that the fine violated the Excessive Fines clause of the Eighth Amendment. Peter Rogan was a principal manager and financial beneficiary of Edgewater Medical Center. Before its closing in 2001, Edgewater’s management company, its vice president of development and marketing, and four physicians were indicted for fraud and other crimes related to bills that Edgewater submitted to the Medicare and Medicaid programs. All six defendants pled guilty and were sentenced to fines and/or prison terms.

Rogan was not indicted—instead, the government filed an action against him under the FCA alleging Rogan conspired with the six indicted defendants to defraud the United States by concealing the fact that many patients came to Edgewater only because of referrals that violated the Stark Law and the Anti-Kickback Statute. After a bench trial in district court, Rogan was found to have known about the fraud and was ordered to pay over $64 million in restitution.

Rogan acknowledged that the bills sent to federal healthcare programs omitted the fact that kickbacks were paid, but argued that the omissions were not material because the government did not rely on the omissions. According to Rogan, “a federal employee in a position to make a decision had to testify that the government was sure to enforce” the Stark Law. The appeals court rejected that argument, noting that a “statement or omission is ‘capable of influencing’ a decision even if those who make the decision are negligent and fail to appreciate the statement’s significance.”
The appeals court also found the $64 million award was not excessive. Rogan argued that the Excessive Fines Clause of the Eighth Amendment prohibited the award because it was grossly disproportionate to the wrong. The appeals court disagreed, noting it was “far from clear that the Excessive Fines Clause applies to civil actions under the False Claims Act.” However, the court ultimately did not reach Rogan’s constitutional argument for several reasons, including that Rogan did not raise the issue below. According to the appeals court, it is “impossible to know whether the penalty was constitutionally ‘excessive’ without knowing what conduct the fine penalizes.” Because Rogan persuaded the district court to exclude evidence that medical services were unnecessary, or never performed, he “has made the record unsuitable to resolution of his constitutional argument.”

In addition, the appeals court found the total award here was less than four times actual damages, which is “well within the single-digit level” that the U.S. Supreme Court in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), held was not “grossly excessive” for punitive damages. Noting that no data has been presented showing what multiplier would be appropriate for deterrence, the appeals court mused “for all we can tell, Rogan’s penalty may be too low.” *United States v. Rogan*, No. 06-4144 (7th Cir. Feb. 20, 2008).

**U.S. Court In Pennsylvania Refuses To Dismiss FCA Action Based On Alleged False Certification Of Stark, Anti-Kickback Compliance**

The U.S. District Court for the Middle District of Pennsylvania refused to dismiss March 12, 2008 a qui tam action under the False Claims Act (FCA) alleging a medical clinic and a hospital submitted false claims to the government based on illegal referrals that violated the Stark Law and the Anti-Kickback Statute. According to the court, relator Rodney Repko, the clinic’s former general counsel, sufficiently pled fraud with the required particularity by alleging every claim submitted to the government during the relevant time period was false in that it certified compliance with the Stark and Anti-Kickback laws. The court did reject, however, Repko’s claims alleging a direct violation of the Stark Law and common law unjust enrichment, noting a relator does not have standing to pursue such claims on behalf of the government.

Repko instituted his qui tam action against defendants Guthrie Clinic, P.C. (clinic), its affiliates, and Robert Packer Hospital (hospital), among others. According to Repko, the clinic entered into various financial agreements with the hospital, such as loans at low interest rates, in exchange for referrals of large volumes of patients to the hospital, for which the hospital then billed Medicare and Medicaid. Repko contended that every claim the hospital submitted to the government for payment was the result of these illegal referrals from physicians employed by the clinic. Defendants moved to dismiss on a number of grounds, including failure to plead fraud with the particularity required by Fed. R. of Evid. 9(b) and the statute of limitations.

The court acknowledged that a relator typically must identify at least some, or even all, false claims that were submitted to the government to sufficiently plead fraud with
particularity, but ultimately concluded that in this case doing so would not advance the purposes of Rule 9(b). “Relator has alleged that every claim submitted to the government by Hospital during the relevant time period was fraudulent” because they stemmed from illegal referrals while certifying compliance with the Stark and Anti-Kickback laws. According to the court, “attachment of some or all of the allegedly fraudulent claims would serve no further purpose consistent with Rule 9(b) because defendants are on notice that the basis of the alleged fraud in each claim is the relationship between defendants, not anything unique to a particular claim” that caused the alleged false claims. For similar reasons, the court held plaintiff sufficiently pled a claim for conspiracy under the FCA.

The court also found these FCA claims were not time-barred because Repko’s claims related back to the original complaint, which was filed during the applicable statute of limitations. In reaching this conclusion, the court rejected the application of the Second Circuit’s decision in United States v. The Baylor Univ. Med. Ctr., 469 F.3d 263 (2006). That case, the court noted, concerned relation-back in the context of the government’s complaint-in-intervention, not an amended complaint filed by the relator who filed the original complaint. The court also held the extension in the FCA statute of limitations provision for discovery of the fraud was applicable, despite defendants’ contention that Repko, as the clinic’s general counsel, had knowledge of the fraud when it occurred. For purposes of the statute of limitations under the FCA, “it is the government’s knowledge, not the relator’s knowledge that is relevant,” the court said.

Finally, the court rejected defendants’ contention that Repko by advancing his complaint was committing ethical violations because he obtained his knowledge in his capacity as the clinic’s general counsel and was subject to state confidentiality rules. The court said the record lacked a sufficient factual basis for rejecting the complaint on this ground and, moreover, defendants failed to address the Pennsylvania ethical rule requiring an attorney to reveal confidential information “to prevent, mitigate or rectify the consequences of a client’s criminal or fraudulent act in the commission of which the lawyer’s services are being or had been used.”

The court did ultimately dismiss Repko’s FCA concealment claim (failure to plead an obligation to pay money to the government and a fraudulent concealment of that obligation); FCA retaliation claim (time-barred under the relevant Pennsylvania whistleblower statute); and Stark Law and common law unjust enrichment claim (lack of standing because no partial assignment of the government’s damages as under the FCA). United States ex rel. Repko v. Guthrie Clinic, P.C., No. 4:04-CV-1556 (M.D. Pa. Mar. 12, 2008).

U.S. Court In Arizona Issues Opinion Dismissing Qui Tam Action Against Hospital Group With Prejudice
The U.S. District Court for the District of Arizona issued a written opinion April 21, 2008 dismissing with prejudice a qui tam action under the False Claims Act (FCA) against IASIS Healthcare LLC based in Franklin, Tennessee. The opinion follows an earlier
bench ruling by U.S. District Court Judge James A. Teilborg finding the relator had failed to plead the fraud with the required particularity under Fed. R. Civ. P. 9(b).

The action was initiated by relator Jerre Frazier under the FCA in March 2005. The complaint was unsealed in August 2007 when the federal government declined to intervene. Frazier served as Vice President of Ethics and Business Practices and Chief Compliance Officer for IASIS from November 1999 to April 2003. The complaint alleged that, since at least 1999, IASIS “knowingly engaged in a number of different illegal schemes to submit false claims for reimbursement from Medicare, Medicaid, and other federal health care programs” that involved paying improper compensation to physicians for illegal referrals in violation of the Stark Law and Anti-Kickback Statute. IASIS moved to dismiss pursuant to Rule 9(b) for failure to plead fraud with particularity.

“Because Mr. Frazier was a corporate insider, he should have adequate knowledge of the alleged fraud to comply with the heightened pleading requirements of Rule 9(b),” Judge Teilborg said at the outset of his opinion. The opinion found Frazier failed to meet the Rule 9(b) burden with regard to his medical necessity claims, i.e. that IASIS billed federal healthcare programs for medically unnecessary procedures performed by physicians with whom it had improper financial relationships.

While Frazier named specific physicians who allegedly performed the procedures and where they practiced, he failed to allege any specific surgeries or dates for the procedures. “Most importantly,” the opinion continued, Frazier “has not stated why the procedures were medically unnecessary.” Frazier also failed to list a single specific “unnecessary procedure” for which IASIS submitted a claim to the government, the opinion added.

The opinion also rejected Frazier’s claims alleging IASIS hospitals submitted annual cost reports that falsely certified compliance with the Stark Law and Anti-Kickback Statute. Judge Teilborg found while some of these allegations met Rule 9(b)’s required level of specificity, "merely alleging a violation of the Stark Law and/or Anti-Kickback Statute does not sufficiently state a claim under the FCA." Specifically, the opinion noted, Frazier described the allegedly improper relationships between certain physicians and IASIS hospitals, but provided no detail “regarding the referral of Medicare-eligible patients as a result of those relationships or the submission of claims to the government for payment.”

Ninth Circuit Holds Federal Rule Of Civil Procedure 8(a) Applies To FCA Retaliation Claim

The Ninth Circuit reversed the dismissal of a plaintiff’s claims of retaliation under the federal False Claims Act (FCA) and California False Claims Act (CFCA), concluding Fed. R. of Civ. P. 8(a)—and not Fed. Re. If Civ. P. 9(b)—applied. Plaintiff Marie Bernadette Mendiondo worked as a nurse at Centinela Hospital Medical Center (CHMC). Mendiondo and two colleagues filed an action against CHMC, Tenet Healthcare Corporation, and three other associated healthcare groups alleging they were wrongfully terminated after complaining about false billing and reimbursement practices and substandard patient care.

Plaintiffs claimed (1) violations of the federal FCA (31 U.S.C. § 3730(h)) and the CFCA (Cal. Gov’t Code § 12653(b)); (2) retaliation in violation of the whistleblower provisions in the FCA and CFCA; (3) retaliation in violation of Cal. Health & Safety Code § 1278.5; and (4) wrongful termination in violation of the public policies embodied in these laws. After the government declined to intervene, plaintiffs dismissed with prejudice the FCA and CFCA violation claims, leaving only their retaliation and wrongful termination claims. CHMC then moved to dismiss the action under Fed. R. of Civ. P. 8(a), 9(b), and/or 12(b)(6). The trial court granted the motion and plaintiffs appealed.

The Ninth Circuit turned first to the threshold issue of whether an FCA retaliation claim must meet the notice pleading standard in Rule 8(a) or the heightened pleading standard in Rule 9(b). The appeals court explained that Rule 8(a) applies to all civil claims except those containing averments of “fraud or mistake,” which must be pled with particularity under Rule 9(b). In this case, because only plaintiffs’ FCA retaliation claim was at issue, and not an FCA violation claim, the Rule 8(a) pleading standard applied, the appeals court held. Accordingly, after reviewing the elements of plaintiffs’ complaint, the appeals court held that “[a]lthough the complaint may be inartfully drawn, it nonetheless contains sufficient facts under the applicable notice pleading standards of 8(a) to survive dismissal under Rule 12(b)(6).” The appeals court then found that plaintiffs’ wrongful termination in violation of public policy claim and claims under the Cal. Health & Safety Code § 1278.5 also contained sufficient facts under Rule 8(a) to survive a dismissal motion. Mendiondo v. Centinela Hosp. Med. Ctr., No. 06-55981 (9th Cir. Apr. 1, 2008).
**Anti-Kickback Issues**

**OIG Finds Partial Sale Of Physician-Owned ASC To Hospital Could Trigger Sanctions**
The partial sale of an ambulatory surgery center (ASC) to a nonprofit hospital could generate prohibited remuneration under the Anti-Kickback Statute and lead to administrative sanctions, according to Department of Health and Human Services Office of Inspector General (OIG) Advisory Opinion No. 07-05 posted June 19, 2007. A company that owns a freestanding multi-specialty ASC requested the opinion regarding its proposal to sell 40% of the ASC to a nonprofit hospital for fair market value. The company is made up of several physician investors, with three orthopedic surgeons owning about 94% of the equity in the company. Under the proposed arrangement, the orthopedic surgeons would sell 40% of the ASC to the hospital; in exchange, they would receive an amount that exceeded the amount they originally invested.

The OIG noted its “longstanding concerns about problematic joint venture arrangements between those in a position to refer business, such as physicians, and those furnishing items or services for which a Federal health care program pays.” Although a safe harbor exists for returns on investment in hospital/physician-owned ASCs, the proposed arrangement did not qualify for safe harbor protection, the OIG said.

Turning to the risk of the proposed arrangement under the Anti-Kickback Statute, the OIG found it unclear whether the proposal could be related, at least in part, to referrals of federal healthcare program business. The transaction takes the form of a purchase of shares for cash, rather than an investment of capital in the company itself. This would allow the orthopedic surgeons selling the shares to realize a gain on their original investment, the opinion said. Because only the orthopedic surgeons would be selling shares and not the other physician investors, the possibility exists “that one purpose of the Hospital’s investment is to reward or influence a subset of the Investing Physicians whose referrals of patients to the Hospital or to the ASC itself may be particularly valuable,” the OIG found. In addition, the return on investment would not be directly proportional to the amount of capital invested by each investor. Thus, based on all these factors, the OIG concluded the arrangement posed a heightened risk of fraud and abuse. *Advisory Opinion No. 07-05 (Dep't of Health and Human Servs. Office of Inspector Gen. June 12, 2007).*

**OIG Greenlights Charitable Foundation’s Cost-Sharing/Premium Subsidies For Chronically Ill**
In an advisory opinion issued July 30, 2007, the Department of Health and Human Services Office of Inspector General (OIG) ruled out administrative sanctions in connection with a nonprofit, tax-exempt, charitable foundation’s arrangement to subsidize out-of-pocket costs of financially needy Medicare and Medicaid patients with certain chronic diseases. Based on objective financial need criteria, the foundation provides premium and cost-sharing grants to patients, including Medicare and Medicaid beneficiaries, with certain chronic diseases for documented out-of-pocket expenses associated with outpatient prescription drug treatment. A healthcare consulting company,
with commercial clients that include pharmaceutical manufacturers, administers the arrangement for the foundation. Most of the funding for the arrangement is provided by manufacturers of drugs that are used to treat diseases covered by the foundation’s disease-specific programs.

The OIG noted two areas required scrutiny under the prohibition against beneficiary inducements and the Anti-Kickback Statute—the donor contributions to the foundation and the foundation’s grants to patients. Citing the totality of the requestors’ certifications, the OIG found the design and administration of the arrangement adequately interposed “an independent, bona fide charitable organization between donors and patients” making improper beneficiary inducements or unlawful foundation referrals unlikely. Among other factors, the OIG noted that no donor exerts direct or indirect control over the foundation’s programs; financial assistance is awarded based on objective criteria and without regard to any donor’s interest or applicant’s choice of product; and the foundation only provides donors with aggregate data of qualifying applicants not information that would allow a donor to correlate the amount or frequency of its donations with the amount or frequency its products are used.

The OIG acknowledged the consulting company’s commercial relationships with its pharmaceutical clients could create a significant risk that the arrangement would be “misused as a conduit for pharmaceutical clients to provide remuneration to Medicare or Medicaid beneficiaries who use the clients’ products.” But the OIG noted the requestors had certified that the consulting company’s commercial operations would remain entirely separate from its role as the arrangement’s administrator by erecting an “ethical wall” including a confidentiality agreement, an independent foundation project team, and regular employee training and monitoring.

The OIG also found that the foundation’s subsidy to financially needy Medicare and Medicaid beneficiaries was unlikely to improperly influence their selection of providers because grants would be distributed on a first-come, first-serve basis to the extent funding is available; eligibility for assistances is based solely on financial need; patients have already selected a provider or specific product before applying for financial assistance; and the foundation has a significant incentive to monitor utilization to keep subsidies to a minimum so as to preserve its own scarce resources. Advisory Opinion No. 07-06 (Dep’t of Health and Human Servs. Office of Inspector Gen. July 23, 2007).

OIG Says It Would Not Impose Sanctions On Charitable Foundation’s One-Time Cash Donation To Senior Residence Program
The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted July 30, 2007 that, although a proposal by a charitable foundation (Requestor) affiliated with a health system to make a one-time cash donation to a senior residence program could generate prohibited remuneration under the Anti-Kickback Statute, the agency would not impose administrative sanctions. According to the opinion, the health system operates the only hospital in a city within a region of 25 counties that are all federally designated “medically underserved areas.” The Requestor is a charitable foundation formed by the health system to assist hospitals and other
nonprofit providers of health services within the region, as well as to provide grants and scholarships to ensure the continuation and improvement of quality healthcare to the region’s residents, the opinion said. The Requestor, the health system, and the hospital are all nonprofit entities exempt from federal taxation.

Under the Requestor’s proposal, it would give a one-time cash donation to a nonprofit senior services entity that operates a retirement community providing affordable housing options for seniors in the region. The retirement community includes independent living cottages, a personal care program for seniors who can no longer function in an independent living environment, and a skilled nursing facility. As part of the skilled nursing facility, the retirement community developed in 2003 a residential project that is designed to “de-institutionalize” nursing home residents in order to improve their quality of life. To finance development of this residential project, the retirement community sought to raise a total of $3.9 million and asked the Requestor to provide a single, unrestricted contribution of $100,000.

The OIG concluded that, under these facts, it was unlikely any purpose of the proposed donation was to generate business for the health system and therefore the donation would not likely result in fraud or abuse. Specifically, the OIG noted the proposed donation was unrestricted as to the use of the donated funds, was proportional to contributions from other regional businesses of similar size to the foundation, and “constituted only a small percentage of the retirement community’s overall fundraising campaign.” The OIG also highlighted that the proposed donation was a “one-time only, fixed-in-advance payment,” and that the Requestor had certified neither the offer nor the amount of the donation took into account the volume or value of any referrals or other business that the retirement community might generate for the health system. *Advisory Opinion No. 07-07* (Dep’t of Health and Human Servs. Office of Inspector Gen. July 23, 2007).

**OIG Finds DME Providers’ Proposal To Provide Patients With Free CHF Assessment Could Be Basis For Sanctions**

In an advisory opinion posted July 30, 2007, the Department of Health and Human Services Office of Inspector General (OIG) concluded that a durable medical equipment (DME) supplier’s proposal to provide patients with a free in-home congestive heart failure (CHF) assessment could generate prohibited remuneration under the Anti-Kickback Statute. According to the opinion, the two requestors operate DME companies that furnish, among other things, home oxygen products and services to a national patient population that includes Medicare and Medicaid program beneficiaries. The requestors proposed to provide patients diagnosed with CHF with an in-home CHF assessment with oximetry testing, free of charge. During the in-home assessment, the patient would also undergo pulse oximetry conducted at rest, with activity, and overnight.

The OIG noted that the proposed arrangement implicated both the Anti-Kickback Statute and the civil monetary penalties (CMP) provision. The OIG concluded the services would constitute prohibited remuneration under the CMP because the value of the testing is more than nominal and could “lead a reasonable beneficiary to believe that he or she is receiving a valuable service that may expedite access to covered oxygen supplies and
contribute to a successful clinical outcome.” In addition, the OIG found the proposal would be likely to influence beneficiaries to select the requestors as their supplier of oxygen or other Medicare-payable goods and services. Finally, the OIG noted that certain aspects of the arrangement “appear calculated to generate subsequent business for the Requestors.” Advisory Opinion No. 07-08 (Dep’t of Health and Human Servs. Office of Inspector Gen. July 30, 2007).

OIG Says It Will Not Impose Sanctions On Retail Warehouse Reward Program
A warehouse club reward program under which certain members receive an annual reward based on the amount spent on purchases, including pharmaceutical purchases, does not run afoul of the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted August 28, 2007. According to the opinion, the requestor, who operates membership warehouse clubs, offers several levels of membership for differing fees. Premium Members receive an annual reward based on the amount spent at the warehouse that year including their pharmaceutical cost-sharing amounts.

The OIG noted that the proposed arrangement potentially implicated the civil monetary penalty (CMP) provision prohibiting beneficiary inducements, as well as the Anti-Kickback Statute. With regard to the CMP, the OIG said the reward based on the amount a Premium Member spends that year on purchases, including Part D pharmaceutical cost-sharing amounts, constituted remuneration to the Premium Member who received it. But the OIG ultimately found it unlikely that the arrangement would induce Premium Members to select the requestor as their provider of items or services payable by Medicare or Medicaid. The opinion noted the absence of a direct tie between the purchase of pharmaceuticals and the reward. In addition, the small annual reward would be “unlikely to drive beneficiaries’ Federal business to Requestor because the availability of Federally reimbursable products at the Warehouses presents a relatively small opportunity for Premium Members to accrue the annual reward.”

Turning to the Anti-Kickback Statute, the OIG found the arrangement presented a low risk of steering beneficiaries to the warehouses to purchase pharmaceuticals or other federally payable items or services and “appear[ed] unlikely to encourage overutilization or otherwise increase costs to Federal health care programs.” The opinion also likened the arrangement to more of an across-the-board price reduction than a kickback scheme. Advisory Opinion No. 07-09 (Dep’t of Health and Human Servs. Office of Inspector Gen. Aug. 28, 2007).

OIG OKs Medical Center Proposal To Pay Physicians For On-Call ED Coverage
A medical center’s proposal to compensate physicians for providing on-call coverage does not run afoul of the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an Advisory Opinion posted September 27. The requestor, a tax-exempt, not-for-profit medical center, runs an emergency department (ED) that always remains open and accepts all people regardless of their ability to pay, the opinion said. Nearly one in four patients visiting the ED has no form of health insurance, whether private or governmental, the opinion noted, and
underinsured and uninsured patients often present through the ED and move on to follow-up care as medical center inpatients.

Faced with a shortage of physicians willing to provide ED on-call coverage, the medical center proposed an arrangement under which it would pay a per diem rate to physicians for each day spent on-call at the ED, except for one and one-half days that each physician must contribute free of charge to the rotation schedule monthly. The medical center certified that the per diem rates paid under the arrangement are, and will be, fair market value for the services provided and are not, and will not, take into account in any way the volume or value of referrals or business generated between the parties, the opinion said.

In finding that it would not impose sanctions on the proposed arrangement, the OIG noted hospital's increasing difficulties in sustaining necessary on-call physician services without providing compensation for on-call coverage. While on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a hospital, it should be possible to structure on-call coverage compensation to satisfy the personal services safe harbor at 42 C.F.R. § 1001.952(d), the OIG explained. Here, the OIG found the personal services safe harbor did not apply to the arrangement because the hospital’s payments to physicians were not “set in advance” as required under the safe harbor. Nevertheless, OIG concluded the arrangement “presents a low risk of fraud and abuse,” pointing to the fact that the payments are fair market value for actual services needed and provided, without regard to referrals.

In addition, the opinion noted that the per diem payments are administered uniformly for all doctors in a given specialty. The opinion also pointed to other facts that tended to minimize the risk of fraud and abuse such as the medical center's legitimate unmet need for physicians to provide the call coverage and monthly call obligations in each specialty were divided as equally as possible, “a practice that suggests that call scheduling is not being used to selectively reward the highest referrers.” Advisory Opinion No. 07-10 (Dep’t of Health and Human Servs. Office of Inspector Gen. Aug. 28, 2007).

OIG Approves Charity’s Proposal To Help Financially Needy Cancer Patients With Out-Of-Pocket Costs

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted October 3, 2007 that it would not impose administrative sanctions in connection with a nonprofit, tax-exempt charity’s proposal to establish a foundation that would provide grants to financially needy cancer patients to defray their out-of-pocket treatment costs. The requesting charitable organization currently offers some financial assistance but mostly provides education and counseling services to patients with cancer and their families.

The foundation proposed by the charitable organization would provide grants to help pay cost-sharing obligations and premiums for the drugs used by financially needy cancer patients, including those covered under federal healthcare programs. The foundation would be funded, in part, by donations from manufacturers of drugs used to treat the
cancers and conditions incident to cancer therapy and by suppliers of the types of services used by the relevant patient population.

The OIG said the proposal was structured to “interpose an independent, bona fide charitable organization between donors and patients” making it unlikely that donor contributions would influence any federal healthcare program beneficiary’s selection of provider, practitioner, supplier, or product. In reaching this conclusion, the OIG cited a number of factors including the foundation’s independent and autonomous status; that awards would be made based on objective financial criteria and on a first-come-first served basis; and that no individual patient information would be conveyed to donors. While the foundation would permit donors to earmark donations for particular disease categories, the organization certified that no donor would directly or indirectly influence the identification of the disease categories.

The OIG also found that the foundation’s grant to financially needy federal healthcare program beneficiaries was not likely to influence their choice of provider, supplier, or product. Specifically, the OIG noted safeguards including that the subsidies would serve to expand beneficiary choice and the organization’s own interest in using scarce resources to fulfill its charitable mission “ensures that the Foundation will have a significant incentive to monitor utilization so as to keep subsidies at a minimum.”


**OIG Says Veterans’ Homes May Accept No-Cost/Low Cost Bids For Therapy Services**

The Department of Health and Human Services Office of Inspector General (OIG) would not impose administrative sanctions under the Anti-Kickback Statute in connection with two proposals to accept low or no-cost bids for therapy services provided to uninsured patients at veterans’ homes, according to Advisory Opinion No. 07-12. The requestor operates long term care facilities for veterans. As required by state law, the requestor issued an Invitation for Bids (IFB) to secure physical therapy, occupational therapy, and speech pathology services at two of its veterans’ homes.

Under the IFB, the veterans’ homes would reimburse the selected contractor the bid price for uninsured patients. For residents covered by public or private health insurance, the contractor would bill those payors directly while the veterans’ home would pick up any cost-sharing amounts due from those residents. Thus, contractors essentially were bidding on how much they would charge to provide their services to the uninsured residents of the veterans’ homes, the opinion noted. The lowest responsive and responsible bidder submitted a no-cost bid for one of the veterans’ homes and a low-cost bid for the other home. If selected, the low bidder would provide the services for free or at low cost to uninsured residents, with savings inuring to the state, the opinion said.

The OIG noted that the proposed arrangement implicated the Anti-Kickback Statute because the requestor “could be giving the Low Bidder exclusive access to Federal health care program business in exchange for the Low Bidder providing the Services to
uninsured residents for free or at discounted rates,” which the requestor would otherwise have to pay. But the OIG ultimately concluded a number of factors mitigated fraud and abuse concerns and therefore it would not impose administrative sanctions with respect to the proposals.

The OIG noted that the bidding process for the services was conducted in an open and competitive manner and in accordance with state requirements. The OIG also perceived a low risk that the agreement would result in inappropriate utilization because the services could only be ordered by the physicians of the veterans’ homes (who had no financial ties to the low bidder) and because the homes had to reimburse the low bidder for all cost-sharing amounts (giving them an incentive to monitor utilization). In addition, the requestor is a state agency and the benefit of the financial savings from the proposed arrangement would insure to the state’s citizens by conserving resources, the opinion said.

Finally, the OIG found the fact that the veterans’ homes would pay cost sharing on behalf of Medicare or Medicaid beneficiaries would not amount to improper inducements. Unlike a private entity, in the context of a state-operated system of veterans’ homes, “the incidental prospect of a State subsidy of cost-sharing amounts is unlikely to influence a veteran’s choice of one of the Veterans’ Homes as his or her nursing facility,” the OIG concluded. Advisory Opinion No. 07-12 (Dep’t of Health and Human Servs. Office of Inspector Gen. Oct. 10, 2007).

OIG Says Arrangement To Allow Optometrists To Become Owners Of ASCs Could Raise Anti-Kickback Concerns

The Department of Health and Human Services Office of Inspector General (OIG) would not rule out administrative sanctions in connection with a proposed arrangement to allow nine optometrists in a group practice to become owners in a surgery center that operates three single-specialty ophthalmology ambulatory surgical centers (ASCs), according to an advisory opinion posted October 19, 2007. The surgery center, according to facts presented in the opinion, is owned jointly by eight ophthalmologists and a hospital owned by a nonprofit hospital system. The ophthalmologists and the hospital also have ownership interests in the group practice, which employs both the optometrists and the ophthalmologists.

At present, the optometrists make referrals to the ophthalmologists for treatment of specific eye diseases or injuries. In general, they refer patients for all non-inpatient services to group practice facilities or to one of the surgery center’s ASCs. The ophthalmologists perform all surgical procedures at the ASCs, although some of the optometrists assist the ophthalmologists in pre- and post-operative work at the ASCs. Under the proposed arrangement, according to OIG, the hospital would sell some of its ownership interests in the surgery center to the optometrists over a three-year period, and some shares also would be reallocated to the ophthalmologists.

The OIG found the proposed investment failed to satisfy the safe harbor for investment interests in hospital/physician-owned ASCs, set forth at 42 C.F.R. § 1001.952(r)(4),
which requires among other things that “ownership is limited to physicians who perform ASC procedures on a regular basis, as demonstrated by meeting a one-third practice income test, and other investors who are not in a position to generate referrals to the ASC or its investors.” Under the proposed arrangement, the optometrists would perform no ASC procedures as defined in the safe harbor, but they would generate referrals to other investors (e.g., the ophthalmologists) and, indirectly, to the ASCs, OIG explained.

The OIG also found "no discernible safeguards to minimize the significant risk that the Proposed Arrangement would be a vehicle to provide the Optometrists with a share of the profits from their referrals to the Ophthalmologists using the Surgical Center ASCs.” The OIG pointed out that the ophthalmologists and the optometrists under the proposed arrangement are in distinctly different positions because the ophthalmologists, unlike the optometrists, personally perform surgical procedures at the ASCs. While the surgical business at the ASCs therefore could be considered an extension of the ophthalmologists’ office practice, this would not be the case for the optometrists. "As a result, the likelihood that they are using their investment in the Surgical Center simply as a vehicle for receiving remuneration for referrals of patients to the Ophthalmologists increases significantly," OIG said. Advisory Opinion No. 07-13 (Dep’t of Health and Human Servs. Office of Inspector Gen. Oct. 19, 2007).

OIG Allows Ambulance Transport Arrangement Involving Certain Payments To County

The Department of Health and Human Services Officer of Inspector General (OIG) would not impose sanctions on an arrangement where ambulance companies under contract with a county government would provide free transport for arrestees and would pay certain fees to the government, according to an advisory opinion posted October 19, 2007. The requestor, a county that operates an emergency medical services (EMS) system, provides ambulance transportation and pre-hospital emergency medical care to county residents. All EMS dispatches are conducted through the County Fire Protection District (FPD). The county has continuously contracted with the same three ambulance companies (Ambulance Services) to serve the EMS system since 1981.

Under the proposed arrangement, the Ambulance Services would bear the cost of transporting uninsured arrestees, but would be able to bill, or seek to collect from, either the individual arrestee or third-party payors other than the county. Ambulance Services also would be required to reimburse the county for the costs it incurs in providing quality assurance oversight, medical oversight, and contract administration services with respect to the EMS system. Lastly, the Ambulance Services would be required to pay FPD a share of the overall estimated costs of providing EMS dispatch services.

The OIG said the proposed arrangement implicates the Anti-Kickback Statute because it requires that the Ambulance Services bear the cost of transporting uninsured arrestees and pay the county for certain services as part of the exclusive contracts to provide emergency ambulance transport services in the county, some of which would be reimbursable under federal healthcare programs. But the OIG pointed to several mitigating factors in its decision not to impose sanctions.
Specifically, the OIG noted the arrangement would be part of a comprehensive regulatory scheme by the county to manage the delivery of EMS and would provide only partial compensation for the actual costs of the county's delivery of oversight and administration related services and the FPD's delivery of dispatch services. The opinion further found the “putative prohibited remuneration” would inure to the public benefit and the arrangement would not fundamentally change the system for delivery of emergency services in the county that has been in place for years. Advisory Opinion No. 07-14 (Dep’t of Health and Human Servs. Office of Inspector Gen. Oct. 19, 2007).

OIG Says Medigap Insurer May Contract With PPO For Hospital Discounts
An insurer that offers Medicare Supplemental Health Insurance (Medigap) policies would not be subject to administrative sanctions for using a “preferred hospital” network to obtain discounts on Medicare deductibles it would otherwise be liable for, the Department of Health and Human Services Office of Inspector General (OIG) found in an advisory opinion posted December 10, 2007.

The requestor, a mutual life insurance company, offers Medigap policies nationwide. Under the proposal, the Medigap insurer would contract with preferred provider organizations (PPOs) and receive a discount of up to 100% on Medicare Part A deductibles when policyholders use the PPOs' network hospitals. To give policyholders incentives to use network hospitals, the Medigap plan would provide a $100 credit off their next renewal premium for using participating hospitals. The opinion also noted that savings realized under the proposed arrangement would be reflected in the reports filed annually with state insurance departments that regulate Medigap premiums.

The OIG said the arrangement implicated both the Anti-Kickback Statute (as remuneration for selecting the network hospital) and the civil monetary prohibition on inducement to beneficiaries (with respect to the premium credit). But the OIG concluded that certain mitigating factors made the risk of fraud and abuse low.

Specifically, the OIG noted the discounts on inpatient deductibles would not increase per service Medicare Part A payments for inpatient services, which are fixed and unaffected by beneficiary cost sharing. In addition, the OIG said the discounts effectively would be invisible to patients and, therefore, were not likely to increase utilization. The proposed arrangement also would be unlikely to affect professional medical judgment, since the patient’s physician or surgeon would receive no remuneration and the patient could still choose any hospital they wanted without incurring any additional out-of-pocket expense.

As to the premium credit for patients who stay in network hospitals, the OIG said this aspect of the proposal implicated the prohibition on inducements to beneficiaries because it was premised on a patient choosing a particular provider from a broader group. “However, there is a statutory exception for differentials in coinsurance and deductible amounts as part of a benefit plan design, if the differential has been properly disclosed to affected parties and otherwise meets any requirements of corresponding regulations,” the
opinion said. Although not technically a differential in a coinsurance or deductible amount, the OIG said the premium credit would have substantially the same effect.

Finally, the OIG noted overall the proposal had the potential to lower Medigap costs for policyholders, particularly because the savings would be reported to state regulators charged with setting Medigap premiums. Advisory Opinion No. 07-15 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 3, 2007).

OIG Blesses HHA’s Provision Of Free Educational Videos To Prospective Patients
The Department of Health and Human Services Office of Inspector General (OIG) would not impose administrative sanctions on a home health agency (HHA) that provides prospective orthopedic patients with free instructional videos on postoperative home-based convalescence, according to an advisory opinion posted December 12, 2007. The requesting HHA provides postoperative care for patients, including many covered under federal healthcare programs, who have had total knee and hip joint replacements. According to the opinion, much of the requestor’s business comes in the form of patient referrals from orthopedic surgeons who have no financial relationship with the HHA.

Before these patients undergo surgery, the HHA provides them with free instructional videos depicting their post-surgical limitations and steps to address these special needs, including recommendations on optimal furniture placement, sleeping and bathing, and negotiating stairs. The videos identify the agency as the producer at the outset and at the very end, but otherwise the HHA and its services go unmentioned, the opinion said.

The OIG first concluded the arrangement would not constitute grounds for imposing civil monetary penalties. The OIG cited a number of factors making it unlikely the videos were worth more than nominal value ($10 or less) to the patients receiving them, but said it lacked “firm evidence” to resolve the issue. The OIG went on to find, however, that the free education videos were unlikely to influence patients to select the HHA as their provider of postoperative items and services payable by Medicare or Medicaid. Specifically, the OIG noted that the videos were generally applicable to surgical patients and lacked any personalized safety or healthcare recommendations.

The OIG distinguished the distribution of free videos under the arrangement from offers by HHAs to provide free in-person and telephone preoperative home safety assessments for patients slated to undergo orthopedic surgery. In the latter instances, the OIG noted, the assessment often is performed by a trained and licensed physical therapist, leaving the patient with the impression they received something of value. By contrast, the videos are more modest and impersonal, the OIG observed. For the same reasons, the OIG found the arrangement did not raise substantial concerns under the Anti-Kickback Statute that would warrant sanctions. Advisory Opinion No. 07-16 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 12, 2007).
OIG Says Individual Excluded From Federal Healthcare Programs May License Invention To Unrelated Company

An individual who is excluded from participating in federal healthcare programs may still license an invention to a new company owned by his adult children without triggering administrative sanctions for violating the exclusion, according to an advisory opinion posted by the Department of Health and Human Services Office of Inspector General (OIG) on December 26, 2007. The individual in question pled guilty to a misdemeanor under 42 U.S.C. § 1320a-7b(a)(2) and was sentenced to three years’ probation and a $2 million fine. As a result, in March 2005, the OIG excluded the individual from participating in Medicare, Medicaid, and federal healthcare programs for a mandatory five-year period, the opinion said. The excluded individual has a patented invention that currently is being marketed outside the United States.

Under the proposed arrangement, the individual’s three adult children would create a new company that would have a royalty-free, non-exclusive license to sell or lease the invention in the U.S. for the life of the patent. Alternatively, the new company could use the intellectual property associated with the invention under a covenant with the excluded individual in which the individual agreed not to sue for infringement. The new company would then lease or sell the invention to independent distributors who would in turn lease or sell the invention to healthcare providers and suppliers. The opinion noted that pursuant to the proposal the new company would be completely independent of the individual, who would have no ownership interest and no rights to current or future payments.

The OIG concluded that the proposed arrangement would not violate the individual’s exclusion. First, the OIG noted that under the proposal the individual would not be directly submitting claims for the invention to federal healthcare programs. Rather, the OIG continued, the scenario here presented the question whether the excluded individual would be indirectly furnishing the invention or causing claims for it to be submitted to federal programs. Answering this question in the negative, the OIG found “the intervening and independent entities” (i.e. the new company and its distributors), together with certifications that the individual “would have no relationship—financial or otherwise”—with the new company, “would sufficiently attenuate [the individual] from any claims submitted to federal healthcare programs by downstream providers or suppliers . . . .”

Although the OIG said the agreement aroused some concerns given the family relationship between the owners of the new company and the individual, it ultimately relied on the individual’s certifications that there were no other agreements that would serve as a conduit for any financial benefit to the individual. Advisory Opinion No. 07-17 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 19, 2007).

OIG Says Charitable Foundation May Subsidize Cost-Sharing/Premiums Of Financially Needy Medicare, Medicaid Patients

In an advisory opinion posted January 3, 2008, the Department of Health and Human Services Office of Inspector General (OIG) ruled out administrative sanctions in
connection with a nonprofit, tax-exempt, charitable foundation’s existing and proposed arrangements to subsidize cost-sharing and premium obligations for outpatient drugs of financially needy Medicare and Medicaid patients. Based on objective financial need criteria, the foundation through a series of charitable funds provides cost-sharing grants for patients with certain serious diseases for documented out-of-pocket expenses associated with outpatient prescription drug treatment. The foundation also is proposing to provide comparable assistance with premium obligations to financially needy Medicare and Medicaid beneficiaries.

A healthcare consulting company, with commercial clients that include pharmaceutical manufacturers, helped to devise and now administers the arrangements for the foundation. Most of the funding for the arrangements is provided by manufacturers of drugs that are used to treat diseases covered by the foundation’s disease-specific programs.

In an opinion that closely mirrored an earlier advisory opinion (No. 07-11), the OIG found the design and administration of the arrangements adequately interposed “an independent, bona fide charitable organization between donors and patients” making improper beneficiary inducements or unlawful foundation referrals unlikely. Among other factors, the OIG noted that no donor exerts direct or indirect control over the foundation’s programs; financial assistance is awarded based on objective criteria and without regard to any donor’s interest or applicant’s choice of product; and the foundation only provides donors with aggregate data of qualifying applicants not information that would allow a donor to correlate the amount or frequency of its donations with the amount or frequency its products are used.

The OIG acknowledged the consulting company’s commercial relationships with its pharmaceutical clients could create a “significant risk” that the arrangements could be “misused as conduits for pharmaceutical clients to provide remuneration to Medicare or Medicaid beneficiaries who use the clients’ products.” But the OIG noted the requestors’ certifications that the consulting company’s commercial operations would remain entirely independent from its role as the arrangements’ administrator by erecting an “ethical wall” including a confidentiality agreement, an independent foundation project team, separate physical space for personnel assigned to the foundation, and regular employee training and monitoring. The OIG cautioned that the advisory opinion would be “without force” should the steps taken to ensure the arrangements operated independently from the consulting company’s commercial operations fail.

The OIG also found the foundation’s subsidies to financially needy Medicare and Medicaid beneficiaries were unlikely to improperly influence their selection of providers because grants would be distributed on a first-come, first-served basis to the extent funding is available; eligibility for assistances is based solely on financial need; patients have already selected a provider or specific product before applying for financial assistance; and the foundation has a significant incentive to monitor utilization to keep subsidies to a minimum so as to preserve its own scarce resources. *Advisory Opinion No. 07-18* (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 19, 2007).
Radiology Group May Prepare, Without Charge, Radiology Test Reports For Critical Access Hospital, OIG Says
The Department of Health and Human Services Office of Inspector General (OIG) said that it would not impose sanctions under the Anti-Kickback Statute in connection with a radiology group preparing free written reports of its interpretations of radiology tests for a rural critical access hospital, according to an advisory opinion posted January 3, 2008. Under the arrangement, the requestor, a small, rural, critical access hospital, has an exclusive contract for radiology services with the radiology group, and via teleradiology, transmits digitized images of hospital patients to the requestor for interpretation.

“The Group interprets the images, prepares written reports documenting the physician’s interpretation, and bills third-party payors, including Medicare, Medicaid, and other payors, for professional radiology services rendered by the Group’s physicians,” the opinion said. The radiology group does not charge the requestor hospital for the written reports of its interpretations that it prepares for inclusion within the patient’s medical record maintained by the hospital.

The OIG highlighted the central issue as whether “the Hospital is receiving something of value from the Group (free written reports) in return for referring Federal payor patients to the Group for professional radiology services, pursuant to the Hospital’s exclusive contract with the Group.” The OIG determined that, while the arrangement could implicate the Anti-Kickback Statute, it would not impose administrative sanctions.

First, the OIG said it was advised by the Centers for Medicare and Medicaid Services (CMS) that, under the applicable Medicare payment rule, the preparation of the written report for radiology services furnished to hospital patients is part of the covered professional service that is reimbursed to the radiologist under Medicare Part B, and therefore the radiologist is obligated to prepare a written report for such patients in order to receive reimbursement. “The Group’s preparation of the written report at its own cost is proper, according to applicable payment rule,” the OIG concluded, noting that CMS also advised that the hospital is not obligated under this payment rule to incur the costs of preparing a written report documenting professional services of radiologists provided to its patients.

Second, “[i]f the Hospital reimbursed the Group for costs incurred for preparing the written report, the Group would receive double payment for the same incurred costs, that is, a payment from the Hospital and a payment from Medicare,” the OIG noted. Therefore, OIG concluded that “the free reports for Medicare patients do not constitute remuneration to the Hospital.”

Acknowledging that it could not “conclude definitively” that the requestor hospital receives no remuneration under the arrangement for non-Medicare patients, OIG said it determined the arrangement posed “a low risk” under the Anti-Kickback Statute. Quoting from its Supplemental Hospital Compliance Program Guidance (70 Fed. Reg. 4858), OIG said “an exclusive arrangements that requires a hospital-based physician or physician group to perform reasonable administrative or limited clinical duties directly related to
the hospital-based professional services at no or a reduced charge would not violate the anti-kickback statute, provided that the overall arrangement is consistent with fair market value in an arm’s-length transaction, taking into account the value attributable to the exclusivity” (emphasis in original).

In this case, the requestor hospital “has certified that overall its exclusive relationship with the [radiology group] is and will continue to be at fair market value in an arm’s length transaction, including the value of the exclusivity (but not including the value attributable to referrals to the Group),” the OIG noted. The radiology group’s preparation of the free reports at issue therefore “appears to be a reasonable and limited service that directly relates to the professional radiology services provided by the Group” under its exclusive relationship with the requestor hospital, the OIG concluded. Advisory Opinion No. 07-19 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 21, 2007).

OIG Allows Physician To Invest In Imaging Center In Area Hit By Hurricane Katrina

The Department of Health and Human Services Office of Inspector General (OIG) will not impose sanctions under the Anti-Kickback Statute regarding a physician’s proposal to establish an Imaging Center in the same building as his medical practice in an area devastated by Hurricane Katrina, under an advisory opinion posted January 3, 2008. According to the opinion, the physician requestor is one of only a small number of physicians still practicing in the unnamed Parish after it was hard hit by the hurricane. Currently, no medical imaging services are available in the Parish.

The opinion noted that the requestor and his brother would each contribute half of the capital necessary to fund the Imaging Center and would each own 50%. The OIG considered the safe harbor for investment in small entities in underserved areas, 42 C.F.R. § 1001.952(a)(3), but found the arrangement would not satisfy the requirement that no more than 50% of investment interests in the entity be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity.

In further examining the facts and circumstances of the arrangement, however, the OIG found the fact that the requestor’s brother would own 50% of the Imaging Center “does not materially increase the risk of fraud and abuse, particularly when viewed in light of the Proposed Arrangement’s substantial potential community benefits.” The opinion noted that the requestor’s brother “is not currently in the health care business, will not be compensated as business manager in any manner that depends on his generating business for the Imaging Center, and will receive a fair market value salary for actual and necessary services rendered to the Imaging Center.”

Finally, the OIG found that any residual risk posed by the arrangement would be offset by the “special conditions” under which the Imaging Center would be established. The OIG explained that access to healthcare is a paramount concern and the “devastation to health care services in the area to be served by the proposed Imaging Center is well-known.” Accordingly, the OIG concluded “the risk of fraud and abuse posed by the
Proposed Agreement is relatively low and offset by potential improvements in access to care in an area still recovering from catastrophic damage to its healthcare infrastructure.”


OIG Approves Hospital “Gainsharing” Arrangements With Physician Groups

The Department of Health and Human Services Office of Inspector General (OIG), in an advisory opinion posted January 14, 2008 (No. 07-21), said an existing arrangement under which a hospital shares a percentage of its cost savings with cardiac surgeons who implement certain cost-reduction measures in the operating room to reduce waste and use of specific supplies would not trigger administrative sanctions. In a separate advisory opinion (No. 07-22) posted the same day, the OIG likewise approved a similar “gainsharing” arrangement with an anesthesiology group aimed at reducing waste and use of specific devices and supplies during certain cardiac surgery procedures.

The OIG said in the two opinions that gainsharing arrangements have the potential to implicate the civil monetary penalty (CMP) and the Anti-Kickback Statute, raising concerns such as stinting on patient care; “cherry picking” healthy patients and steering sicker and more costly patients to other hospitals; payments for patient referrals; and unfair competition, or a “race to the bottom” among hospitals. At the same time, the OIG acknowledged that “[p]roperly structured, arrangements that share cost savings can serve legitimate business and medical purposes.” The OIG found the arrangements at issue “markedly different from ‘gainsharing plans’ that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost lowering-activities.”

Under the existing arrangement described in Advisory Opinion No. 07-21, the hospital will pay the group of cardiac surgeons, all of whom currently have active medical staff privileges at the hospital, 50% of first-year cost savings achieved by implementing 25 specific cost-saving measures in their operating room practices designed to curb the inappropriate use or waste of medical supplies. At the end of the first year, cost savings would be calculated separately for each of the 25 recommendations. A program administrator paid by the hospital to oversee the arrangement detailed the specific cost-saving opportunities in an “Executive Summary” based on historic practices at the hospital’s cardiac surgery department, the opinion said. The 25 cost savings recommendations were grouped into four categories—refraining from opening disposable components of the cell saver unit until a patient experiences excessive bleeding; 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.

The existing arrangement discussed in Advisory Opinion No. 07-22 involved a nearly identical scenario in which the hospital will pay an anesthesiology group, all of whom currently have active medical staff privileges at the hospital, 50% of first-year cost savings achieved by implementing five specific cost-saving opportunities. The program administrator likewise detailed the cost-saving measures—grouped as “use as needed”
recommendations; product substitution; and product standardization—in an “Executive Summary of Value Share for Cardiac Anesthesia.”

The OIG found both arrangements implicated the CMP because they “might have induced physicians to reduce or limit the then-current medical practice at the Hospital,” adding that “whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.” Nonetheless, the OIG found sufficient safeguards to mitigate its fraud and abuse concerns.

For example, the OIG highlighted that “specific cost-saving actions and resulting savings were clearly and separately identified,” allowing transparency and individual physician accountability. The OIG also noted “credible medical support for the position that implementation of the recommendations did not adversely affect patient care.” In additions, the arrangements protected against inappropriate reductions in services by using objective historical and clinical measures to establish baseline thresholds beyond which no savings will accrue to the groups. For example, the arrangement in Advisory Opinion No. 07-21 established a 30% “floor” for the cell saver measure based on best practice utilization. The cardiac surgical group will not receive any savings resulting from reductions in cell saver use below this threshold, the opinion explained. Both arrangements also required the hospital requestor and the surgical groups to provide written disclosure of the arrangements to patients; limited financial incentives in duration and amount; and reduced individual physician incentives by distributing profits to members of the groups on a per capita basis.

As to the Anti-Kickback Statute, the OIG noted concerns that the arrangements could have been used to disguise remuneration from the hospital to reward or induce referrals by the physicians or their respective groups. The OIG also observed that the arrangements did not fall under the personal services and management contracts safe harbor because the payment owed to the groups was calculated on a percentage basis and therefore the aggregate compensation was not set in advance. But again, the OIG concluded the arrangements included mitigating factors that significantly lowered the risk of fraud and abuse.

Specifically, the OIG noted that the arrangements limited participation to surgeons and anesthesiologists already on the medical staff; potential savings derived from procedures on federal healthcare program beneficiaries were capped based on the prior year’s admissions of federal healthcare program beneficiaries; and the contract year was limited to one year. The OIG also said the cost-saving recommendations represented a change in operating room practice that could expose the surgeons to some additional liability. “It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice,” the OIG said. Advisory Opinion No. 07-21 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 28, 2007) and Advisory Opinion No. 07-22 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 28, 2007).
HHS OIG Says PAPs May Donate Drugs To Free Clinics And FQHCs For Financially Needy Who Lack Drug Coverage

A nonprofit corporation’s program that arranges for pharmaceutical manufacturer patient assistance programs (PAPs) to provide donated drugs to free clinics and federally qualified health centers (FQHCs) for use by financially needy patients who lack any form of outpatient prescription drug coverage would not trigger administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted February 1, 2008. The nonprofit corporation, referred to in the opinion as the “Partnership,” is funded by state appropriations, contributions from individuals and foundations, and participant fees from free clinics and FQHCs.

On behalf of its affiliated free clinics and FQHCs, the Partnership’s role in the proposed arrangement is to seek participation in various bulk replacement PAPs sponsored by pharmaceutical companies that provide in-kind donations in the form of free drugs. Under the arrangement, FQHCs and free clinics would distribute the donated PAP drugs to patients meeting certain income requirements and who lack any form of outpatient prescription drug insurance.

The OIG first examined, then rejected, the application of the new safe harbor for certain FQHC arrangements, 42 C.F.R. § 1001.952(w). The OIG found the arrangement did not fit squarely within the safe harbor because the FQHCs were not required to make the requisite determinations regarding benefit to underserved populations and the free drugs offered by PAP sponsors were not offered to all FQHC patients regardless of payor status.

With respect to the free clinics, the OIG cited its main concerns as whether the arrangement could serve as a vehicle for the PAP sponsors to offer or pay remuneration to induce the clinics to purchase or order the sponsors’ products or to influence the prescribing patterns of clinic physicians. But the OIG ultimately concluded it would not impose sanctions in connection with the arrangement, finding no apparent remuneration provided by the PAPs to the Partnership or the affiliated free clinics. “[W]hile the Arrangement more generally benefits the affiliated free clinics through the conservation of clinic funds that might otherwise be used to purchase medications, the benefit insures to the public good in the form of increased availability of healthcare items and services for an underserved population,” the OIG said.

In addition, the free clinics treat only uninsured patients and therefore are not in a position to generate business for any PAP sponsor that would be payable by a federal healthcare program. On this point, the OIG noted a heightened risk of fraud and abuse in the case of the FQHCs than the free clinics, since the FQHCs are in a position to generate federal healthcare program business. The OIG concluded, however, that the additional risk was sufficiently lessened by a number of safeguards, including the structuring of the arrangement to prevent the FQHCs from obtaining excess stock. The OIG also highlighted the arrangement’s transparency, including written agreements between each PAP sponsor and the Partnership and the requirement that the FQHCs segregate inventory and maintain detailed electronic records to create an audit trail for the
distribution of PAP drugs. Finally, the OIG said the arrangement “relates directly to the core clinical services provided by the FQHCs and helps ensure the availability of safety net health services for otherwise underserved populations.” *Advisory Opinion No. 08-01* (Dep’t of Health and Human Servs. Jan. 28, 2008).

**HHS OIG Blesses Marketing Firm’s Proposal To Offer Charitable Contributions As Incentive For Physician Surveys**

A market and research firm’s proposal to encourage physicians and other healthcare professionals to complete online surveys by offering to make a charitable contribution of their choosing would not generate prohibited remuneration under the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted February 5, 2008. The requesting firm provides research services to pharmaceutical and medical companies to help them develop clinical, marketing, and other data about how physicians diagnose and treat certain illnesses relevant to the entities’ products. The firm has a web-based program to help gather real-time market research data from targeted clinicians to benchmark educational needs, current product usage by indication, brand awareness and effectiveness, clinician attitudes, effectiveness of detailing programs, current best practices, and competitive product analysis, the opinion explained.

Under the proposed arrangements, the firm would encourage participation in program surveys by offering the opportunity to designate a public charity to which the firm or one of its clients would make a monetary charitable contribution “in the name of” the healthcare professional. “Notwithstanding the lawful purposes of most charitable donations, in some circumstances, payments characterized as ‘charitable donations’ are nothing more than disguised kickbacks intended to induce referrals,” the OIG noted at the outset of its analysis, enumerating a number of scenarios in which these concerns may arise. But the OIG ultimately concluded the proposed arrangement did not implicate the Anti-Kickback Statute because it “would be structured to prevent health care professionals from receiving any actual or expected economic or other actionable benefit from the charitable contributions.”

In reaching this conclusion, the OIG noted a number of factors, including that all donations would be made directly to the charities and the healthcare professionals would not be entitled to any tax deduction or other monetary benefit from the donation. In addition all designated charities would be § 501(c)(3) organizations, would be public charities, and would meet the public support test of Internal Revenue Code § 509(a), minimizing the risk that the donations would be made to private foundations or other organizations subject to the direction or control of the designating healthcare professional. Finally, the healthcare professional must certify that neither he or she, nor any immediate family member, hold a position on the board of the designated charity, is employed by the charity, or has any other financial relationships with the charity. “Given the facts and circumstances of the Proposed Arrangement, the actual or expected benefits to the health care professionals who complete a survey and designate a charity would be wholly intangible in the form of potential personal satisfaction,” the OIG concluded.

**OIG Gives Green Light To Health System’s Proposal To Provide Prompt Pay Discounts To Patients**

A healthcare system’s proposal to provide prompt pay discounts to all of its insured patients, including those covered by Medicare and Medicaid, would not trigger administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted February 8, 2008. The health system, which owns and operates two acute care hospitals and a critical access hospital, proposed offering discounts to all patients for prompt payment of their cost-sharing amounts and amounts owed for non-covered services for which patients received an advanced beneficiary notice, according to the opinion.

While the health system’s proposed arrangement could generate improper remuneration to federal healthcare program beneficiaries, the OIG said it would not impose administrative sanctions under the Anti-Kickback Statute. In addition, the OIG concluded that the proposed arrangement did not constitute grounds for the imposition of civil monetary penalties under federal fraud and abuse laws.

In its request letter to the OIG, the health system explained that the proposed prompt pay discounts were aimed at reducing its accounts receivables and costs of debt collection, and to boost its cash flow. The proposed discounts, according to the opinion, would range from 5-15% depending on the timing of the payment and size of the remaining balance owed by the patient. Under the proposed arrangement, the health system would offer prompt pay discounts on inpatient and outpatient services to beneficiaries of federal healthcare programs along with all other insured patients. The health system further certified it would not publicly advertise the prompt pay discount opportunity, but rather would only notify patients during the billing process (e.g., when a patient pays his or her cost-sharing amount, or in billing statements sent to a patient in the mail).

The OIG found the discounted fees for inpatient services met the anti-kickback safe harbor for waivers of beneficiary coinsurance and deductible amounts for inpatient hospital services, set forth at 42 C.F.R. § 1001.952(k). According to the OIG, the arrangement met all the conditions set forth in the safe harbor, including that the facility cannot claim the waived amount as bad debt or otherwise shift the burden to the Medicare or Medicaid programs, and must make the waiver without regard to the patient’s reason for admission, length of stay, or diagnostic-related group. Under the safe harbor, the waiver also may not be a part of a price reduction agreement between the facility and a third-party payor.

Turning next to the proposed arrangement as applied to outpatient services, the OIG noted the absence of a safe harbor in this respect. The OIG concluded the proposed discounts were not “disguised” referral payments, noting the proposal incorporated various commitments to ensure the discount functioned as a legitimate prompt pay incentive and "not a means to induce patients to self-refer," the opinion said. In particular,
the OIG emphasized the health system’s certification that it would not advertise the discount opportunity, and would notify third-party payors of its prompt payment discount policies. The OIG also specified as mitigating factors the fact that the health system would notify patients (or their representatives) of the prompt pay discounts only during the course billing, and that these discounts would bear a reasonable relationship to the amount of avoided collection costs. “We believe that these features reduce the likelihood that the proposed arrangement would be used . . . to draw additional patient referrals" and are "consistent with the characterization” of the prompt payment discount as a means to achieve “more successful bill collection,” OIG said. Advisory Opinion No. 08-03 (Dep’t of Health and Human Servs. Office of Inspector Gen. Jan. 30, 2008).

OIG OKs Free Trial Rx Program For Hemophilia Patients
A manufacturer’s proposal to provide a one-time free trial of its medication to patients with hemophilia A, including Medicare and Medicaid beneficiaries, was structured to avoid triggering sanctions under the Anti-Kickback Statute (AKS), the Department of Health and Human Services Office of Inspector General (OIG) said February 12, 2008. The advisory opinion said the proposed arrangement mitigated concerns of “unscrupulous physicians reselling or billing” for the free samples because it was structured in a way that physicians would never have possession of the medication. The OIG also found the proposal included other safeguards that distinguished it from “problematic programs that offer free goods or remuneration to prescribers as a means to ‘seed’ or introduce new products into the marketplace.”

The requestor is a manufacturer of healthcare products and pharmaceuticals including the recombinant antihemophilic factor VII product at issue in the advisory opinion. Under the proposal, the manufacturer would give one complimentary trial sample of the medication to hemophilia A patients. Patients’ physicians would initiate the enrollment process, and the requestor would limit the number of enrollment forms available to physician practices or hemophilia treatment centers to no more than 20 per year. After obtaining a prescription from the physician, a pharmacy under contract with the requestor would dispense the medication directly to the patient, without the physician ever taking possession of the sample. The requestor also certified that the proposed arrangement would comply with the Prescription Drug Marketing Act of 1987 (PDMA).

The OIG concluded that the proposed arrangement did not provide any direct or indirect monetary or economic remuneration to the physicians, nor any other benefit that would warrant administrative sanctions. The OIG also concluded that the risk of abuse was low with respect to the free, one-time supply provided to hemophilia patients. Specifically, the OIG noted the proposal would entail no cost to federal healthcare programs given the safeguards in place to prevent billing for the free samples. Moreover, the OIG found a low risk of patient steering since Medicare beneficiaries choosing to stay on the medication would face substantial cost-sharing amounts, no clinical barriers existed to switching between competing treatments, and patients could not self-enroll in the program. The result may have been different, the OIG suggested, “on different facts or with a non-PDMA compliant sampling program,” the OIG added. Advisory Opinion No. 08-04 (Dep’t of Health and Human Servs. Office of Inspector Gen. Feb. 5, 2008).
OIG Approves Pharmaceutical Company’s Proposal To Place Electronic Kiosks In Certain Physicians’ Offices

A pharmaceutical company’s proposal to place in certain physicians’ offices electronic kiosks that offer patients free disease screening questionnaires would not generate prohibited remuneration under the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted February 22. The pharmaceutical company requestor develops, manufactures, and markets pharmaceutical products that are reimbursable under federal healthcare programs, including Medicare and Medicaid. The requestor explained that it currently places in physicians’ waiting rooms informational pamphlets on different “disease states” for use by physicians. Some of these pamphlets contain questionnaires that are designed to help patients determine if they should talk with their physician about a particular disease or condition.

Under the proposed arrangement, the requestor would place freestanding kiosks that offer voluntary interactive questionnaires in certain physician waiting rooms. The interactive questionnaires would consist of several questions on each of four disease states that patients would be able to answer using the kiosk keyboard. Upon answering all the questions, the patient could then generate a printout that would contain the screening questions along with the patient’s responses. The questionnaires would advise patient users to talk to their doctor about the screening results. In addition, the requestor explained that the questionnaires would not mention requestor’s drug products or contain any advertisement or incentives for using the kiosks. Moreover, the kiosk itself would display only a small image of requestor’s logo, but would not mention any drug names.

Because the questionnaires would not offer patients incentives for using the kiosks, the OIG concluded the proposed arrangement would not provide anything of value to patients and, therefore, would not implicate the Anti-Kickback Statute. The OIG did note, however, that this form of "direct-to-consumer" advertising could increase the risk of overutilization and of steering patients to brand-name drugs over cheaper generic equivalents. "The may also implicate Federal or state consumer protection laws, Food and Drug Administration regulations, or Federal Trade Commission regulations," the OIG observed.

Next, the OIG concluded the proposed arrangement did not present a potential kickback from requestor to the participating physicians to induce them to prescribe the requestor’s pharmaceutical products. The OIG highlighted that participating physicians would merely host the kiosks, but would not receive space rental or utilities fees or other compensation in connection with the proposed arrangement. In addition, the OIG concluded that the kiosk-generated questionnaires would not save any appreciable amount of physician or staff time. And the kiosks “would not enhance the attractiveness of the Participating Physicians’ office practices to prospective such that they would be likely to select a Participating Physician because he or she offered a kiosk in the waiting room,” the opinion said. Advisory Opinion 08-05 (Dep’t of Health and Human Servs. Office of Inspector Gen. Feb. 15, 2008).
OIG Issues Final Safe Harbor Rule Protecting Remuneration Provided To Federally Qualified Health Centers

The Department of Health and Human Services Office of Inspector General (OIG) issued a final rule in the October 4, 2007 Federal Register (72 Fed. Reg. 56632) establishing a safe harbor under the Anti-Kickback Statute to protect certain arrangements involving goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under § 330 of the Public Health Service Act. In order to fall under the safe harbor, the remuneration "must contribute to the health center’s ability to maintain or increase the availability, or enhance the quality, of services available to a medically underserved population," according to the rule.

OIG noted that it modified its July 2005 proposed rule significantly in response to public comments. The final rule, among other things, eliminates the proposed requirements that arrangements that do not comply with the safe harbor be terminated and that arrangements must comply with all relevant requirements of the health center’s § 330 grant funding. Under the final rule, remuneration must be medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center’s § 330 grant. In addition, according to the rule, protected arrangements must be pursuant to a contract, lease, grant, loan, or other agreement that is written, signed by the parties, and covers all of the remuneration to be provided. The amount of the remuneration must be specified and may not be conditioned on the volume or value of federal healthcare program business generated between the parties. The final rule was effective December 3, 2007.

Stark Law

CMS Issues Final Stark Phase III Regulations

The Centers for Medicare and Medicaid Services (CMS) posted August 27, 2007 the long-awaited Phase III final rule on the physician self-referral prohibition. The Stark Phase III final regulations were published in the September 5, 2007 Federal Register (72 Fed. Reg. 51012) and were effective December 4, 2007. According to the 516-page display copy posted by CMS, the final rule responds to comments on the March 26, 2006 Phase II interim final rule with comment period (69 Fed. Reg. 16054), which set forth the self-referral prohibition and applicable definitions, interpreted various statutory exceptions, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse. CMS said the Phase III final rule does not create any new exceptions and in general reduces “the regulatory burden on the health care industry through the interpretation of statutory exceptions and modification of the exceptions that were created using the Secretary’s discretionary authority . . . .”

With respect to indirect compensation arrangements, CMS explained in the final rule that the relationship between the physician and his or her physician organization is disregarded and the physician “stands in the shoes” of his or her physician organization. As a result, "many arrangements that would have constituted indirect compensation arrangements if analyzed under Phase I and Phase II are now deemed to be direct compensation arrangements, and the indirect compensation arrangements exception
cannot be used,” the final rule said. Moreover, under the Phase III final rule, “many arrangements that may not have met the definition of an ‘indirect compensation arrangement’ under the Phase I and Phase II analysis will constitute direct compensation arrangements that must satisfy the requirements of an exception in order for the physician to make DHS referrals to the entity furnishing DHS.” CMS said deeming more arrangements to be direct compensation arrangements “will reduce the risk of fraud and abuse by closing an unintended loophole in the definition of "indirect compensation arrangement" and "will ease compliance by simplifying the analysis of many arrangements."

The final rule also eliminated the safe harbor within the definition of fair market value, recognizing concerns about the availability of the surveys identified in the safe harbor. CMS emphasized, however, that it will continue to scrutinize fair market value as it is an essential element of many Stark exceptions. According to CMS, the final rule also expands the regulations regarding physician recruitment and retention payments to permit recruitment of more physicians into extended areas when needed. In addition, the final rule provides relief for inadvertent violations of the self-referral prohibition, CMS said. Under the rule, parties that inadvertently exceed the limit on non-monetary compensation by no more than 50% may continue to satisfy the requirements of the exception if the amount is repaid within 180 days of its receipt or the end of the calendar year, whichever is earlier.

On November 15, 2007, CMS issued a final rule (72 Fed. Reg. 64161) delaying for one-year the application of the so-called “stand-in-the-shoes” provision of the Stark Phase III final rule to academic medical centers (AMCs) and nonprofit integrated health systems. The “stand-in-the-shoes” provision in the final Phase III rule therefore does not apply to certain compensation arrangements between AMCs or nonprofit integrated health systems until December 4, 2008, according to the new final rule.

CMS said the one-year delay was necessary to re-evaluate any unintended impacts of this provision. CMS explained that it had received informal comments on the “stand-in-the-shoes” provision from industry stakeholders who expressed concern about the effect of the provision in the AMC setting or similar settings where “support payments” or other monetary transfers are common. According to these commenters, “support payments” from AMCs and nonprofit integrated health systems to physician groups previously did not trigger application of Stark laws, but now would need to satisfy the requirements of an exception under the Stark Phase III final rule.

In addition, commenters argued it was unlikely that “support payments” would meet the requirements of any available exception because of the nature of such payments (i.e., they generally are “not tied to specific items or services provided by a faculty practice plan (or nonprofit group within the health system), but rather are intended to support the overall mission of the AMC or nonprofit integrated health system”). CMS said that the new final rule responds to these concerns by delaying the application of the “stand-in-the-shoes” provision with respect to compensation arrangements at AMCs that are between faculty practice plans and another component within the same AMC, and to compensation
arrangements involving nonprofit integrated health systems where the arrangement is between an affiliated designated health services entity and an affiliated physician practice within the same integrated health system.

CMS said it was concerned about the potential for “significant disruption” within the healthcare industry if the provision required many compensation arrangements that previously did not trigger application of the Stark laws to satisfy the requirements of an exception.

**CMS Says Amending Recruitment Agreement To Provide For Additional Compensation Would Violate Stark**

A hospital may not amend the income guarantee loan agreement portion of its recruitment agreement with a physician to delete the excess receipts provision under the physician self-referral statute, § 1877 of the Social Security Act (Stark Law), the Centers for Medicare and Medicaid Services (CMS) said in an Advisory Opinion. The hospital requestor, a small acute care facility, recruited the physician and agreed to provide financial assistance in return for the physician’s agreement to relocate to the geographic area served by the hospital in order to provide medical services.

One part of the financial assistance agreed upon was an income guarantee loan. Under the terms of that loan, the parties agreed that, for 12 consecutive months the hospital would guarantee the physician monthly revenue of $14,585, plus up to $19,296 per month for actual start-up and operating expenses directly attributable to the physician’s medical practice (Physician Expenses), less the monthly amount collected by the physician attributable to his performance of services for the Medical Group where he was also going to be practicing (Physician Receipts). The loan agreement also included an excess receipts provision, which specified that, if the Physician Receipts exceeded the sum of the guaranteed revenue and Physician Expenses in any monthly period, the Physician would be obligated to remit such excess to the hospital, up to the amount of the then-outstanding principal and accrued interest under the income guarantee loan.

Four days before the Stark Law became effective, the parties executed an amended agreement that limited the monthly Physician Expenses to the actual additional incremental costs that the Physician or the Medical Group incurred and that were directly attributable to the physician. Under the Stark Phase II regulations, an income guarantee offered by a hospital to a physician joining a physician practice could only include amounts for practice expenses that are the “actual additional incremental costs attributable to the recruited physician,” CMS explained. See 42 C.F.R. § 411.357(e)(4)(iii).

In response to the hospital’s query of whether it could delete the excess receipts provision in the amended agreement, CMS answered in the negative. “[A]lthough the recruitment exception in 42 C.F.R. § 411.357(e) does not require the use of an excess receipts provision such as the one contained in the Arrangement, we conclude that the parties cannot now delete it from the Arrangement,” CMS said. The opinion explained that the parties may not now amend their arrangement to provide for further compensation to the
AMCs Get New Comfort On Stark Law Compliance

In a favorable decision in a qui tam case under the False Claims Act (FCA) challenging whether a hospital and various faculty physicians qualified for the Academic Medical Centers (AMC) exception under the Stark regulations, the U.S. District Court for the Western District of Kentucky found that the indirect flow of funds from the AMC (a Children's hospital) to faculty members was protected by the AMC exception. This case serves as yet another example that AMCs (including Children's hospitals) are indeed vulnerable to Stark Law charges and that appropriately and carefully structuring arrangements to fit within the AMC exception is an essential part of any AMC's compliance program.

The decision notes a lack of prior case law interpreting the AMC exception and given that lack of precedent, the court relied on its view of the overall purpose of the Stark Law and regulations, which it saw as "prevention of healthcare fraud, more than . . . ensuring rigid adherence to any particular regulatory provision." The court also relied heavily on Centers for Medicare and Medicaid Services' (CMS') comments in the preambles for an interpretation of the many elements of the AMC exception.

In applying the Stark Law to the funds flow to faculty, the court assumed without deciding that the payment arrangements created at least an indirect compensation arrangement. Although the arrangement predated the adoption of the AMC exception, the court concluded that the exception still applied because it is an administrative interpretation of what Congress intended in the Stark Law.

One area of contention was whether faculty provide "substantial" academic and/or clinical teaching services to qualify for the AMC exception even though falling short of the "8 hours per week/20% of professional time" safe harbor, and what documentation is necessary to fit within the safe harbor. In this case, the court took a flexible approach, noting that the regulations do not require fitting within the safe harbor or using any particular timekeeping system. The court found that the time reports the hospital compiled were sufficient in light of other facts and circumstances, including affidavits from the defendant physicians, awards the faculty received for quality teaching, the size of the medical education program (over 100 residents and medical students), the frequency of rounding with residents, annual performance reviews, and academic accomplishments noted on the defendant faculty members' curricula vitae.

The plaintiffs also disputed how broadly the compensation elements of the AMC exception should be applied, arguing that the physicians' entire compensation, including compensation from private practice paid by their professional corporation, had to fit within the AMC compensation parameters (set in advance, fair market value, not related to volume or value of referrals). Instead, the court limited the inquiry to faculty salaries,
though it appears in this case that faculty salaries were the only portion of the funds flow that originated, at least indirectly, with the hospital. There is no mention in the opinion of payment by the hospital for other services from faculty. As for compensation that was paid, the set in advance prong was satisfied through an annual Personnel Action Form listing faculty salary for the coming year for each faculty physician. The court found that for fair market value, it was reasonable to rely on published surveys (in this case, the Association of Administrators in Academic Pediatrics' Medical School Pediatric Faculty Compensation Surveys). The plaintiffs relied on compensation allegedly being above the median, but the court noted that the safe harbor for compensation at the median has been repealed by CMS and that it was not mandatory in any event and that the defendant physicians appeared to be "highly qualified and arguably at or near the top of [their] profession." The plaintiff's expert never actually concluded that anyone's compensation was above fair market value, even one physician paid near or above the high end of the range for his specialty (whom the court noted had a myriad of duties and responsibilities). If the original salaries are consistent with fair market value and do not vary thereafter as the number of referrals or related revenues change, then the volume or value requirement for faculty compensation also is satisfied.

There were two points of contention over whether the structure of the entities qualified as AMC components. The first disputed point related to the two majority tests—that a majority of the medical staff is faculty and that faculty generate a majority of hospital admissions. The hospital produced data to support the medical staff composition. For the admissions test, given CMS' emphasis in the preambles on flexibility in applying the AMC exception, the court was willing to infer that the majority standard was met given that faculty accounted for a majority of net revenue and plaintiffs had no contradictory evidence. The second disputed point related to whether there was sufficient written documentation of the arrangements between the hospital and the Medical School. In this case, the affiliation dated back to 1962 with a general, apparently brief, affiliation agreement that is automatically renewed until either party withdraws. The plaintiffs argued that the lack of "a lengthy, detailed contract" coupled with management not being aware of any contract requiring funding of the Medical School transformed the payments into an "under the table" arrangement to incentivize referrals to the hospital. The court refused to mandate a more comprehensive affiliation agreement, finding that the 1962 agreement, supported by annual written memoranda specifying the amount of financial support for the Department of Pediatrics and generally referring to the agreement, constituted sufficient written documentation of the relationship for the AMC exception.

In this case, the plaintiffs did not question that all funds transferred by the hospital were used to support, directly or indirectly, the missions of teaching, indigent care, research, or community service. Given the flexibility applied by the court, and by CMS in the various preamble passages cited in the court’s opinion, it is not unreasonable to expect that this mission requirement for the use of hospital funding would be broadly interpreted, particularly with respect to indirect support of these missions.

The court also addressed and rejected allegations that the arrangement failed to comply with the AMC exception because the compensation paid to faculty violated the Anti-
Kickback Statute. First, the court expressly declined to apply the "one purpose" test to invalidate an arrangement (AMC funding support) that was clearly contemplated as an acceptable arrangement under the Stark regulations. Next, the court noted that there were only general allegations of a violation of the Anti-Kickback Statute with no specific supporting facts, the defendants produced affidavits of no improper intent underlying the payments, and it seemed illogical that the only Children's Hospital in the state would need to induce referrals via kickbacks to physicians. United States ex rel. Villafane v. Solinger, No. 3:03-cv-519 (W.D. Ky. Apr. 8, 2008). This summary is an excerpt from an article written by Gerald M. Griffith, Jones Day, Chicago, IL, for Health Lawyers Weekly.

Other Developments

OIG Withdraws Proposed Rule On Exclusion Authority For Entities Submitting Claims Containing Excessive Charges

The Department of Health and Human Services Office of Inspector General (OIG) withdraw a proposed rule from September 15, 2003, which sought to provide further guidance on the OIG’s exclusion authority under § 1128(b)(6)(A) of the Social Security Act. The regulations interpreting § 1128(b)(6)(A) provide that the OIG may exclude individuals or entities that have “[s]ubmitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual’s or entity’s usual charges or costs for such items or services.”

The proposed rule would have further defined “substantially in excess” to cover “only those charges or costs that are more than 120% of an individual’s or entity’s usual charges or costs.” Commenters on the proposed rule argued the 120% benchmark was too low or arbitrary, and that a single, fixed benchmark was not appropriate across all types of providers or across all items or services. Some were concerned providers would opt to raise their prices to other payors rather than lower their charges to Medicare and state healthcare programs, which could result in increased healthcare costs across the industry. OIG apparently agreed, stating that a single benchmark is “unadvisable at this time” and that it would continue to review billing patterns on a case-by-case basis.

DOJ Says It Opposes Proposed Legislative Changes To FCA

The Department of Justice (DOJ) is not in favor of pending legislation that would amend certain aspects of the False Claims Act (FCA), DOJ Deputy Assistant Attorney General, Civil Division, Michael Hertz told the Senate Judiciary Committee during a February 27, 2008 hearing. “While the Administration is sympathetic to some of the proposed amendments, it cannot support the bill in its current form,” Hertz said in prepared testimony. According to Hertz, “many provisions of the [bill] deal with issues that have not yet been fully resolved by the courts” and DOJ does not see a pressing need for major amendments at this time.

The hearing focused on the False Claims Act Correction Act (S. 2041) introduced in September 2007 by Senators Charles Grassley (R-IA) and Richard Durbin (D-IL) with
the aim of addressing a number of recent federal court rulings they said have eroded a whistleblower’s ability to bring a qui tam action on behalf of the government under the 1986 amendments to the FCA.

Notably, S. 2041, which also is backed by Judiciary Committee Chairman Patrick Leahy (D-VT) and Ranking Member Arlen Specter (R-PA), would narrow the application of the public disclosure bar, including providing that only the DOJ may seek to dismiss a relator’s claims based on that ground. The legislation also would provide that a relator does not create a public disclosure by obtaining information from a Freedom of Information Act request or exchanges from law enforcement if such information is not otherwise publicly disclosed.

Hertz told the panel that DOJ was particularly concerned about the legislation’s proposal for “narrowing the public disclosure bar to permit those with no first hand knowledge beyond that available in the public domain to serve as relators.” The “correction” responds to the U.S. Supreme Court’s 6-2 decision in *Rockwell Int’l Corp. v. United States*, No. 05-1272 (U.S. Mar. 27, 2007), which held the public disclosure bar is jurisdictional and that the relator in the case did not qualify as an original source because he did not have “direct and independent knowledge” of the information on which his complaint was based.

John Clark, an attorney who represents qui tam relators, said the public disclosure bar was intended to benefit the government, but “has evolved into little more than a cudgel for defendants seeking to escape judgment for their misdeeds.” Clark, a former U.S. Attorney for the Western District of Texas, currently is with the firm Goode Casseb Jones Riklin Choate & Watson in San Antonio, Texas. John T. Boese, testifying on behalf of the U.S. Chamber of Commerce, said in his prepared testimony that the Chamber opposes S. 2041 “because it will not assist the DOJ in its fraud fighting efforts, it will not increase the monies returned to the Treasury, and it will not encourage more whistleblowers to bring new allegations of real fraud to the attention of the Government.” According to Boese, an attorney with the law firm Fried Frank Harris Shriver & Jacobson LLP in Washington DC, the bill would “increase the possibility that False Claims Act enforcement will be abused by qui tam relators’ counsel, particularly in the 80% of qui tam cases in which the DOJ declines to intervene because the cases are meritless.”

The bill also would provide that government employees may act as relators after they disclose the fraud to their supervisors, the Inspector General, and the Attorney General, and wait one year for the government to act. But Hertz argued permitting government employees to serve as relators “is unsound public policy as all government employees have an obligation to report fraud.”

Another key provision of S. 2041 would remove the requirement that false claims be presented to a government employee and instead apply liability directly to any false claim regarding government money or property. The issue arose following the D.C. Circuit’s decision in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (2004), which
held false claims to government “grantees” were not “presented” to a government employee.

According to Clark, the Totten decision has sparked a number of lower court decisions “effectively creat[ing] ‘fraud free zones’ in a vast array of situations in which the federal government uses an outside entity—such as an insurance company or state agency—to administer its programs.” But Boese commented that the bill would “create an administrative nightmare for any person, company, or institution that pays or receives Federal money” and "greatly expand the scope of the Act to private contract disputes which do not affect the Treasury." The Supreme Court is considering the “presentment” issue in the case of United States ex rel. Sanders v. Allison Engine Co. Inc., 471 F.3d 610 (6th Cir. 2006), which in a split decision rejected the analysis in Totten.

The Senate Judiciary Committee April 3, 2008, ordered the bill to be favorably reported with an amendment in the nature of a substitute. The bill now moves to the full Senate for consideration.

DOJ Issues Guidelines For Selecting Corporate Monitors In DPAs
The Department of Justice (DOJ) has issued new internal guidelines for using and selecting corporate monitors in deferred prosecution agreements (DPA). The process used by federal prosecutors to award often lucrative contracts for oversight and monitoring of companies that enter into DPAs to avoid criminal prosecutions has come under scrutiny lately. Lawmakers, including Senate Finance Committee Chairman Max Baucus (D-MT), have focused in particular on the no-bid contract award to former Attorney General John Ashcroft to monitor Zimmer Holdings under a DPA stemming from allegations that the company paid illegal kickbacks to surgeons for using and promoting its knee and hip replacement products. The contract reportedly is worth between $28 million and $52 million.

Testifying at a hearing March 11 before the House Judiciary Commercial and Administrative Law Subcommittee, U.S. Attorney for the Northern District of Georgia David Nahmias said the principles set forth in the new DOJ guidance focus on, “the selection of a respected, highly qualified monitor who is suitable for the assignment and free from actual or perceived conflicts of interest.” Nahmias, who chairs a DOJ advisory committee panel on white collar crime, added that the agency would continue to review and analyze the best practices of federal prosecutors who handle corporate criminal cases as the agency considers additional guidance. “It is important that we avoid imposing an inflexible policy that fits one type of case—which may be the unusual case—but constrains the ability of prosecutors to resolve other types of cases in the best interests of the public and victims,” Nahmias said.

The guidelines require prosecutors to obtain the Office of the Deputy Attorney General’s approval of the proposed monitor. The guidelines also specify that each U.S. Attorney’s Office and DOJ component must create a standing or ad hoc committee of prosecutors to consider the selection or veto of monitor candidates.
House Judiciary Chairman John Conyers, Jr. in his opening statement at the hearing said congressional oversight of these agreements is essential for transparency. Conyers also commented that the DOJ guidance still fails to ensure uniformity in the agreements themselves. “While it might be necessary to fashion some agreements on a case-by-case basis, general uniformity could ensure their fair application,” said Conyers. As to the selection of corporate monitors, Conyers said he hoped the recent DOJ guidelines would be “successfully implemented” to help avoid “the potential for Department politicization.” Conyers also called for independent judicial oversight of corporate settlement agreements.

John Ashcroft also testified at the hearing about his contract to monitor Zimmer, although he qualified that his remarks were confined by his ethical responsibilities under the agreement. Ashcroft provided general details about his monitoring responsibilities, emphasizing that monitoring fees under DPAs are paid by the defendant companies, not by the taxpayer, which “helps insulate a monitor from political pressure.”

The Senate Judiciary Committee cleared the bill on April 3, 2008 with an amendment in the nature of a substitute. The bill now moves to the full Senate for consideration.

**OIG Refines Provider Self-Disclosure Protocol**

The Department of Health and Human Services Office of Inspector General (OIG) has refined the requirements of the OIG Provider Self-Disclosure Protocol (SDP), under which healthcare providers can voluntarily report fraudulent conduct affecting Medicare, Medicaid, and other federal healthcare programs, the agency said in an April 15, 2008 Open Letter to Health Care Providers. The letter notes that the OIG has streamlined its processes for resolving SDP cases. “A provider's submission of a complete and informative disclosure, quick response to OIG’s requests for further information, and performance of an accurate audit are indications that the provider has adopted effective compliance measures,” the letter said. Accordingly, when the OIG negotiates the resolution of its “applicable administrative monetary and permissive exclusion authorities in exchange for an appropriate monetary payment,” it generally will not require the provider to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement, the letter said.

The OIG explained in the letter that “[d]isclosures that are characterized as mere billing errors or overpayments are not appropriately addressed by the SDP and should be submitted directly by the provider to the appropriate claims-processing entity, such as the Medicare contractor.” The open letter also sets forth four additional submission requirements: (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the federal healthcare programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and (4) a statement of the laws potentially violated by the conduct.
HEALTH INFORMATION TECHNOLOGY

Senate HELP Committee Approves Health Information Technology Bill
The Senate Health, Education, Labor, and Pensions (HELP) Committee June 27, 2007 approved the Wired for Health Care Quality Act of 2007 (S. 1693), which is directed at helping healthcare providers across the country adopt health information technology (IT). S. 1693 “will modernize health care for the 21st century” by establishing objectives for “improving healthcare through technology, reducing administrative costs and diminishing fatal errors caused by lack of information,” according to a press release issued by HELP Committee Chairman Edward M. Kennedy (D-MA). Along with Kennedy, the bill was sponsored by HELP Committee Ranking Member Mike Enzi (R-WY) and Senators Hillary Clinton (D-NY) and Orrin Hatch (R-UT).

The legislation is designed to encourage the adoption of health IT by providing, in both fiscal years 2008 and 2009, $163 million in loans and grants to states and healthcare providers for the development of health IT systems. The legislation also authorizes the appropriation of “such sums as may be necessary” for each of fiscal years 2010 through 2012. Along with health IT grants provided to healthcare providers demonstrating financial need, grants also would be provided to states for the purpose of establishing low-interest loan programs to help providers acquire health IT systems. Moreover, grants would be directed at facilitating the implementation of regional and local health information exchange plans and integrating health IT into the clinical education of healthcare professionals. The bill codifies the role of the National Coordinator for Health Information Technology within the Department of Health and Human Services (DHHS) in coordinating the policies of federal agencies regarding health IT. The legislation also contains provisions requiring that “the national strategy on health IT include strong privacy protections, including methods to notify patients if their medical information is wrongfully disclosed.”

DHHS Announces Demonstration To Encourage Use Of EHRs
Department of Health and Human Services (DHHS) Secretary Michael Leavitt announced October 30, 2007 a five-year demonstration project that will provide financial incentives to physician groups using certified electronic health records (EHRs). The program, which is designed to encourage small to medium-sized physician practices to adopt EHRs, will require all participating practices to use a certified EHR system to perform specific functions that can positively affect patient care processes, DHHS said. The core incentive payment to practices will be based on performance for certain quality measures, the release said, with an enhanced bonus based on how well integrated the EHR is in helping manage patient care.

“By linking higher payment to use of EHRs to meet quality measures, we will encourage adoption of health information technology at the community level, where 60 percent of patients receive care,” Leavitt said. “We also anticipate that EHRs will produce significant savings for Medicare over time by improving quality of care. This is another step in our ongoing effort to become a smart purchaser of health care--paying for better, rather than simply paying for more,” Leavitt added.
FCC Announces $400 Million Plan To Create And Expand Broadband Telehealth Networks

The Federal Communications Commission (FCC) will provide $400 million to fund a three-year pilot program directed at creating and expanding broadband telehealth networks that will connect healthcare facilities across the United States, FCC Chairman Kevin J. Martin announced November 13, 2007. Under the Rural Health Care Pilot Program (RHCPP), "the Commission will be taking a major step towards the goal of connecting healthcare facilities across the nation with one another through broadband telehealth networks for the benefit of patients," Martin said.

The significant new funding for RHCPP will expand access to healthcare to American’s rural and underserved communities. In addition, by facilitating telemedicine, the program will "reduce costs and travel time for consumers, help decrease medical errors, and enable health care providers to quickly share critical patient-care information." Martin, joined by Department of Health and Human Services (DHHS) Secretary Michael O. Leavitt, presented further details on the RHCPP initiative at a meeting of the American Health Information Community (AHIC) held in Chicago, according to an FCC press release.

Healthcare facilities that qualify to participate in RHCPP will be eligible to receive funding to “leverage existing telehealth networks or build-out new, comprehensive systems for telehealth projects,” the release said. Participants would be eligible for “universal service funding” to support up to 85% of the costs associated with the design, engineering, and construction of innovative and highly efficient broadband systems. In addition, participants in the pilot program would have the option to receive such funding support for connecting a state or regional network to the public Internet or to one of the nation’s two dedicated national networks—Internet-2 or NationalLambdaRail (NLR). Program participants also would be strongly encouraged to coordinate in the use of their telehealth networks with DHHS and, in particular, the Centers for Disease Control and Prevention (CDC) in order to more effectively respond to national, regional, or local public emergencies (e.g., bioterrorism, pandemics, or other disease-related outbreaks).

HHS Seeking Communities For EHR Demo

The Department of Health and Human Services (DHHS) is asking community leaders to apply for a new demonstration project that will provide Medicare incentive payments to physicians for using certified electronic health records (EHRs) to improve patient care. According to DHHS, the project, which will be open to small- and medium-sized primary care physician practices, is expected to reduce medical errors and improve the quality of care for an estimated 3.6 million people. Over the five-year span of the demos, financial incentives will be provided to as many as 1,200 physicians and total payments could be up to $58,000 per physician or $290,000 per practice.

The application period is open through mid-May 2008 for communities interested in becoming one of 12 sites that will be selected. The Centers for Medicare and Medicaid Services (CMS) anticipates the project launching in four sites in 2008, with the remainder
beginning in 2009. After the communities are identified, CMS will be begin recruiting physician practices in those areas to participate.

**Hospital Employee Indicted For Selling Celebrities’ Medical Information To Media**
Lawanda Jackson, an administrative specialist at the UCLA Medical Center, has been indicted for selling celebrities' private medical information to the media, according to a press release issued April 29, 2008 by the U.S. Attorney’s Office for the Central District of California. According to the release, Jackson was charged with one count of illegally obtaining individually identifiable health information for commercial advantage. The indictment alleges that Jackson received at least $4,600 from a media outlet in exchange for providing information she obtained from the private medical records of celebrity patients at the UCLA Medical Center. Jackson faces 10 years in prison if convicted on the charge.

**Nurse Pleads Guilty To HIPAA Privacy Violation**
An Arkansas nurse pled guilty April 15, 2008 to violating the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) by wrongfully disclosing individually identifiable health information for personal gain, U.S. Attorney for the Eastern District of Arkansas Jane W. Duke announced. Andrea Smith was a nurse with Northeast Arkansas Clinic in Jonesboro, Arkansas. On November 28, 2006, Smith accessed the private medical information of an unnamed clinic patient and disclosed the information to her husband Justin Smith. Justin then contacted the patient saying he intended to use the information against the patient in “an upcoming legal proceeding,” the indictment charged. In exchange for her guilty plea, the Department of Justice agreed to dismiss the one remaining count of her two-count indictment. Smith faces a maximum penalty of 10 years’ imprisonment, a fine of not more than $250,000, or both, and a term of supervised release of not more than three years. The clinic, which terminated Smith, was not charged in connection with the case.

**HEALTH POLICY**

**California Senate Fails To Pass Healthcare Reform Legislation**
On January 28, 2008, the California Senate failed to pass comprehensive healthcare reform legislation (A.B. x1 1) that would have required all state residents to obtain health insurance coverage either individually or through their employers. The bill was previously approved by the Assembly on a party line vote of 46 to 31, with the Democratic majority unanimously supporting the legislation.

A.B. x1 1 required the state to establish a new purchasing pool to provide access to subsidized, affordable coverage for individuals and families with incomes between 100% and 250% of the federal poverty level (FPL). In addition, it limited the premiums that low- and moderate-income individuals would have been required to pay based on income level. The legislation also required that employers provide healthcare coverage to their workers, or pay into the state-run purchasing pool to subsidize coverage primarily for low-income individuals and families.
The Senate’s vote on the legislation came after the California Legislative Analyst’s Office (LAO) completed its assessment of how the legislation would impact the state budget in the long term, and also in light of the currently projected $14 billion budget deficit. In its review letter sent January 22 to Senate President Pro Tem Don Perata (D), LAO projected the cost of subsidizing coverage for low-income residents under the legislation would significantly exceed revenues during the first five years of implementation.

In a January 29, 2008 press conference, Governor Arnold Schwarzenegger (R) vowed to continue pressing for healthcare reform legislation, stating “just because the Senate . . . missed a golden opportunity and did not pass . . . health care reform doesn’t mean we should walk away from reforming our broken health care system.”

**House And Senate Clear Mental Health Parity Bills**

By a 268-148 vote, the House approved March 5, 2008 legislation (H.R. 1424) that requires insurance companies and employers offering mental health coverage to provide it on par with the coverage offered for other physical illnesses. The Paul Wellstone Mental Health and Addiction Equity Act of 2007, introduced by Representatives Patrick Kennedy (D-RI) and Jim Ramstad (R-MN), builds on the mental health parity law passed in 1996.

The legislation, which amends the Employee Retirement Income Security Act and Public Health Service Act, applies to businesses with 50 or more employees that offer mental health coverage and requires parity to other medical benefits on a financial basis (e.g., deductibles, copayments, coinsurance, and out-of-pocket expenses) and with respect to treatment limitations.

The House bill must now be reconciled with the Senate version (S. 558), which was passed in September 2007 by unanimous consent. The Mental Health Parity Act of 2007 was introduced by Senators Pete Domenici (R-NM), Edward M. Kennedy (D-MA), and Mike Enzi (R-WY).

Among other sticking points between the two measures, the House bill requires parity with respect to alcohol and drug abuse treatment. Health insurers and businesses favor the Senate legislation, as does the White House, which issued a statement of administration policy March 5, 2008 “strongly opposing” H.R. 1424. According to the White House statement, the House bill “would have a negative effect on the accessibility and affordability of employer-provided health benefits and would undermine the uniform administration of employee benefit plans.” The administration also objected to the House bill’s funding offset provisions, which would increase the Medicaid drug rebate and impose controversial restrictions on physician-owned specialty hospitals.

In a statement, the Pharmaceutical Research and Manufacturers of America (PhRMA) said they supported mental health parity legislation but not the "unwarranted increase in the Medicaid rebate" under the House bill. "H.R. 1424 would result in a 33 percent increase in the basic Medicaid rebate," on top of increases some pharmaceutical
companies had to pay as a result of changes to the rebate formula under the Deficit Reduction Act of 2005, PhRMA Senior Vice President Ken Johnson said. "We do not believe that increasing this rebate tax is an appropriate way to pay for other discretionary programs," he added.

The Congressional Budget Office (CBO) has estimated that the House and Senate mental health parity bills, if enacted, would increase premiums for employer-sponsored health insurance by an average of roughly 0.4%.

HEALTHCARE ACCESS

California Appeals Court Voids County’s Income Eligibility Cap For Subsistence Medical Care
A California appeals court invalidated May 23, 2007 San Diego County’s income eligibility cap for indigent residents to qualify for the state’s mandated safety net for medical care. Reversing a lower court decision, the appeals court found the cap was contrary to the state law requiring the provision of subsistence medical care to indigent populations because it failed to take into account an individual’s ability to pay.

California Welf. and Inst. Code § 17000 requires state counties and cities to provide a system of “last resort” subsistence medical care to all medically indigent residents who are not eligible for other public assistance programs, a population often called the “working poor.” San Diego County instituted a financial eligibility cap under which individuals who earned more than $1,078 per month were denied any subsistence medical care under the county’s safety net program.

Plaintiffs are individuals with serious medical conditions who were denied any coverage under the county’s program because their monthly incomes exceeded the individual cap. Plaintiffs filed a class action in court to challenge the eligibility cap, arguing it did not consider individual residents' ability to pay and was based on flawed assumptions. The trial court approved the income cap, rejecting plaintiffs’ argument that § 17000 “precludes a standard based on a flat amount of income.”

The California Court of Appeal, Fourth District, reversed, holding that the county’s eligibility standard was void because the inflexibility of the cap denied any medical care to indigent residents, especially the working poor, whose monthly salary exceeded the cap by even $1, without considering their ability to pay for some or all of their medical care. The appeals court rejected the county’s argument that invalidating the cap would require it to “provide universal health insurance,” pointing out that § 17000 is designed to allow only necessary treatment for serious illness and injury, not all types of medical care. In addition, § 17000 allows benefits only to those indigents who do not have other assistance (i.e. from relatives, friends, or public and private institutions) and permits the setting of a property limit, which in this case the county established as $2,000. Alford v. County of San Diego, No. D048758 (Cal. Ct. App. May 23, 2007).
HIPAA

Ninth Circuit Finds HIPAA Limits On Medical Record Copying Fees For Individuals Not Applicable To Law Firm’s Request

A provision in the Health Insurance Portability and Accountability Act (HIPAA) regulations requiring copies of medical records to be made available to “individuals” for a reasonable cost-based fee is not applicable to records requests made by a law firm on behalf of an individual and therefore does not bar a copying service from charging the firm higher copying fees, a federal appeals court ruled August 27, 2007. The Ninth Circuit affirmed the lower court’s dismissal of a lawsuit filed by Kirk Webb and the law firm, Mann & Cook, which had requested copies of Webb’s medical records and been charged by the copying service, Smart Document Services (SDS), at a rate higher than would have been charged to Webb had he directly requested copies of his medical records.

Mann & Cook initially requested Webb’s medical records on his behalf from his treating hospital, and the hospital then passed the request to SDS. After SDS charged Mann & Cook at a higher than cost-based rate, the law firm passed that cost onto Webb. Webb and Mann & Cook (collectively, plaintiffs) filed a class action in state court, invoking California’s unfair competition law, Cal. Bus. & Prof. Code § 17200, which allows independent causes of action for violations of other state and federal laws. In this case, plaintiffs asserted that SDS violated HIPAA, specifically its fee limitations (45 C.F.R. § 164.524(c)(4)), by charging Webb, through his agent (Mann & Cook) higher than a reasonable, cost-based fee. Granting SDS’ motion to dismiss, the U.S. District Court for the Central District of California concluded that the HIPAA fee limitations apply only to individual patients who request records on their own behalf, and not to attorneys who act as agents of their clients.

On appeal, the Ninth Circuit first concluded that it had jurisdiction over the case, regardless of the fact that HIPAA does not provide a private right of action. In this diversity case, according to the appeals court, California law, under Cal. Bus. & Prof. Code § 17200, directed it to examine federal law because plaintiffs’ claim was based on SDS’ allegedly unlawful and unfair conduct in violating HIPAA.

Turning to the merits of the case, the appeals court noted that HIPAA explicitly restricts fee limitations to requests made by the individual and concretely defines "individual" in a way that excludes others acting on that individual’s behalf. The appeals court rejected plaintiffs’ argument that, regardless of the plain meaning of the regulations, the term “individual” therein should be interpreted to include authorized attorneys because such interpretation would be more consistent with HIPAA’s purposes, namely to make personal health information more accessible to individuals. "Most notably, in the proposed rules, DHHS explicitly considered adopting a broader definition of ‘individual’ that would have included legal representatives, but in the final rule ultimately decided against it." In addition, the appeals court rejected plaintiffs’ argument based on California agency law that Mann & Cook essentially was “the individual” making the request under HIPAA. The appeals court highlighted state appellate court precedent holding otherwise,
i.e., that a lawyer’s records request is not the same as the client’s request for his or her own medical records. *Webb v. Smart Document Solutions*, No. 05-56282 (9th Cir. Aug. 27, 2007).

**U.S. Court In Florida Finds No Basis Under HIPAA For Psychotherapist To Refuse Production Of Notes**

The U.S. District Court for the Middle District of Florida held September 28, 2007 that a psychotherapist must produce her notes related to the treatment of a deceased patient in a case involving the deceased’s life insurance policy. In so holding, the court found no basis under the Health Insurance Portability and Accountability Act (HIPAA) for the psychotherapist to withhold her notes. Plaintiff Lori Evenson sued defendant Hartford Life and Annuity Insurance Company claiming she is the beneficiary of a life insurance policy issued by Hartford to her husband. According to Hartford, it denied coverage and rescinded the policy because the decedent failed to disclose in-patient treatment for alcohol addiction.

Hartford issued a subpoena to third party Georgia Howorth-Fair, M.S. for her entire file regarding her treatment of decedent. Howorth-Fair produced some records, but not her psychotherapy notes. Even after being presented with an authorization by plaintiff, Howorth-Fair refused to produce her psychotherapy notes based on HIPAA. Howorth-Fair contends that because patients do not have a right of access to her notes, the litigants in this case also had no right to the notes.

The court first addressed Howorth-Fair’s argument that under HIPAA individuals have no right of access to psychotherapy notes, thus she is under no obligation to provide them to Hartford. According to the court, the interpretation “of the plain meaning of section 164.524 hinges on who is an ‘individual.’” The Ninth Circuit recently found the definition of “individual” as “the person who is the subject of the protected health information” applies to § 164.524 of HIPAA, the court said. Thus, “[u]nder the plain meaning of the statute, section 164.524 does not support the psychotherapist’s argument because the request for her notes is not being made by the person who is the subject of the protected health information.” *Evenson v. Hartford Life and Annuity Ins. Co.*, No. 6:07-cv-224-Orl-28UAM (M.D. Fla. Sept. 28, 2007).

**Georgia Appeals Court Finds HIPAA Does Not Necessarily Bar Ex Parte Contact With Prior Treating Physicians**

The Georgia Court of Appeals reversed and remanded a trial court’s grant of an injunction preventing a medical malpractice defendant-physician from contacting ex parte other physicians who treated the subject of the malpractice suit. In holding that the trial court erred in finding the Health Insurance Portability and Accountability Act (HIPAA) prohibited the ex parte contact, the appeals court found that such meetings “do not necessitate the disclosure of health information protected by the HIPAA privacy rule.”

Plaintiff Amanda Moreland sued Dr. Michael Austin and his employers (collectively, Austin) after her husband died while in Austin’s care at the Coliseum Medical Center.
Both with her complaint and during discovery, Moreland produced her husband's medical records, including documents relating to his prior treatment by three cardiologists. Austin contacted each physician and asked for “an assessment of Mr. Moreland's cardiovascular status and his prognosis” while under their care. Moreland objected to such contact, claiming it violated the HIPAA privacy rule.

The appeals court found HIPAA did not preclude all ex parte communications with the prior treating physicians because such communications may not include the disclosure of protected health information. According to Austin, all of the protected health information possessed by Mr. Moreland's prior treating physicians was disclosed with the consent of Mrs. Moreland prior to the effective date of HIPAA. Under HIPAA, the appeals court explained, covered entities may continue to disclose protected health information pursuant to a consent or authorization obtained prior to the effective date of the HIPAA privacy rule. 45 C.F.R. § 164.532(a). Thus, the appeals court remanded to the trial court to determine whether the cardiologists possessed any protected health information regarding Mr. Moreland that was not already disclosed in accordance with 45 C.F.R. § 164.532(a) or in accordance with the notice and consent provisions of 45 C.F.R. § 164.512(e)(1)(ii)(A). If it determines that they do, the appeals court instructed, the trial court may issue an order restricting the ability of the prior treating physicians to disclose such information to Austin except in accordance with the HIPAA privacy rule and the Georgia Civil Practice Act. Austin v. Moreland, No. A07A1206, A07A1207 (Ga. Ct. App. Oct. 10, 2007).

New York Court Of Appeals Finds Court May Compel HIPAA Authorization For Ex Parte Contact With Physician When Plaintiff Puts Medical Condition At Issue

New York's highest court found November 27, 2007 in three consolidated cases that a court may compel a plaintiff who puts his or her medical condition at issue to authorize the defendant's counsel to contact ex parte his or her treating physician. In the title case, Manuel Arons, individually and as executor of his late wife's estate, brought a medical malpractice and wrongful death action against several physicians, other medical professionals, and two hospitals alleging two of the physician defendants failed to tell his wife that her MRI revealed hydrocephalus, thus delaying proper medical care and resulting in her death.

One of the physician defendants requested an authorization that complied with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) so that his attorneys could interview the decedent's treating physician. Plaintiff refused. The trial court granted a motion to compel the authorization. The appeals court reversed. In the other two cases, medical malpractice plaintiffs similarly refused to sign HIPAA-compliant authorizations for ex parte interviews with their treating physicians.

The New York Court of Appeals found no conflict between New York law and HIPAA on the subject of ex parte interviews of treating physicians because HIPAA does not address this subject. Accordingly, the high court said, "the Privacy Rule does not prevent this informal discovery from going forward, it merely superimposes procedural prerequisites."
As a practical matter, the high court continued, “this means that the attorney who wishes to contact an adverse party's treating physician must first obtain a valid HIPAA authorization or a court or administrative order; or must issue a subpoena, discovery request or other lawful process with satisfactory assurances relating to either notification or a qualified protective order.” Thus, in the three cases before it, the high court found "entirely proper" the trial courts' orders compelling authorizations for ex parte interviews with plaintiffs' treating physicians.

"Plaintiffs waived the physician-patient privilege as to this information when they brought suit, so there was no basis for their refusal to furnish the requested HIPAA-compliant authorizations," the high court held. The high court also added a cautionary note: "it bears repeating that the treating physicians remain entirely free to decide whether or not to cooperate with defense counsel."

A dissent argued the issue should be addressed by the legislature and not the courts. The dissent noted the high court's ruling "substantially modifies" the statutory scheme contained in the New York Civil Practice Law and Rules by allowing one party to unilaterally obtain information about an adverse party's medical condition. Arons v. Jutkowitz, Nos. 147, 148, 153 (N.Y. Nov. 27, 2007).

**HOME HEALTHCARE**

U.S. Supreme Court Rules Home Healthcare Workers Employed By Third Parties Not Entitled To Overtime Pay

Home healthcare workers employed by a private company or employer are not covered by the Fair Labor Standards Act’s (FLSA's) requirements pertaining to overtime compensation or the minimum wage, and therefore are not entitled to overtime pay, the U.S. Supreme Court ruled June 11, 2007 in a unanimous decision. The home healthcare worker in this case, Evelyn Coke, is a 73 year old woman who sued her employer, Long Island Care at Home (Long Island), alleging she was denied overtime and was not paid a minimum wage for her work. Coke had worked for Long Island for more than 20 years and claimed that her job sometimes entailed four, 24-hour days a week and sleeping at the client’s home. Coke sought a judgment for unpaid wages, arguing she was entitled to them under the FLSA.

The FLSA exempts from its minimum wage and maximum hour rules “any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves.” 29 U.S.C. § 213(a)(15). Department of Labor (DOL) regulations, 29 C.F.R. § 552.3, define the term “domestic service employment” as “services of a household nature performed by an employee in or about a private home . . . of the person by whom he or she is employee . . . such as cooks, waiters, butlers, valets, maids, . . . caretakers, . . . babysitters employed on other than a casual basis.” DOL regulations, 29 C.F.R. § 552.109(a), also provide the statutory exemption includes those “companionship” workers who “are employed by an employer or agency other than the family or household using their services.”
In addressing Coke’s argument that the DOL’s third-party regulation falls outside the scope of its authority, the Court explained that the FSLA “expressly instructs the agency to work out the details” of its broad references to “domestic service employment” and “companionship services.” The Court acknowledged that the DOL had been inconsistent in interpreting the “companionship exemption.” But the Court determined that this was not a valid basis for disregarding the DOL’s current interpretation of the regulations. DOL participated in notice-and-comment rulemaking in developing new regulations in this area and therefore the agency’s interpretive changes did not create “unfair surprise.”


**Maryland Appeals Court Upholds Change To Licensing Requirements For Home-Based Hospice Providers**

A change in the law governing the licensing of home-based hospice providers in Maryland was not unlawful under the Maryland or U.S. Constitutions, a state appeals court ruled September 28, 2007. The appeals court rejected a provider’s challenge to the change after it lost its license under the new law to offer home-based hospice services in two counties absent a Certificate of Need (CON).

VNA Hospice of Maryland (VNA) held a statewide license to provide home-based hospice care service in Maryland. Under Maryland’s licensing law, Md. Code Ann. Health General Article § 19-906, VNA had been exempted from the requirement to obtain a CON because it delivered hospice care services before January 1, 1987. The case arose after the Maryland General Assembly in 2003 amended the § 19-906 requirements to require a general home-based hospice like VNA to obtain a CON to operate in specific jurisdictions or counties. The CON requirement did not apply to those jurisdictions where the hospice provider had been administering services during the 12-month period ending on December 31, 2001.

As a result of the change, the Department of Health and Mental Hygiene (Department) amended VNA Hospice of Maryland’s (VNA’s) license so that it could no longer provide hospice services in two of the eight Maryland counties where it had been serving home-based hospice patients. After its administrative appeal was unsuccessful, VNA sought redress in court. The court found the 2003 amendments abrogated VNA’s vested property right in providing home-based hospice services and that the exemption from the CON requirement under the amended § 19-906 was arbitrary and unconstitutional.

The Maryland Court of Special Appeals reversed, concluding that § 19-906 was not unconstitutional. After reviewing the case law, the appeals court concluded that like other professional licenses, a license to deliver home-based hospice was a conditional, not absolute, right that was subordinate to the state’s police power concerning public health. And while VNA’s license still was subject to procedural due process requirements before being altered or revoked, VNA made no arguments on this ground, the appeals court noted.

The appeals court also rejected VNA’s argument that the loss of its license amounted to an unlawful “taking” without compensation in violation of the U.S. Constitution’s Fifth
Amendment. The appeals court found no federal jurisprudence that the alteration or revocation of a healthcare provider’s license constitutes a taking of “property.”

According to VNA, § 19-906 was unconstitutional under the Maryland Declaration of Rights because it granted existing hospice care providers in the two Maryland counties at issue an “exclusive franchise” to provide hospice care. The exemption from the CON requirements for those offering services in 2001 did not create an unconstitutional monopoly; rather, the distinction was reasonably required “to ensure that new health care services and facilities are developed only as needed,” the appeals court concluded. *Department of Health and Mental Hygiene v. VNA Hospice of Md.*, No. 526 (Md. Ct. Spec. App. Sept. 28, 2007).

**HOSPITALS AND HEALTH SYSTEMS**

**Florida High Court Finds Hospital Has No Duty To Ensure Staff Physicians Have Malpractice Insurance**

The Florida Supreme Court held May 24, 2007 that hospitals have no statutory duty to monitor the compliance of staff-privileged physicians with financial responsibility requirements. In so holding, the high court resolved a split between several state appeals courts on this issue. Plaintiffs Lena Horowitz and her husband sued Dr. Derek V. Jhagroo for allegedly negligent treatment of Horowitz’ infected thumb. The treatment at Jhagroo’s office led to the amputation of the thumb at Plantation General Hospital, where Jhagroo had privileges. The malpractice action resulted in a verdict against Jhagroo of $859,200.73. However, the Horowitzes were unable to collect the judgment because Jhagroo failed to maintain malpractice insurance or otherwise comply with the financial responsibility requirements of § 458.320, Florida Statutes (2006).

The Horowitzes sued Plantation, alleging the hospital breached a statutory duty by failing to ensure the financial responsibility of Jhagroo as a physician who had been granted staff privileges. The Horowitzes argued because of that failure, Plantation was liable for the first $250,000 of the unsatisfied judgment. The trial court, relying on cases decided by three state appeals courts, granted the Horowitzes summary judgment, agreeing with the other courts that § 458.320(2) mandates financial responsibility as a condition to maintaining staff privileges and therefore imposes a duty on the hospital to ensure physician compliance. On appeal, Florida’s Fourth District Court of Appeal reversed. The Florida Supreme Court agreed to hear the case to resolve the conflict between the districts.

After first finding no common law duty on the part of hospitals to monitor the financial responsibility of physicians, the high court turned to plaintiffs’ statutory causes of action and found no evidence of legislative intent to hold a hospital liable for a physician’s failure to comply with the requirements of § 458.320. “If the Legislature intended to impose an affirmative duty on a hospital to ‘condition’ the grant of staff privileges on a physician’s establishing financial responsibility, it would have included this requirement in the sections governing a hospital’s grant of staff privileges,” the high court held. *Horowitz v. Plantation Gen. Hosp. Ltd. Partnership*, No. SC05-331 (Fla. May 24, 2007).
Texas Supreme Court Finds Hospital May Not Maintain Lien Against Patient For Charges Not Covered By Workers Comp

The Texas Supreme Court held June 1, 2007 that a hospital may not maintain a lien against two patients for the difference between its full charges and what it was paid by the patients’ workers compensation carrier. Because hospitals cannot sue such patients for the discount directly, the high court said, hospitals may not try to accomplish the same thing indirectly by filing a lien. Donald Linnstaedter and Kenneth Bolen were injured in an auto collision while riding together in the course of their employment. Both were treated at a hospital owned and operated by the Daughters of Charity Health Services of Waco. Their reasonable and necessary hospital charges totaled $22,704.25, of which their workers' compensation carrier paid only $9,737.54.

The hospital filed a lien against Linnstaedter’s and Bolen’s cause of action against the other driver in the accident. The claim was eventually settled for $175,000, but the tortfeasor's insurer paid $12,966.71 of that amount to the hospital to discharge its lien. Linnstaedter and Bolen (plaintiffs) sued the hospital to recover the money.

The Texas Supreme Court noted two relevant Texas laws—the Texas Property Code, which grants hospitals a lien on any cause of action a patient may have against a tortfeasor, and the Texas Labor Code, which prohibits hospitals from pursuing a private claim against a workers' compensation claimant for all or part of the costs of treatment. The Labor Code bars not only lawsuits against such patients, but also liens against their assets, the high court noted. “We think both can be given effect by limiting hospital liens involving compensation to amounts due under the workers' compensation system,” the high court ruled. The Labor Code contains guidelines that are intended to provide both fair and reasonable reimbursement and effective cost control, the high court reasoned. Daughters of Charity Health Servs. of Waco v. Linnstaedter, No. 05-0108 (Tex. June 1, 2007).

Fifth Circuit Denies Class Certification To Uninsured Patients Who Sued Clinic For Undiscounted Charges

The Fifth Circuit refused July 19, 2007 to certify a class of uninsured patients (plaintiffs) who sued the tax-exempt Ochsner Clinic Foundation for charging them allegedly unreasonable rates for medical treatments. According to the appeals court, the uninsured patients failed to identify how a court could craft or enforce meaningful injunctive relief on a class-wide basis.

According to plaintiffs, Ochsner unreasonably billed them its standardized “chargemaster” rates, while patients with private insurance, Medicare, or Medicaid received discounts on those amounts. Plaintiffs sought class certification under Fed. R. of Civ. P. 23(b)(2) or (3). Generally, to qualify for class-wide injunctive relief, class members must have been harmed “in essentially the same way” and injunctive relief must “predominate over monetary damage claims.” In addition, the injunctive relief must be specific, the appeals court explained.
Plaintiffs could not meet these standards because they failed to identify any way to determine the generally applicable injunctive relief they sought—i.e. requiring Ochsner to provide them with a "mutually affordable" rate—given the specific circumstances applicable to each class member such as the timing of the services and the various discounts the clinic offered. The Fifth Circuit also commented that Rule 23(b)(2) certification was “inappropriate when the majority of the class does not face future harm.” Here, the appeals court noted, prohibiting Ochsner from charging its full chargemaster rate in the future would be meaningless since the clinic already instituted an automatic 35% discount to uninsured patients.

The Fifth Circuit found certification under Rule 23(b)(3) inapplicable as well because it was unlikely plaintiffs “could ever demonstrate that the chargemaster rates are unreasonable,” taking into account multiple factors such as services rendered, a patient’s financial status, and customary fees for similar services. Moreover, the appeals court concluded, “the fact-specific rather than class-oriented nature of the claims . . . predominates not only at the plaintiff’s level . . . but also in determining a ‘reasonable’ charge for each service from along the mélange of third-party payer discounts.”

**Maldonado v. Ochsner Clinic Found., No. 06-30573 (5th Cir. July 19, 2007).**

**U.S. Court In Florida Finds Patient Failed To Prove Hospital Charges Unreasonable**

A federal court in Florida held July 20, 2007 that a plaintiff claiming she was charged unreasonably high prices for her hospital care did not present enough evidence to overcome the hospital’s summary judgment motion in her lawsuit. Plaintiff Barbara Colomar was treated at Mercy Hospital. On discharge, she received a bill for $12,863. Because the Authorization Form signed by plaintiff did not expressly set forth price terms, Florida law requires the amount charged to be reasonable. Plaintiff sued Mercy alleging the charges were unreasonable and claiming breach of contract and violations of the Florida Deceptive and Unfair Trade Practices Act (FDUTPA). Mercy moved for summary judgment.

The U.S. District Court for the Southern District of Florida noted differential pricing claims—in which a provider accepts a lower amount for the same service from another patient—while relevant to determining a reasonable price, were not enough standing alone to prove unreasonableness. The court also found plaintiff’s evidence that she paid 155% more than Medicare would have paid was “not enough, as a matter of law, to defeat Mercy’s motion for summary judgment.” In addition, the court pointed out that plaintiff did not submit any evidence regarding what other commercial payors, such as health maintenance organizations or other insurers, would have paid. The court also noted the absence of data comparing Mercy’s charges to charges of other hospitals in the same market and of what Mercy’s actual costs were. **Colomar v. Mercy Hosp., Inc., No. 05-22409-CIV-SEITZ/MCALILEY (S.D.Fla. July 20, 2007).**
Illinois Appeals Court Affirms Judgment Against Hospital For Negligent Credentialing, Upholds $7.7 Million Damages Award

An Illinois trial court properly upheld a $7.7 million jury verdict to a medical malpractice plaintiff who sued a hospital for negligent credentialing of a foot surgeon, an Illinois appeals court ruled July 26, 2007. Plaintiff Jean Frigo sued Dr. Paul Kirchner and Silver Cross Hospital and Medical Center (Silver Cross) for medical malpractice. Frigo alleged Kirchner negligently performed an elective bunion surgery. Frigo later amended her complaint to add a negligent credentialing claim against Silver Cross after she learned the hospital gave Kirchner category II surgical privileges even though he had not completed a 12-month podiatric surgical residency and was not board certified as required by the hospital's bylaws and by Joint Commission standards.

Kirchner settled with Frigo for $900,000 prior to trial and the case proceeded against Silver Cross. The jury ultimately returned a verdict in favor of Frigo, awarding her over $7.7 million in damages. Silver Cross moved for a judgment notwithstanding the verdict, arguing Frigo’s negligent credentialing claim was barred by the applicable statute of limitation and other state statutes. In addition, Silver Cross argued that Frigo had failed to adequately prove her negligent credentialing claim. The trial court denied the motion, and then credited Silver Cross with $900,000 paid to Frigo in the earlier settlement, resulting in a net judgment of over $6.8 million. Silver Cross appealed.

The appeals court found Frigo’s negligent credentialing claim was not time barred because it “related back” to allegations in the original complaint. Silver Cross also argued it was prevented from defending itself against Frigo’s negligent credentialing claim because the Illinois Medical Studies Act barred the introduction of evidence about what the hospital’s credentials committee reviewed in deciding to grant Kirchner category II surgical privileges. Rejecting this argument, the appeals court noted that Frigo’s amended complaint alleged Silver Cross deviated from its regulations and bylaws as well as Joint Commission standards when it gave Kirchner category II surgical credentials. Citing state court precedent, the appeals court said Silver Cross’ regulations and bylaws and the Joint Commission standards did not fall within the purview of the privileges set forth in the Medical Studies Act.

The appeals court also summarily rejected Silver Cross’s argument that Frigo’s negligent credentialing claim was barred by §10.2 of the state’s Hospital Licensing Act, which immunizes hospitals against any claim based upon its credentialing decisions. The appeals court found §10.2 only had been applied to limit the remedies available to physicians aggrieved by a hospital’s peer-review process and saw "no reason" to extend its application to negligent credentialing cases. Finally, the appeals court held the jury’s verdict finding Silver Cross liable for Frigo’s injuries was well supported by the record, including testimony from Frigo’s multiple experts indicating that Kirchner lacked experience and did not properly treat Frigo’s foot prior to surgery. Frigo v. Silver Cross Hosp., No. 1-05-1240 (Ill. App. Ct. July 26, 2007).
Minnesota High Court Finds State Peer Review Statute No Bar To Patient’s Negligent Credentialing Claim

A patient’s negligent credentialing claim against a hospital under Minnesota common law is not barred by the state’s peer review statute, the Minnesota Supreme Court ruled August 18, 2007. The high court reversed a state appeals court decision holding that Minnesota does not recognize a common law cause of action for negligent credentialing of a physician against a hospital.

Plaintiffs Mary and Michael Larson brought a medical malpractice claim against Dr. James Wasemiller and Dr. Paul Wasemiller in connection with Mary’s gastric bypass surgery. The Larsons also alleged a claim against St. Francis Medical Center (St. Francis), where the surgery was performed, for negligent credentialing of Dr. James Wasemiller. On certified questions from the trial court, the appeals court held Minnesota did not recognize a common law cause of action for negligent credentialing, reasoning it was within the province of the state supreme court or the state legislature to establish a new cause of action.

The state high court concluded a tort of negligent credentialing “is inherent in and the natural extension of well-established common law rights,” including a patient’s right to bring a cause of action against a hospital that breaches its duty to protect the patient from harm by third persons, and to exercise reasonable care in granting physician privileges. The state high court also noted that the tort of negligent credentialing was recognized as a common law tort by a substantial majority of the other common law states.

The high court further concluded that Minnesota’s peer review statute did not bar a patient’s negligent credentialing claim. The high court rejected the argument that the peer review statute’s confidentiality provision made it impossible for a hospital to defend against a negligent credentialing claim. The high court also rejected the argument that the liability limitations in the peer review statute conflicted with recognizing the tort of negligent credentialing. “Although stated in the negative, the language of [the peer review statute] implies that a review organization shall be liable for granting privileges where the grant is not reasonably based on the facts that were known or that could have been known by reasonable effort,” the high court said. Finally, the high court concluded the policy considerations underlying the tort of negligent credentialing outweighed those reflected in the peer review statute. *Larson v. Wasemiller*, No. A05-1698 (Minn. Aug. 16, 2007).

Grassley, Baucus Probe Report Of Arizona Specialty Hospitals Using 911 For Emergencies

Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Charles Grassley (R-IA) sent letters August 23, 2007 to several Arizona specialty hospitals after a local news station reported they used 911 to transport 150 patients to community hospitals for emergency care. “A hospital ought to be able to treat complications quickly and on-site, or it shouldn’t be called a hospital and allowed to perform serious surgery,” Grassley said in a press release. “The more I hear about surgery at specialty hospitals, the more concerned I am. Patients admitted to specialty [hospitals] often have no clue that
they’re not in a traditional hospital until there’s a complication and then it can be too late.” Baucus and Grassley requested further information from the hospitals regarding every patient transferred to a full-service community hospital during the past five years. In addition, the lawmakers asked if the hospitals have procedures in place for emergency situations and whether the facilities are accredited by the Joint Commission, among other things.

**Texas Supreme Court Finds Hospitals Need Not Exhaust Administrative Remedies In Payment Dispute With Insurer**

The Texas Supreme Court found August 31, 2007 a group of hospitals that sued Aetna for breach of contract and other state law claims need not exhaust administrative remedies under the Medicare Act because the case did not concern beneficiary rights. Thus, the trial court had jurisdiction over the payment dispute, the high court held.

Aetna-owned NYLCare, a health maintenance organization and Medicare Advantage organization, and contracted with North American Medical Management of Texas (NAMM) to administer its plan. The Centers for Medicare and Medicaid Services (CMS) made capitation payments to Aetna which then made monthly payments to NAMM. NAMM was required to deposit the payments into a fund that was designated to pay covered claims for healthcare services rendered by healthcare providers to NYLCare members. NAMM then contracted with various hospitals to provide services to NYLCare enrollees. The hospitals alleged that NAMM grossly mismanaged its accounting and failed to track claims accurately.

In August 2000, NAMM notified the Hospitals and NYLCare that it was no longer able to satisfy its financial obligations. After Aetna refused the Hospitals’ numerous demands for payment, the Hospitals wrote a letter to CMS, but the agency responded that Medicare Advantage regulations limited its ability to intervene in payment disputes. The hospitals then sued Aetna in state trial court for $13,067,759.19 in unpaid services, asserting claims based on the Texas Insurance Code, breach of contract, breach of fiduciary duty, and quantum meruit. Aetna then moved to dismiss the claims, arguing the trial court lacked subject matter jurisdiction because the hospitals failed to pursue their administrative remedies under the Medicare Act.

Reversing the trial court’s dismissal of the case, the Texas Supreme Court cited the Fifth Circuit decision, *Rencare, Ltd. v. Humana Health Plan of Tex., Inc.*, 395 F.3d 555 (5th Cir. 2004), which found similar claims did not arise under the Medicare Act. The high court said Aetna’s contention “that the hospitals must first seek an administrative determination of some 6,000 claims misconstrues a claim seeking payment for services provided to Medicare patients as a claim for Medicare benefits.” Instead, the high court noted that “failing to pay due to insolvency or a dispute about who is contractually obligated to pay is different from failing to pay due to lack of coverage.” Thus, the high court agreed with the Fifth Circuit’s determination that “the administrative review process attendant to Part C does not extend to claims in which an enrollee has absolutely no interest.” *Christus Health Gulf Coast v. Aetna, Inc.*, No. 05-0710 (Tex. Aug. 31, 2007).
Louisiana Supreme Court Rules Wrongful Death Lawsuit Against Hospital Following Hurricane Katrina Not Subject To Medical Malpractice Act

A lawsuit stemming from the death of a hospital patient in the aftermath of Hurricane Katrina sounded in general negligence and not medical malpractice, the Louisiana Supreme Court ruled September 5, 2007. The high court reversed an appeals court decision that held the action had to be submitted to a medical review panel before proceeding in court pursuant to the Louisiana Medical Malpractice Act (LMMA). The high court concluded the allegations in the complaint that the hospital failed to ensure its facility had enough emergency power to sustain life support systems and to implement an adequate evaluation plan did not constitute medical negligence under the LMMA.

The family of Althea LaCoste, who died following Hurricane Katrina, sued Pendleton Methodist Hospital, L.L.C, where LaCoste had been admitted on August 28, 2005. According to plaintiffs, LaCoste died when her life support systems failed because the hospital lacked emergency power and the hospital failed to evacuate her. Specifically, plaintiffs alleged negligent and intentional conduct by the hospital in the design, construction, and maintenance of its facility with respect to its emergency power systems and its ability to keep out flood waters and in its failure to implement an adequate evacuation plan.

Pendleton Methodist, as a qualified healthcare provider under the LMMA, alleged plaintiffs’ action was one of medical malpractice and therefore subject to the LMMA’s medical review panel requirement. The trial court found the allegations did not implicate medical treatment or professional skill and instead related to the hospital’s deficient emergency systems and planning. The appeals court reversed, holding the issues raised by complaint were related to the treatment and care the hospital provided to LaCoste after her admission, equating the failure to have sufficient emergency power to the failure to ensure adequate medical supplies.

Citing the narrow application of the LMMA as a derogation of common law tort rights, the Louisiana Supreme Court reversed the appeals court decision. In reaching this conclusion, the high court noted that most of the factors relevant to determining whether a claim sounded in medical malpractice or general negligence weighed in favor of a finding that the LMMA was inapplicable. For example, the high court noted the range of allegations regarding the hospital’s design, construction, and maintenance all suggested premises liability and general negligence rather than “a dereliction of professional medical skill.” Moreover, the high court concluded that medical expert evidence would not be necessary to establish the hospital’s alleged wrongful conduct—i.e. a complete inability to transfer a patient because of a lack of emergency power, a poorly designed building, or inadequate protection from floodwaters.

A dissenting opinion said it was clear LaCoste “died from the condition for which she was admitted because of lack of treatment and not because she suffered from any other independent injury.” Thus, the dissent contended, at issue in the instant action was the hospital’s failure to provide treatment, which fell within the LMMA. Lacoste v.
Texas Appeals Court Holds Hospital Occurrence Report Privileged
An “occurrence report” regarding a nurse’s injury from a patient prepared for a hospital’s safety committee was protected from discovery under the Texas medical peer review privilege, an appeals court in the state ruled September 13, 2007. The appeals court concluded the report was privileged because it was prepared for a “medical committee” and used to help evaluate the safety of the hospital’s environment.

Shantha Abraham, a nurse, sued her employer Intracare Hospital after she was injured by a psychiatric patient. The hospital objected to a number of documents she sought during discovery, arguing some were protected under the medical peer review committee privilege. At issue in this dispute was an “occurrence report” that was completed for the hospital’s safety committee. The trial court ruled the report was not protected by the statutory medical committee and peer review privilege.

On appeal, Intracare argued the hospital’s safety committee is a “medical committee” as defined by statute established to evaluate medical and healthcare services provided; that the safety committee requires the completion of an occurrence report for unusual events, accidents, or injuries; and the reports are used by the hospital to investigate and analyze medical and healthcare services. Abraham contended, however, that the report was not shielded from discovery because it amounted to a routine business record unrelated to her medical care and that it was not part of the evaluative process.

The Texas Court of Appeals agreed with Intracare, finding it had established that the safety committee qualified as a medical committee under the relevant statute as a panel authorized to evaluate safety standards for hospital patients, visitors, and personnel. The appeals court also was not persuaded by Abraham’s argument that, because the report was created the same day as the incident, it was merely a routine record and not part of the evaluative process. “Even if the document does not relate to Abraham’s medical care, it is a document created for and reviewed by the hospital committee in the evaluative process of developing and maintaining a safe hospital environment,” the appeals court said. In re Intracare Hosp., No. 14-07-00127-CV (Tex. App. Sept. 13, 2007).

Ohio Appeals Court Says No Need To Name Negligent Staffer In Action Against Hospital For Negligent Credentialing
A plaintiff does not need to name as a party an allegedly negligent physician to maintain an action for negligent credentialing against a hospital, an Ohio appeals court ruled October 12, 2007. Loretta Schelling sued Dr. Stephen Humphrey and Community Hospitals of Williams County alleging Humphrey negligently performed her two podiatric surgeries. The surgeries were performed at Community Hospitals, where at the time Humphrey had full privileges. Schelling asserted a negligent credentialing claim against Community Hospitals, citing Humphrey’s history of criminal conduct—namely a number of felony offenses for theft that eventually cost him his state medical license.
Subsequently, Humphrey filed for bankruptcy. Schelling reached an agreement with his bankruptcy trustee and dismissed the negligence claim against Humphrey, leaving only her negligent credentialing claim against Community Hospitals. Community Hospitals moved to dismiss, arguing the element of staff physician negligence could not be addressed for purposes of the credentialing claim without including Humphrey as a party to the action. The trial court agreed and dismissed the action.

Reversing, the Ohio Court of Appeals, Sixth Appellate District, held a negligent credentialing claim can be made without the physician being a named party. The state high court has made clear “that medical malpractice and negligent credentialing, while they may be factually intertwined, are distinct claims,” the appeals court said. “Determining that staff physician negligence must be proven as an element of a negligent credentialing claim against an employer does not interpose a legal requirement to name the staff physician as a defendant and prove the negligence claim in the same complaint. They are separate causes of action,” the court held. Schelling v. Humphrey, No. WM-07-001 (Ohio Ct. App. Oct. 12, 2007).

U.S. Court In California Enjoins Cancellation Of Hospital Lab’s Medicare And Medicaid Payments

A federal district court in California enjoined January 10, 2008 the Department of Health and Human Services (DHHS) Secretary from canceling a hospital’s approval to receive Medicare and Medicaid payments for clinical laboratory services before revocation of its certification under the Clinical Laboratory Improvement Act of 1986 (CLIA). In July 2007, the Centers for Medicare and Medicaid Services (CMS) determined Victor Valley Community Hospital was “out of compliance” with proficiency testing requirements and improperly referred proficiency testing samples to an outside laboratory. CMS on September 11, 2007 informed Victor Valley that it was revoking the CLIA certification for the hospital’s laboratory and canceling its Medicare and Medicaid approval.

Although Victor Valley filed an administrative appeal, which stayed the CLIA certification revocation, CMS refused to stay the cancellation of the hospital’s Medicare and Medicaid approvals pending the outcome of the appeal. Victor Valley challenged the validity of the regulations allowing the DHHS Secretary to cancel Medicare payments before the administrative appeal of a CLIA certification revocation was completed. The DHHS Secretary argued the court lacked subject matter jurisdiction because Victor Valley failed to exhaust administrative remedies and, alternatively, did not satisfy the requirements for a preliminary injunction.

The U.S. District Court for the Central District of California granted the hospital’s request for injunctive relief. The court found Victor Valley’s challenge to the agency's “cancellation regulations” arose under the Medicare Act and therefore 42 U.S.C. § 405(h) bars the court from exercising subject matter jurisdiction unless the hospital complied with the presentment and exhaustion requirements of 42 U.S.C. § 405(g). After determining that Victor Valley had met the presentment requirement by filing an appeal with an agency administrative law judge, the court concluded exhaustion could be waived in a case challenging the validity of a regulation. Specifically, the court found waiver of
exhaustion was appropriate because the claim was “collateral to a substantive claim of entitlement (collaterality)”; “colorable in its showing that denial of relief will cause irreparable harm (irreparability)”; and “one whose resolution would not serve the purposes of exhaustion (futility).”

Turning to the factors for granting a preliminary injunction, the court determined Victor Valley had established a likelihood of success on the merits of its challenge. The court also found Victor Valley had shown a possibility of irreparable injury. The court noted that Victor Valley is one of four hospitals servicing roughly 500,000 people, operates an emergency department and labor delivery unit, 43% of its patients are Medi-Cal beneficiaries, and 21% are Medicare beneficiaries. Victor Valley demonstrated that if the cancellation of its Medicare and Medicaid payments went into effect, it would likely have to trim its operations or shut down completely. “[T]hese potential injuries to Plaintiff and the community it serves, if realized, would be far-reaching and permanent,” the court observed. Thus, while the balance of hardships did not tip sharply in the hospital’s favor because of the government’s strong interest in taking prompt action to ensure safe, accurate, and reliable laboratory tests, the court nonetheless issued the preliminary injunction based on Victor Valley’s likely success on the merits and the possibility of irreparable injury. Victor Valley Community Hosp. v. Leavitt, No. EDCV 07-1180-VAP-OP (C.D. Cal. Jan. 10, 2008).

Eighth Circuit Says Hospital Had Contractual Immunity From Staff Physician’s Due Process Suit
A physician could not sue a hospital that revoked his privileges for breaching his due process rights under the hospital bylaws, the Eighth Circuit ruled February 19, 2008. According to the appeals court, the bylaws specifically provided the hospital with immunity from suit. Dr. Horst Blume sued Marian Health Center (hospital), claiming it breached its contract with him by terminating his privileges without giving him a hearing as provided for under the hospital bylaws. The district court held the hospital had breached its contract as a matter of law and a jury returned a verdict in Blume’s favor on damages. The hospital appealed; Blume’s estate was substituted as a party following his death.

The Eighth Circuit reversed, finding the hospital had contractual immunity from suit. The appeals court noted that at trial both parties conceded the hospital bylaws created a contract. And in any event, the appeals court said, given the subtlety of Iowa law on the subject and the detailed character of the bylaws in question, treating them as a contract was neither an obvious error nor manifestly unjust.

Turning to the breach of contract claim, the appeals court pointed to a provision in the bylaws providing “absolute immunity to . . . the hospital . . . for any actions" related to "proceedings for suspension . . . of clinical privileges or for . . . revocation of appointment, or for any other disciplinary action.” The appeals court held the immunity provision encompassed Blume’s claims, rejecting his argument that Iowa law required a hospital staff member be afforded certain due process rights before the revocation of his privileges. The appeals court found no Iowa statute governing the due process rights of a
hospital’s staff members and “therefore no legislative public policy that weighs in here against the immunity provision in the hospital’s bylaws.” While some state courts have found certain common law due process rights for staff physicians, no Iowa case law indicates that a contractual agreement not to enforce those common law rights would be invalid, the appeals court reasoned.

Blume argued that to allow the immunity clause to trump the promises of due process in the bylaws would render his arrangement with the hospital nugatory. “The promises still create a moral obligation on the part of the hospital, moreover, and may create a scruple against their violation; Dr. Blume just does not have an action if the hospital violates them,” the appeals court observed. If the immunity clause rendered the promises illusory, that would simply mean Dr. Blume had no contract under which to sue, the appeals court added. *Estate of Blume v. Marian Health Ctr.*, No. 07-1711 (8th Cir. Feb. 19, 2008).

**AHRQ Reports National Hospital Bill Hit $875 Billion In 2005, Lists Most Expensive Conditions**

In 2005, the nation’s hospitals billed nearly $875 billion in total charges, up 89% since 1997, according to a new statistical brief issued by the Agency for Healthcare Research and Quality (AHRQ). The charges represent 39.2 million hospital stays, compared to 34.7 million admissions in 1997, and do not include hospital outpatient care, emergency care for patients not admitted to the hospital, or physician fees for the admissions. According to the brief, based on data from the Healthcare Cost and Utilization Project, one-fifth of the national hospital bill was for treatment of five conditions: coronary artery disease, pregnancy and delivery, newborn infants, acute myocardial infraction, and congestive heart failure. Topping the list of hospital conditions with the most expensive charges was coronary artery disease ($46 billion) followed by pregnancy and delivery ($44 billion), the brief said. The brief also noted that almost two-thirds of the national bill for hospital care was billed to Medicare ($411 billion) and Medicaid ($124 billion), while $272 billion was billed to private insurers.

**Joint Commission Establishes Task Force To Address Concerns Regarding Revised Medical Staff Standard MS.1.20**

The Joint Commission has established a special 16-member task force that will examine implementation issues related to revised hospital medical staff standard MS.1.20, to become effective in July 2009, according to a press release issued January 3, 2008 by the Joint Commission. The intent of revised standard MS.1.20, which was approved by the Joint Commission’s Board of Commissioners in June 2007, “is to support and reinforce a productive working relationship between the medical staff and the governing body while minimizing disruptions to the hospital, including the medical staff,” the release said. “We recognize and are addressing the concerns that hospitals and medical staffs have raised about the implementation of MS.1.20,” said Paul M. Schyve, M.D., the Joint Commission’s senior vice president.

The Task Force will analyze the potential impact of implementing the revised standard by examining case examples and factual information, with the objective of gaining a better understanding of the practical implementation issues related to hospital compliance.
Towards that end, the Task Force will examine and evaluate the four central concepts of the revised standard: the flexibility allowed the organized medical staff and governing body on the placement of documents in or outside of the medical staff bylaws; the expectation that the decisions of the Medical Executive Committee reflect the wishes of the organized medical staff; the expectation that organizations with productive working relationships among leadership will find the voting requirements of the organized medical staff reasonable to implement; and the method to limit items requiring joint approval so as not to burden the hospital. The Task Force also aims “to allay concerns related to the amount of time and money required to meet the requirements of the revised standard within a well-functioning organization,” the release said.

California Appeals Court Rejects Patient’s Action Against Hospital For Failing To Disclose Prompt Pay Discount

A patient could not sue a hospital under California’s unfair competition and consumer protection laws for allegedly failing to disclose its prompt pay discount policy in billing invoices, a state appeals court ruled March 5, 2008. Terry D. Buller brought a proposed class action on behalf of consumers who have private medical insurance and who had received a bill for medical services provided by Sutter Health and Alta Bates Summit Medical Center (defendants). According to Buller, defendants’ billing invoices overstated the amount due because of their undisclosed policy of discounting consumers' balances for prompt payment.

Buller alleged defendants’ failure to inform consumers about the 10% to 44% discount they offered for paying bills promptly (generally within 30 days) violated the California Unfair Competition Law (UCL) and the Consumers Legal Remedies Act (CLRA). The trial court dismissed Buller’s complaint without leave to amend and the California Court of Appeal, First District, affirmed.

A business act or practice violates the UCL if it is unlawful, unfair, or fraudulent, the appeals court explained. The appeals court found Buller’s claim did not satisfy the “fraudulent” prong because he failed to allege defendants had a duty to disclose the prompt payment discount policy. “Accordingly, patients in his position are not likely to be operating under the expectation that they are entitled to a discount,” the appeals court observed. Moreover, the appeals court said, the complaint contained no allegation that the initial amount defendants charged was improper on its face.

The appeals court also found Buller’s action could not be sustained under the “unfairness” prong as he made no claim that his allegations were directly connected to any legislatively declared policy or threatened competition. “Indeed, taken to its logical conclusion, [Buller’s] argument would effectively require a business to disclose all discretionary discounts it might offer,” the appeals court reasoned. In fact, the appeals court mused, “when viewed from the standpoint of consumers in general we believe [defendants’] practice is beneficial rather than harmful, inasmuch as they apparently are not required to offer privately insured patients any discount whatsoever.” Buller v. Sutter Health, No. A118541 (Cal. Ct. App. Mar. 5, 2008).
U.S. Court In Louisiana Orders Hospital To Produce Documents Sought In FTCA Action
A federal court in Louisiana denied a hospital’s motion to quash a request for production of documents based on privilege under the Healthcare Quality Improvement Act (HCQIA) and/or the Health Insurance Portability and Accountability Act (HIPAA), finding that such statutes do not bar production, but rather entitle the documents to a protective order. In so holding, the court ordered the hospital to produce the documents subject to the terms of a protective order.

Plaintiff Linda Vezina sued the United States under the Federal Tort Claims Act (FTCA) for injuries she suffered when she was treated by Dr. James Austin, an employee of the Department of Health and Human Services working at Southwest Louisiana Center for Health Services and Women & Children’s hospital. During discovery, plaintiffs requested documents concerning Austin’s physician’s file, credentials, and peer review data from Women & Children’s. Women & Children’s filed a motion to quash, claiming that some of the documents requested were protected by privileges under HCQIA and/or the HIPAA.

The court found “clear” that neither HCQIA nor HIPAA “categorically prohibit production.” According to the court, under the statutes, “patient information is entitled to the protection of a court protective order, however, it is not prohibited from being produced.” Accordingly, after an in camera review of the documents, the court ordered Women & Children’s to produce the documents within certain parameters enumerated in a protective order. Vezina v. United States, No. 07-0904 (W.D. La. Mar. 27, 2008).

U.S. Court In Pennsylvania Says Plaintiff Sufficiently Pled Corporate Negligence Against Hospital But Failed To Meet Certificate Of Merit Requirement
While a plaintiff adequately stated a claim of corporate negligence against a hospital, he failed to timely file the required Certificate of Merit (COM) and therefore the claim must be dismissed, a federal trial court in Pennsylvania ruled April 17, 2008. The court dismissed the claim, however, without prejudice, allowing plaintiff to show reinstatement was warranted because of a reasonable explanation or legitimate excuse for his noncompliance with the COM requirement.

Plaintiff Robert Stroud sued Abington Memorial Hospital, various physicians, and other individuals and entities for medical malpractice in connection with the death of his father, James Stroud. James Stroud was admitted to the hospital for a total knee replacement and died several days later from a bowel obstruction. Plaintiff alleged defendants failed to communicate adequately concerning his father’s care and the hospital specifically failed to have and enforce proper policies and procedures for interdepartmental communication. The complaint asserted a number of claims including corporate negligence (direct liability) and vicarious liability against the hospital and sought punitive damages. The hospital moved to dismiss, arguing plaintiff failed to state a claim for corporate negligence and failed to timely file a COM as required under Pennsylvania Rules of Civil Procedure.
The U.S. District Court for the Eastern District of Pennsylvania concluded plaintiff had sufficiently pled a claim for corporate negligence. In the complaint, plaintiff alleged that the hospital was directly liable under a corporate negligence theory because it breached its duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for patients. Although plaintiff did not expressly plead that the hospital actually or constructively knew of these alleged defects, this was not required under federal pleading rules, the court said.

But the court nonetheless dismissed the claim because plaintiff failed to comply with the state's COM requirement. Specifically, plaintiff originally filed a COM only as to a vicarious liability theory, not a direct liability theory, within the 60-day filing period. Pennsylvania civil procedure rules require a COM, which essentially provides a written statement from a relevant expert that a reasonable probability of professional negligence exists, as to each theory of liability or, alternatively, a single COM listing both theories.

The Pennsylvania Supreme Court’s decision in Womer v. Hilliker, 908 A.2d 269 (Pa. 2006), set forth a strict construction of the 60-day deadline for filing a COM but did allow a plaintiff to set out certain equitable considerations that would constitute a “reasonable explanation or legitimate excuse” for noncompliance, the court here observed. To meet this standard under state case law, the district court continued, appears to require a showing that the noncompliance “was due to some intervening event that could not have been reasonably expected” and that goes beyond a “misunderstanding of the law governing the applicability of the COM requirement . . . .” While plaintiff had not made this showing, the court said it would allow him to present additional evidence that, for example, he did have a written statement from an appropriate licensed professional on the corporate negligence claim but his attorney simply failed to check the appropriate boxes on the original COM form. Stroud v. Abington Mem’l Hosp., No. 06-4840 (E.D. Pa. Apr. 17, 2008).

Illinois Appeals Court Dismisses Action Alleging Deceptive Practices By Nonprofits In Uninsured Billing

The Illinois Appellate Court, First District, affirmed April 14, 2008 the dismissal, with prejudice, of an uninsured patient’s class action against not-for-profit hospitals in Illinois for violating the state’s Consumer Fraud and Deceptive Business Practices Act (Act). Plaintiff Antonio Galvan filed the action against Northwestern Memorial Hospital specifically, and other hospitals, challenging their practices of charging uninsured patients more for services than they charge insured patients. Galvan, who is uninsured, received emergency treatment at Northwestern following an automobile accident. Northwestern sent him a bill for over $87,000 and later asserted a lien on the $240,000 tort settlement he received.

In his lawsuit, Galvan alleged Northwestern’s practice of billing uninsured patients gross or list hospital charges, which was more than 50% what it charged insured patients, was unfair and deceptive. Galvan also asserted a claim for unjust enrichment. The trial court dismissed the action with prejudice. The appeals court affirmed.
The appeals court rejected Galvan’s claim that Northwestern’s billing practices with respect to uninsured patients were unfair in violation of the Act. Specifically, the appeals court found Galvan had failed to allege Northwestern actually profited from charging higher rates to uninsured patients. In addition, he could not allege unfairness based on high prices because he received numerous medical procedures and therapies during his 15-day stay at Northwestern. The appeals court also said Galvan’s claim that Northwestern’s uninsured billing practices amounted to oppressive pricing ignored the “obvious difference between an insured patient and one uninsured.” According to the appeals court,

That an uninsured patient is charged a higher rate for medical services is the flip side of the revenue-stream coin. Those that have incurred the expense of medical insurance guaranteeing payment to a medical services provider receive reduced billing rates; those that have incurred no expense to guarantee payment to a medical services provider must bear the full cost for those services.

The appeals court also agreed with the lower court that Galvan failed to establish a deception claim under the Act—i.e. that Northwestern failed to disclose it charged uninsured patients at least double what it charged uninsured patients. While the court acknowledged that Galvan adequately pled Northwestern concealed information about its rates and billing practices from him, he failed to plead that he suffered any damages from the concealment, or that any alleged damages were proximately caused by the concealment, the appeals court said. The appeals court noted that Galvan was taken to Northwestern for emergency care, and there was no evidence he would have sought care elsewhere had the hospital disclosed their rates upfront.

Finally, the appeals court affirmed the dismissal of Galvan’s unjust enrichment claim because, “until a trial court adjudicates the rights of the parties and enforces the lien,” Northwestern “has retained no benefit.” Galvan v. Northwestern Mem’l Hosp., No. 05 CH 1800 (Ill. App. Ct. Apr. 14, 2008).

**INDIVIDUAL/PATIENT RIGHTS**

**Second Circuit Finds Intended Organ Recipient Had No Property Right In Donated Kidney Because Of Incompatibility**

A specified organ recipient could not have derived a medical benefit from a donor’s kidney and therefore had no cause of action under the New York common law of conversion or the state’s public health statutes after an organ donor network gave the kidney to someone else, the Second Circuit held. The case arose after the death of Peter Lucia. His widow sought to donate his kidney to plaintiff Robert Colavito (now deceased), 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 later said 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 in federal district court, for fraud, conversion, and violations of New York Public Health Law Articles. After rejecting the fraud claim, the Second Circuit certified to the New York high court questions about whether plaintiff could maintain his claims for conversion and statutory violations. 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 also concluded that plaintiff had no statutory cause of action under New York’s Public Health Law since a donee is defined as someone “who needs the donated organ” and both kidneys were medically incompatible with plaintiff.

The Second Circuit said the state high court’s ruling left one further question—whether Lucia’s kidneys were in fact incompatible with plaintiff, noting the district court never determined whether compatibility remained a genuine issue of material fact. Exercising its discretion to decide this issue in the first instance, the appeals court found ample evidence that Lucia’s kidneys were in fact incompatible with plaintiff. Thus, the appeals court affirmed the grant of summary judgment to defendants. Colavito v. New York Organ Donor Network, Inc., No. 05-1305-cv (2d Cir. May 21, 2007).

**Sixth Circuit Strikes Down Michigan Abortion Law**

A three-judge panel of the Sixth Circuit found June 4, 2007 a Michigan law that regulated abortion methods was unconstitutional because it presented an “undue burden” on a women’s right to terminate her pregnancy. The ruling comes after the U.S. Supreme Court in April 2007 upheld the federal Partial Birth Abortion Act of 2003, which criminalizes a particular type of abortion known as an “intact dilation and extraction,” or alternatively “D&X.” Gonzales v. Carhart, 127 S. Ct. 1610 (2007). The Sixth Circuit here said its holding squared with the Court’s Gonzales ruling because the Michigan law was written to encompass other commonly used abortion procedures, such as “dilation and evacuation,” or D&E, which the Court consistently has held may not be prohibited.

Michigan’s Legal Birth Definition Act creates protected legal status for a partially delivered fetus that it terms a “perinate,” which is defined as “a live human being at any point after which any anatomical part of the human being is known to have passed beyond the plan of the vaginal introitus until the point of complete expulsion or extraction from the mother’s body.” The Act essentially criminalizes any abortion procedure that results in the injury or death of a “perinate” unless excused by stated exceptions for preserving the health or life of the mother. Six healthcare facilities and four obstetrician-gynecologists (plaintiffs) challenged the Act. The Michigan Attorney General subsequently issued an opinion purporting to limit the Act’s scope, saying it only banned D&X, not other commonly used abortion procedures.

The district court found the Act unconstitutional, holding it imposed 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), it failed to adequately protect the health of the mother as required in Stenberg v. Carhart, 530 U.S. 914 (2000) (striking down a Nebraska ban on partial birth abortions), and it was void for vagueness.
Affirming, the Sixth Circuit said the Supreme Court’s intervening decision in *Gonzales* did not alter the outcome, since that ruling left in place the holding in *Stenberg* that prohibiting D&E would amount to an unconstitutional undue burden. Unlike the federal statute, which applies only to abortion procedures that involve the delivery of a living fetus to certain “anatomical landmarks,” the statutory language of the Michigan law would clearly prohibit D&E, the appeals court said. The appeals court refused to construe the Act as applying only to D&X, as the Michigan Attorney General determined, because to do so would be “entirely at odds with the language of the statute.” *Northland Family Planning Clinic, Inc. v. Cox*, Nos. 05-2417/2418 (6th Cir. June 4, 2007).

**Third Circuit Rejects Action Alleging City Health Center Violated Constitutional Rights By Giving Minor Emergency Contraceptive**

An unemancipated minor and her parents could not maintain an action alleging their constitutional rights were violated when a health center run by the city of Philadelphia provided her with emergency contraception, the Third Circuit ruled. Sixteen-year-old Melissa Anspach visited a health center operated by Philadelphia’s Department of Public Health where she asked for and obtained emergency contraception, known as the “morning after pill.” She took the first dose at the center and the second dose at home as instructed by the center’s nurse. Melissa became ill after taking the second dose and at that point told her parents she had taken emergency contraception.

Melissa and her parents (plaintiffs) sued the city and certain of its employees and agents (defendants) under 42 U.S.C. § 1983, alleging defendants violated their constitutional rights to parental guidance by giving Melissa medication without parental consent. Plaintiffs also claimed violations of their right to the free exercise of religion under the First Amendment.

The appeals court determined that Melissa’s parents could not maintain their claim for a substantive due process violation based on state interference with family relations because “the conduct complained of was devoid of any form of constraint or compulsion.” Melissa could have called her parents had she chosen to and she was only given the pills after asking for them, the appeals court noted. The nurse’s conduct of telling Melissa when and how to take the pills did not amount to coercion, the appeals court added.

The Third Circuit also found no constitutional right to parental notification of a minor child’s exercise of reproductive privacy rights. Previous cases relied on by plaintiffs involved the constitutional limits on a state to interfere with a minor’s right to an abortion, not a parent’s affirmative right to receive notification of a minor’s reproductive decisions, the appeals court reasoned. Similarly, the appeals court rejected plaintiffs’ claimed First Amendment violations, again noting no evidence Melissa was compelled or coerced to act contrary to her religious beliefs. *Anspach v. City of Philadelphia*, No. 05-3632 (3d Cir. Sept. 21, 2007).
Maine High Court Rejects Payors’ Challenge To Calculation Of “Cost Savings” From Health Program Used To Set Offset Payments

The Maine Supreme Judicial Court upheld May 31, 2007 the methodology used by the Dirigo Health Board of Directors (Board) to calculate savings generated from a newly enacted healthcare program for purposes of determining payment offsets due from payors. In 2003, the Maine legislature passed a broad measure (the Act) aimed at providing increased access to affordable health insurance in the state. As part of this effort, the legislature also created the Dirigo Health program, which was intended to help small businesses afford health insurance for their employees through various subsidies.

The program, which was only funded for the first year of its operation, called for several additional funding sources, including recouping the savings insurers and third-party administrators were expected to realize because of the Act. The amount of these “savings offset payments” due from payors was to be calculated using “aggregate measurable cost savings.” For 2005, the Board set the amount at $136.8 million, which the Superintendent of Insurance reduced to $43.7 million.

Several entities representing health insurers and other payors, including the Maine Association of Health Plans and the Maine State Chamber of Commerce (collectively, the Association), challenged the Board’s method for calculating aggregate measurable cost savings. The Act did not define the term, but provided that the Board should determine “the aggregate measurable cost savings, including any reduction or avoidance of bad debt and charity care costs to health care providers in this State as a result of the operation of Dirigo Health and any increased MaineCare enrollment due to an expansion in MaineCare eligibility occurring after June 30, 2004.” According to the Association, the Board impermissibly included savings realized under the Act that were not a direct result of the operation of the Dirigo Health program.

The Maine Supreme Judicial Court held the Board’s calculation was a reasonable interpretation of the ambiguous statutory language. The high court said the Board’s interpretation was entitled to deference because the legislature explicitly established the Board as a highly specialized body to supervise the operations of Dirigo Health. Based on legislative history, the high court said initially aggregate measurable cost savings were understood to be generated mostly from reductions in bad debt and charity care along with expansions in MaineCare eligibility, as the Association argued. But after enactment, it became clear that these savings might not be as extensive as originally thought. As a result, the legislature ultimately created a working group to study the appropriate methodology for making the calculation, and left the Board with the ultimate authority to interpret the statutory term. Maine Ass’n of Health Plans v. Superintendent of Ins., No. CUM-06-519 (Me. May 31, 2007).
New Connecticut Law Aimed At Protecting Consumers From Unfair Health Insurance Policy Rescissions

Connecticut Governor Jodi Rell signed into law June 13, 2007 new legislation intended to protect consumers from unfair health insurance rescissions, cancellations, or limitations of their individual policies, according to a press release issued by state officials. The measure, “An Act Concerning Postclaims Underwriting,” was passed unanimously by both houses of the General Assembly. According to the release, state authorities have “received a steadily increasing number of calls from people suffering catastrophic illness and needing assistance because their insurance policies were rescinded or their claims were denied.” The new law prohibits the practice of “post-claims underwriting,” in which insurers scrutinize a policyholder’s medical records only after a claim is submitted for treatment of a medical condition. The law will require insurers to obtain the approval of the Connecticut Insurance Department before rescinding a policy, putting the burden on the insurer to prove the insured knowingly omitted or misstated material information. Under the measure, a violation of the Act amounts to a per se violation of the Connecticut Unfair Insurance Practices Act.

Pennsylvania Appeals Court Says Subscriber Has Standing To Sue Nonprofit For Maintaining Excess Reserves

A subscriber to a health insurance policy provided by Independence Blue Cross (IBC) has standing to sue the nonprofit corporation for allegedly maintaining excess reserves in violation of Pennsylvania's nonprofit law, a state appeals court ruled July 2, 2007. According to the appeals court, IBC’s bylaws gave subscribers certain rights and duties that placed them in the same class as directors, members, and officers who are specifically empowered in the nonprofit law to challenge “corporate action.”

Jules Ciamaichelo and Rob Stevens, Inc. (plaintiffs) filed a class action against IBC, a nonprofit hospital corporation, on behalf of themselves and other subscribers and policyholders for alleged violations of Pennsylvania’s Nonprofit Corporation Law. Rob Stevens, Inc. has a contract with IBC to provide health insurance coverage for its employees under a group policy. Ciamaichelo, the President of Rob Stevens, Inc., is a subscriber of the group policy. According to plaintiffs, IBC, as a nonprofit health insurer of last resort, violated the Nonprofit Law by accumulating reserves that were not needed for ongoing operations or financial solvency.

The trial court ruled that it lacked subject matter jurisdiction because the action amounted to a challenge to IBC’s rates and reserves, which are governed exclusively by the Pennsylvania Department of Insurance. The appeals court affirmed. The Pennsylvania Supreme Court, in a November 21, 2006 decision, reversed, holding 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. The high court remanded the case to the appeals court to first address a third objection raised by IBC, and overruled by the trial court, that plaintiffs lacked standing under the Nonprofit Law.
On remand, the Pennsylvania Commonwealth Court held Ciamaichelo, as a subscriber, had standing but that Rob Stevens, Inc., as the group policyholder, did not. At issue was plaintiffs’ claim that IBC violated the Nonprofit Law by failing to apply all incidental profits to the maintenance and operation of its lawful activities. The Nonprofit Law confers standing to sue under this provision on any nonprofit member, director officer, or person “otherwise” affected by the nonprofit’s “corporate action.” The appeals court found that IBC’s Articles of Incorporation placed subscribers in the same class as members, directors, and officers and therefore they had standing to sue under the Nonprofit Law. Specifically, the appeals court noted that the Articles empowered subscribers to take “corporate action,” including nominating and removing directors and also to propose and challenge “corporate action” that could affect their status, rights, or duties. Unlike subscribers, however, policyholders did not have any special status, rights, or duties under IBC’s Articles and therefore Rob Stevens, Inc. did not have standing to sue.

A dissenting opinion argued that because a single subscriber has no governance rights under IBC’s Articles or the Nonprofit Law, he or she is not a person “otherwise” affected for purposes of challenging a corporate action. *Ciamaichelo v. Independence Blue Cross*, No. 1969 C.D. 2002 (July 2, 2007).

**Regence Blue Shield Settles Lawsuit Over High Performance Network**

Regence BlueShield has agreed to a settlement with the Washington State Medical Association (WSMA), the American Medical Association (AMA), and six physician plaintiffs in connection with Regence’s creation of the Select Network program, which rated physicians based on certain factors. Regence previously announced it had voluntarily withdrawn the Select Network program and apologized to the physicians and members for any misunderstanding that may have been caused by its initial communications about the Select Network program, according to a press release issued August 8, 2007 by WSMA. Under the settlement, Regence will provide WSMA with the opportunity to offer meaningful input into any new or revised performance measurement program before it is implemented; physician reports and scores will be posted on Regence’s website in a readable electronic format and will include explanations of various aspects of the ratings; and physicians will have an opportunity to appeal their scores.

**NY AG Warns Health Plans About Concerns On Physician Ranking Programs**

New York Attorney General Andrew M. Cuomo sent letters August 16, 2007 to Aetna and Cigna Healthcare expressing serious concerns about the companies’ plans to rank physicians according to quality and cost-effectiveness. The resulting ratings would then be used to steer consumers toward the highest rated physicians. According to the letter, such programs, as currently designed, “are likely to confuse or even deceive consumers.” In July, Cuomo sent a similar letter to UnitedHealthcare, objecting to its proposal for ranking physicians. The letters outlined several concerns, including that the rankings are based on claims data that carry “several significant risks of error” for ranking purposes; that the insurers fail to disclose the accuracy rate of the rankings; and that the insurers
“have a profit motive to recommend doctors who cost less,” but may not necessarily be the most qualified.

In further developments, Cuomo sent October 18, 2007 to three more healthcare companies expressing serious misgivings about their existing or planned programs to rank physicians according to quality and cost-effectiveness. The letters were sent to New York City-based Empire Blue Cross Blue Shield, asking it to justify its existing Blue Precision ranking program; Rochester-based Preferred Care, directing it to halt the launch of its planned ranking program and provide more details about the system; and New York City-based HIP Health Plan/GHI, asking it to refrain from launching such programs with out prior consent from the AG.

Subsequently, Cuomo announced that Cigna, Aetna, and Empire Blue Cross Blue Shield all agreed to adopt his model for doctor ranking programs. Cuomo’s model reforms doctor ranking programs by compelling insurers to fully disclose to consumers and physicians all aspects of their ranking system. Insurers must also retain an oversight monitor, known as a Ratings Examiner (Rx), who will oversee compliance with all aspects of the agreement and report to the Attorney General every six months, Cuomo said. In addition, under the model, insurers must agree that their rankings for doctors are not based solely on cost and to clearly identify the degree to which any ranking is based on cost. The companies will use established national standards to measure quality and will employ several measures to foster more accurate physician comparisons, Cuomo added. Cuomo announced November 26, 2007 an agreement with state lawmakers to pass legislation in New York based on his Doctor Ranking Model Code.

United Healthcare Reaches $20 Million Multi-State Settlement Involving Claims Payment Services

United Healthcare will pay up to $20 million and implement an extensive process improvement plan under a landmark, multi-state settlement to resolve allegations concerning the company’s claims payment services. The settlement was announced September 6, 2007 by insurance regulators from the five states that led negotiations with United Healthcare—Iowa, Arkansas, Connecticut, Florida, and New York. The settlement stems from an investigation into complaints about United Healthcare’s claims practices.

The investigation uncovered numerous problems, including not applying fee schedules and deductibles correctly, violating prompt pay rules, and being unable to correct problems pointed out by state regulators, according to a press release posted by the New York State Department of Insurance. Thirty-six states and the District of Columbia have signed on to the settlement agreement. More than $13 million will be immediately distributed to the participating states. New York will receive the largest share, about $3.7 million. As part of the settlement, United Healthcare also agreed to adhere to a detailed three-year process improvement plan for their claims payment system with quarterly reviews and yearly benchmarks, according to a press release posted by the Iowa Insurance Division. United HealthCare could face additional penalties of up to $20 million if it fails to meet the annual process improvement benchmarks, the release said.
California’s DMHC Fines Kaiser $3 Million For Faulty Quality Oversight

The California Department of Managed Health Care (DMHC) announced July 26, 2007 that it was fining Kaiser Foundation Health Plan (Kaiser) $3 million after an investigation found oversight of quality assurance programs at its 29 medical centers lacking. DMHC said the fine would be reduced by $1 million provided Kaiser fully completed proposed corrective measures.

Based on a review of 228 randomly selected case files, DMHC found Kaiser deficient under state law in two respects—“the lack of adequate health plan oversight of quality assurance programs, and the significant variation and inconsistent handling of quality-of-care cases referred for medical peer review.” To address these problems, Kaiser must establish new reporting processes as well as a uniform set of standards for its medical centers. Kaiser also must establish a new regional Member Concerns Committee to report to the health plan on specific member complaints, DHMC said. In a statement, Kaiser emphasized that DHMC’s survey was “not, at any level, about the actual quality of care provided to Kaiser Permanente’s members.”

California Regulators Require Blue Cross To Discontinue Use Of Confidentiality Agreement In Provider Contracts

The California Department of Managed Health Care (DMHC) issued November 1, 2007 to Blue Cross of California an order to cease and desist requiring providers to sign a confidentiality agreement prior to opening negotiations. According to DMHC, “the requirement is illegal as an unfair and unreasonable contract, because it limits and conditions the selection and use of a provider’s legal counsel in negotiations of new contracts.” In addition, the agreement's definition of confidentiality is overbroad and the agreement does not impose the same requirements on Blue Cross that it does on providers, DMHC said.

Before issuing the cease and desist order, DMHC announced October 26, 2007 that Blue Cross had voluntarily agreed to stop using the agreement. DMHC noted that if Blue Cross was allowed to continue its practice, “the confidentiality agreements could force hospitals to either accept terms that might not give them the best reimbursement rate possible, or to terminate their contracts altogether, both of which could have a devastating impact on southern California . . . .”

In the order, DMHC states that “Blue Cross’ market share in California is sufficiently large that the threat of not contracting with physicians and hospitals who refuse to sign the Agreement presents an unjustifiable risk of insufficient provider networks and lack of access to health care for Blue Cross enrollees.” Thus, DMHC used its authority under the Knox-Keene Act to “order the discontinuance of the unsafe or injurious act or practice.”

Health Net Fined $1 Million For Failing To Disclose Compensation Based On Plan Rescission

The California Department of Managed Health Care (DMHC) announced November 15, 2007 it has fined Health Net $1 million for failing to disclose information about a bonus
program paid to employees for cancelling health policies. According to DMHC, it has been investigating since 2005 health insurers engaged in the illegal practice of post-claims underwriting or rescinding health policies without proving that the applicant willfully misrepresented themselves on the health application. On two occasions during its investigation of Health Net, investigators asked Health Net officials about the existence of any compensation or bonus programs and were told none existed. However, on November 8, 2007 following an order entered in a case against the company, Bates v. Health Net, the plan disclosed to regulators the existence of compensation paid to a company employee based in part on rescission of healthcare policies, DMHC said. According to DMHC, “although Health Net officials have agreed to pay the $1 million fine for non-disclosure, the fine does not have any effect on other aspects of the DMHC’s investigation into the rescission practices of the plan.”

**California Regulator Seeks $12.6 Million Fine From Blue Shield For Improper Rescissions, Claims Handling**

California Insurance Commissioner Steve Poizner said December 13, 2008 that his office is pursuing $12.6 million in fines and penalties against insurer Blue Shield for improper healthcare rescissions and “shoddy” claims handling. According to Poizner’s press release, a California Department of Insurance Market Conduct Exam, based on 2004 and 2005 data, revealed over 1,200 violations of the law, half of which were related to improper rescission. “Blue Shield committed serious violations that completely undermine the public trust in our healthcare delivery system,” said Poizner. Blue Shield already has refunded $1 million in claims at the Commissioner’s request and also agreed to improve its claims processing services and beef-up training of its representatives. Other problems uncovered in the exam included failure to pay claims on a timely basis, failure to pay required interest on claims, and inaccurate or incomplete Explanations of Benefits provided to claimants.

**Nevada High Court Says Medical Providers Have No Private Right Of Action Under Prompt Pay Law Against Insurers**

Medical providers have no private right of action to sue casualty insurers in court for violating Nevada’s prompt pay statute, the state’s high court ruled. The high court concluded the medical providers could seek redress through administrative channels to enforce prompt pay requirements and then seek judicial review if necessary.

A physician and a chiropractor group (plaintiffs) initiated the lawsuit against ten casualty insurance companies alleging they failed to promptly pay the doctors for medical services provided to the companies’ insureds. Plaintiffs sought a declaration in state court that they had a private right of action to recover damages under the state’s “prompt pay” statute, Nev. Rev. Stat. 690B.012, which requires casualty insurance companies to approve, pay, or deny claims within a limited time frame. The insurance companies moved to dismiss, arguing plaintiffs had no private right of action under the statute.

The district court found plaintiffs did enjoy a private right of action under the prompt pay law, but concluded that “primary jurisdiction” rested with the Nevada Insurance Commissioner. Thus, the district court said plaintiffs must first exhaust their
administrative remedies before seeking judicial review. On appeal, the insurance companies contended the district court, by concluding the Nevada Insurance Commissioner had “primary” rather than “exclusive” jurisdiction, improperly created a right to bring an independent action under the statute.

The Nevada Supreme Court agreed, holding plaintiffs had no private right of action under the statute and that the Nevada Insurance Commissioner had “exclusive original jurisdiction” to ensure compliance with the Insurance Code. The high court went on to find that plaintiffs, as medical providers, had a direct pecuniary interest in the Commissioner’s enforcement of the prompt-pay statute and therefore had standing to seek an administrative hearing. Finally, after exhausting the administrative process, plaintiffs could seek judicial review of the outcome under the Nevada Administrative Procedure Act, the high court held. Allstate In. Co. v. Thorpe, No. 44467 (Nev. Nov. 21, 2007).

California Appeals Court Allows Subscriber To Proceed With Action Alleging Health Plan Engaged In Postclaims Underwriting

A California health services plan must show a willful misrepresentation or omission or that it made reasonable efforts to ensure a subscriber’s application was accurate and complete as part of the precontract underwriting process in order to lawfully rescind the contract later, a state appeals court ruled December 24, 2007. Finding these issues in dispute, the California Court of Appeal, Fourth Appellate District, reversed the grant of summary judgment in favor of California Physicians’ Service, doing business as Blue Shield of California (Blue Shield), in plaintiffs Cindy and Steve Hailey’s lawsuit for breach of contract, breach of the covenant of good faith and fair dealing, and intentional infliction of emotional distress.

In a statement following the decision, Blue Shield said it was pleased with the appeals court's ruling "that the law does not require proof of intentional misrepresentation before a policy can be rescinded if the plan completed initial underwriting before the policy was issued." At the same time, Blue Shield said the ruling called into question longstanding precedent that insurers can rely on representations made by individuals in their signed applications. Blue Shield, which filed a petition for rehearing January 8, 2008 predicted that "[i]f the courts were to change their view and require insurers to verify every answer on millions of applications for health coverage, the process of obtaining individual coverage would take much longer, would be much more expensive and the number of uninsured would rise."

Cindy Hailey filled out a Blue Shield application for herself, her husband Steve, and their son and obtained coverage on December 15, 2000. According to Cindy, she believed the application form sought information only about her health, not that of Steve or their son. In February 2001, Steve was admitted to the hospital for stomach problems. Blue Shield initiated an underwriting investigation at that time, learning from his medical records that he had a history of undisclosed health issues. Subsequently, Steve was hospitalized following an automobile accident and racked up substantial medical bills, including the ongoing need for physical therapy and nursing care.
In June 2001, Blue Shield informed the Haileys that their health insurance coverage had been retroactively canceled to December 15, 2000. The Haileys sued Blue Shield, alleging it engaged in "postclaims underwriting," which is prohibited under the Knox-Keene Health Care Service Plan Act absent a showing of "willful misrepresentation." See Cal. Health and Safety Code § 1389.3. Blue Shield moved for summary judgment and cross-claimed seeking to recover the money it spent on Steve’s medical care before the rescission. The trial court granted summary judgment to Blue Shield, holding the Haileys’ misrepresentations and omissions justified rescission, and awarded the plan over $104,000.

Reversing, the appeals court found a triable issue of fact as to whether the Haileys willfully misrepresented Steve’s medical history, saying the application Cindy completed, while understandable, was “no model of clarity.” The appeals court next held that a plan has a duty under § 1389.3 to investigate the accuracy and completeness of a subscriber’s application before it issues a contract. Here, for example, the “tragic situation” in which the Haileys now find themselves “could have been averted” had Blue Shield simply asked Cindy if she had included information for her husband and son. Instead, the record showed Blue Shield conducted an extensive investigation into Steve’s medical history, including obtaining his medical records, after he was hospitalized in February 2001, and apparently did little to determine whether the original application was accurate, the appeals court said.

"[W]e believe the Legislature has placed a concurrent duty on the plan to make reasonable efforts to ensure it has all the necessary information to accurately assess the risk before issuing the contract, if the plan wishes to preserve the right to later rescind where it cannot show willful misrepresentation," the appeals court commented. Thus, because Blue Shield failed to show it made reasonable efforts to ensure the accuracy and completeness of the Haileys' application during the precontract underwriting process, and because the Haileys raised a triable issue of fact as to whether they willfully misrepresented Steve’s physical condition, summary judgment should not have been granted.

The appeals court also concluded that a triable issue of fact existed on the Haileys’ bad faith claim. “The facts presented here raise an inference Blue Shield may have acted in bad faith by delaying its decision to rescind the policy,” the appeals court said. Specifically, the appeals court noted Blue Shield began investigating Steve’s medical condition in February 2001, but waited almost four months, until after his automobile accident, to rescind the policy. “[A] health care services plan may not adopt a ‘wait and see’ attitude after learning of facts justifying rescission by continuing to collect premiums while keeping open its rescission option if the subscriber later experiences a serious accident or illness that generates large medical expenses,” the appeals court observed. Finally, the appeals court held the Haileys could maintain their claim for intentional infliction of emotional distress, finding Blue Shield’s actions could rise to the level of “extreme and outrageous” conduct to support such a claim. Hailey v. California Physicians’ Serv., No. G035579 (Cal. Ct. App. Dec. 24, 2007).
California Agencies Take Action Against PacifiCare To Halt Claims Handling Violations

California Department of Insurance (CDI) Commissioner Steve Poizner and Cindy Ehnes, Director of the California Department of Managed Health Care (DMHC), announced January 29, 2008 joint action against PacifiCare in response to thousands of alleged claims handling violations. The enforcement action potentially implicates between $650 million to $1.3 billion depending on whether the alleged violations are shown to be non-willful or intentional, DMHC said in a press release.

CDI and DMHC launched a joint investigation in 2007 into PacifiCare’s alleged unfair practices, including wrongful denials of covered claims; incorrect payment of claims; lost documents including certificates of creditable coverage and medical records; failure to timely acknowledge receipt of claims; multiple requests for documentation that was previously provided; failure to address all issues and respond timely to member appeals and provider disputes; and failure to manage provider network contracts and resolve provider disputes.

As a result of a CDI self-audit of PacifiCare’s unfair pre-existing condition denials, more than $1 million has already been recovered for California consumers and health providers who were impacted by PacifiCare’s alleged violations, the press release said. In addition, according to the release, “CDI’s market conduct examinations reviewed PacifiCare files processed between July 1, 2005 and May 31, 2007, and have identified 130,000 violations of law by PacifiCare in its claims handling practices and handling of provider data including tracking of provider disputes and maintaining network lists.”

California Appeals Court Says Lawsuit Alleging Health Plan Engaged In Postclaims Underwriting May Proceed As Class Action

A lower court improperly denied class certification in a lawsuit under California’s Unfair Competition Law (UCL) alleging a health plan violated state statutes by engaging in postclaims underwriting in rescinding individuals’ short term health insurance policies, a state appeals court ruled February 27, 2008. In a decision following rehearing of the case, the California Court of Appeal, Second District, Division 3, again reversed a state trial court decision denying class certification in the case. The appeals court remanded with instructions on what factors the lower court should consider in deciding the class certification issue.

Plaintiff Augusto Ticconi sued Blue Shield of California Life and Health Insurance Co. (Blue Shield) under California’s UCL, Cal. Bus. & Prof. Code § 17200 et seq., alleging that Blue Shield engaged in postclaims underwriting prohibited by Cal. Ins. Code § 10384. In addition, Ticconi alleged Blue Shield violated Cal. Ins. Code §§ 10113 and 10381.5 by failing to attach his application to or endorse it on the insurance policy when issued, and later rescinding the policy on the ground he had made misrepresentations in that application.

Further, Ticconi alleged that in the prior four years, Blue Shield had rescinded a large number of policies with applications that were incorporated by reference but not attached
to or endorsed on the policy, and that such conduct constituted an unfair and unlawful business practice under California’s UCL. Subsequently, Ticconi filed a motion for certification of a class of similarly situated insureds.

In opposing the motion, Blue Shield contended, among other arguments, that the class was not “easily ascertainable” because it would be comprised of individuals having varying degrees of “unclean hands,” and therefore the case would require litigating individual issues of fraud and misrepresentation. The trial court agreed and denied plaintiff’s motion on the ground that Blue Shield’s defenses of fraud and unclean hands raised individual issues that predominated over the common issues related to liability.

In a July 2007 opinion, the appeals court reversed, ruling that under longstanding California precedent the equitable defense of unclean hands is not available in a UCL action based on the violation of statutes such as Cal. Ins. Code §§ 10113 and 10381.5. That opinion also stated that Blue Shield had violated those statutes by failing to attach applications or endorse them on insurance policies when issued.

Blue Cross sought a rehearing in the case. The instant opinion issued by the appeals court noted that violations of Cal. Ins. Code §§ 10113 and 10381.5, “if proven,” would provide a legal basis for a UCL action. The appeals court found "unavailing" Blue Shield's argument that §§ 10113 and 10381.5 are regulatory in nature and would not provide a basis for a UCL action because they do not proscribe any conduct. Similar to its previous decision, the appeals court's revised opinion reversed the trial court’s decision and found the lower court relied on “erroneous assumptions” when it weighed the legal and factual issues of unclean hands in deciding to deny plaintiff’s motion for class certification. “The fact that class members must individually demonstrate their right to recover, or that they may suffer varying degrees of injury, will not bar a class action,” the appeals court said. “[N]or is a class action precluded by the presence of individual defenses against class plaintiffs.” Ticconi v. Blue Shield of Cal. Life & Health Ins. Co., No. B190427 (Cal. Ct. App. Feb. 27, 2008).

California Regulators Order Reinstatement Of Wrongfully Rescinded Health Coverage
The California Department of Managed Health Care (DMHC) called for the immediate reinstatement of 26 consumers’ healthcare coverage after finding their policies were wrongfully rescinded. DMHC also ordered a re-review of all other rescissions over the past four years, “which could potentially restore coverage to thousands of Californians,” according to the agency's press release.

Since 2005, DMHC has been investigating health insurers engaged in the illegal practice of post-claims underwriting or rescinding health policies without proving that the applicant willfully misrepresented themselves on their health application. Of the state’s five largest health plans offering coverage in the individual market, two have been fined thus far—one for unfair rescission practices and the other for paying a bonus to employees for canceling health policies, DMHC said.
In addition to reinstatement for the 26 consumers, DMHC also is ordering plans to use a fair outside arbiter to review every rescission uncovered in DMHC’s investigation and determine remedies, such as payment of medical care and premiums, for any wrongful rescissions. Plans also must immediately institute uniform business practices for rescission, the release said.

Meanwhile, one day earlier, Los Angeles City Attorney Rocky Delgadillo announced his office filed a civil suit against WellPoint, Inc. and two of its subsidiaries alleging they unlawfully canceled health coverage and denied or delayed authorizing claims. The complaint, filed in Los Angeles Superior Court, claims WellPoint, Anthem Blue Cross of California, and Anthem Blue Cross Life engaged in unlawful and deceptive business practices in violation of California’s unfair competition laws.

U.S. Court In Florida Allows Hospital’s Claims Against HMO For Alleged Underpayments After It Left Network
A hospital may move forward with claims seeking to recoup alleged underpayments against a health maintenance organization (HMO) that withdrew from the hospital’s network but continued to take advantage of discounted rates. Boca Raton Community Hospital, Inc. (Boca Raton Hospital) sued HMO Great-West Healthcare of Florida, Inc. (Great-West) seeking to recover over $2 million in alleged underpayments. In March 1989, Boca Raton Hospital entered into a “Preferred Hospital Agreement” with Private Health Care Systems, Inc. (PHCS). PHCS negotiates discounted rates for medical services with healthcare providers and then contracts those rates with health insurers and plan administrators in exchange for a brokerage fee.

In April 1989, Great-West agreed to participate in the “Preferred Hospital Agreement” with Boca Raton Hospital. Under the agreement, Boca Raton Hospital agreed to accept discounted rates in exchange for being added to Great-West’s network of providers. Three months later, in July 1989, Great-West decided to delegate certain “nonmaterial administrative services” to its wholly owned managed care subsidiary, One Health Plan of Florida, Inc. (One Health), which also would assume all the previous functions performed by PHCS. PHCS subsequently informed Great-West that pursuant to the agreement it previously signed, which prohibited assignment, it could no longer participate in any PHCS-preferred provider organization (PPO) network. Great-West never told Boca Raton Hospital about its withdrawal from the PHCS network. As a result, the hospital continued to accept discounted payments from Great-West.

In its lawsuit, Boca Raton Hospital sought to recover the difference between its “usual and customary charges” and the payments it did receive from Great-West between the time Great-West withdrew from the PHCS network in 1998 and May 20, 2005. The Hospital asserted a claim under the Employee Retirement Income Security Act (ERISA) to recoup the alleged underpayments and equitable common law claims.

The U.S. District Court for the Southern District of Florida held that, as a matter of law, Great-West withdrew from the PHCS PPO network in July 1998 and therefore had no contractual right to participate in or claim rate discounts under the agreement from that
point forward. The court rejected Great-West’s argument that by continuing to accept payments and enjoy the benefit of patient referrals Boca Raton Hospital had ratified its role as a participating carrier under the agreement. According to the court, it was unclear when the hospital had “full,” actual knowledge of Great-West’s withdrawal from the PHCS network to support a ratification defense.

The court also refused to find ERISA preempted Boca Raton Hospital’s common law equitable claims. The court cited precedent that “state law claims brought by healthcare providers against plan insurers have too remote an effect on ERISA plans to be preempted by the Act.” According to the court, the “commercial realities” of the health care industry require that health care providers be able to rely on insurers’ representations as to coverage.” The court also said that ERISA does not preempt “run of the mill” claims by non-ERISA entities against ERISA plans and a healthcare provider’s claim against an insurance provider is thought to have only an indirect effect on the relationship between the principal ERISA entities.

Finally, the court held that, for purposes of the statute of limitations, the Hospital’s cause of action accrued at each point in time when Great West allegedly “underpaid” on claims, not in July 1998 when Great West withdrew from the network. Applying the applicable statute of limitations, the court did limit the recovery period for the Hospital to between August 7, 2001 and May 20, 2005. Boca Raton Community Hosp., Inc. v. Great-West Healthcare of Fla., No. 06-80750-CIV (S.D. Fla. Mar. 17, 2008).

Florida Appeals Court Finds HMO Must Pay Pathology Provider For “Professional Component” Of Services

The Florida District Court of Appeal, Third District, affirmed April 16, 2008 a lower court’s holding that an out-of-network provider of pathology services to a health maintenance organization (HMO) was an intended third-party beneficiary to the HMO’s member contracts and was entitled to payment for all of its billed services. Health Options, Inc. (HOI), an HMO, had a written agreement with Palmetto Pathology Services (PPS) to provide services to HOI’s members. In 1999, HOI refused to continue paying for “non-patient specific services,” claiming that the component was essentially an element of overhead, while PPS referred to these services as the “professional component of clinical pathology” or “PC-CP.”

PPS sued to recover payment for the disputed services asserting claims against HOI for declaratory relief, breach of implied contract, quantum meruit, open account, account stated, and breach of a third-party beneficiary contract. HOI removed the case to federal court, alleging that PPS’ third-party beneficiary claim was preempted by the Employee Retirement Income Security Act (ERISA) and thus was a federal question. However, the federal court disagreed and sent the case back to state trial court, which directed a verdict in favor of PPS on liability. A jury rendered a damages verdict of $1,132,219, plus interest. HOI appealed.

The appeals court noted that Florida courts have not precluded medical providers from bringing common law claims against an HMO where the claim is based on allegations
that the HMO violated provisions of Florida’s HMO Act. In addition, the Florida Supreme Court has recognized that medical providers may be intended third-party beneficiaries of contracts between an HMO and its members, the appeals court said.

After rejecting HOI’s arguments that it was not contractually obligated to pay for the disputed services, the appeals court turned to whether PPS was an intended third-party beneficiary of the HOI member contracts. In holding that it was, the appeals court found “no dispute that a contract existed between HOI and its members, and that the contract was intended to directly benefit medical providers rendering services to HOI’s members.”


Michigan Supreme Court Holds Insurance Commissioner May Disregard Findings Of Independent Review Organization

The Michigan Commissioner of the Office of Financial and Insurance Services (OFIS) is not bound by the recommendations of an independent review organization (IRO) on issues of medical necessity and clinical review, the state’s high court ruled April 23, 2008. Reversing a previous order requiring an insurance company to pay for an insured’s treatment at an out-of-network facility, the high court held the Commissioner could decline to follow an IRO’s determination that an insured’s treatment should be covered.

Douglas Ross was insured through his employer by health maintenance organization Blue Care Network of Michigan (BCN). Ross suffered from multiple myeloma among other things and his initial treatment was not successful. Ross was eventually seen at the Myeloma Institute for Research and Therapy at the University of Arkansas for Medical Sciences (UAMS), an out-of-network provider. Ross was admitted to UAMS and according to a physician there had only one week to live without aggressive treatment. BCN refused to pay for all of Ross’ treatment at UAMS. Because Ross died during treatment, plaintiff Desiree Ross, the administrator of his estate, filed a “step one member grievance” to challenge BCN’s failure to cover the services from UAMS.

The BCN denied the appeal, finding Ross had not received a referral from his primary care physician, there was no indication the services were not available in-network, and that it considered the treatment experimental. Plaintiff filed a “step two member grievance,” which was denied. Plaintiff then requested an external review with the OFIS Commissioner under the Patient’s Right to Independent Review Act (PRIRA).

The OFIS assigned the case to an independent review organization (IRO), which determined Ross’ care was an emergency and that the treatment provided to him was not experimental and recommended that BCN’s denial of payment be reversed. The OFIS Commissioner questioned, however, the IRO’s opinions and found Ross’ treatment did not constitute an emergency over the entire period of time in which he received care. Rather, the Commissioner concluded only his inpatient admission to the facility was a medical emergency and the remainder of the services could have been provided in-network.
Plaintiff appealed to the trial court, which reversed the Commissioner’s findings. The Michigan Court of Appeals affirmed, 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. Specifically, the appeals court found the PRIRA “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.”

The Michigan Supreme Court reversed, emphasizing in particular the PRIRA’s repeated use of the term “recommendation” in describing the IRO’s role in reviewing claim denials. Moreover, the high court noted, the PRIRA expressly allows the Commissioner to disregard the IRO’s recommendation so long as sufficient explanation for doing so is provided. Thus, “an IRO’s recommendation concerning whether to uphold or reverse a health carrier’s adverse determination is merely a recommendation and is not binding on the commissioner,” the high court held.

A dissenting opinion argued the Commissioner’s review under the statute “is limited to ensuring that an IRO’s recommendations are not contrary to the terms of coverage under the covered person’s health-benefit plan.” Ross v. Blue Care Network of Mich., No. 131711 (Mich. Apr. 23, 2008).

LEGAL REPRESENTATION ISSUES

New York Court Rules Physician’s Emails With Attorney Via Hospital’s System Not Privileged

A physician’s communications with his attorney via his hospital-employer’s email system were not protected from discovery under the attorney-client privilege or work product doctrine in a subsequent employment dispute, a New York court ruled October 17, 2007. According to the court, because hospital policy explicitly prohibited personal use of its email system and informed employees of potential monitoring, the physician could not claim these communications were privileged.

The case involved an employment dispute between Dr. W. Norman Scott and Beth Israel Medical Center and Continuum Health Partners Inc. (collectively, BI). Under his employment contract, BI had to pay Scott $14 million in severance if he was terminated without cause. Scott sued BI for breach of contract alleging he was terminated without cause.

At issue in the instant case was whether Scott waived his attorney-client privilege when he communicated with his attorney via BI’s email system. Scott moved for a protective order, arguing the emails were privileged under the attorney-client privilege and work product doctrine. Specifically, Scott cited N.Y. C.P.L.R. § 4548, which states that “no communication . . . lose[s] its privileged character for the sole reason that it is communicated by electronic means or because persons necessary for the delivery or facilitation of such electronic communication may have access to the content of the communication.” BI argued, however, that its email policy, which it disseminates to all
employees, expressly prohibits personal use of its email system and advises that the hospital may monitor an employee’s email.

The New York Supreme Court, New York County, found the emails at issue were not privileged because they were sent over the hospital’s email system. BI’s email policy was critical to the court’s determination, the opinion noted. “A ‘no personal use’ policy combined with a policy allowing for employer monitoring and the employee’s knowledge of these two policies diminishes any expectation of confidentiality,” the court said. Despite his arguments to the contrary, the court found Scott had actual and constructive knowledge of the email policy, given that BI had widely disseminated its policy and that Scott, as a hospital administrator, was “charged with knowledge” of the email policy. The court also concluded that the work product doctrine was inapplicable, finding his attorney’s “pro forma notice” at the end of the emails was “not a reasonable precaution to protect its clients.” *Scott v. Beth Israel Med. Ctr., Inc.*, No. 602736/04 (N.Y. Sup. Ct. Oct. 17, 2007).

**LONG TERM CARE**

**Grassley Calls For Public “Watch List” Of Suspect Nursing Homes**

Senate Finance Committee Ranking Member Charles Grassley (R-IA) has called on the Centers for Medicare and Medicaid Services (CMS) to develop a public “watch list” to identify nursing homes that “yo-yo” out of compliance with federal quality standards. Grassley made the request in a July 23, 2007 letter to then CMS Acting Administrator Herb Kuhn, citing a Government Accountability Office (GAO) report released in April that found many nursing homes with a history of deficiencies continue to “cycle in and out of compliance, harming residents while avoiding sanctions.” GAO also said current enforcement approaches are not doing enough to deter nursing homes from repeatedly violating federal health and safety standards. According to Grassley, while consumers have access to nursing home information through Medicare’s “Nursing Home Compare” website, they often are not privy to information about “repeat offenders” because sanctions are not publicly reported or are rescinded based on short-term fixes that “mask permanent problems.”

**CMS Releases List Of 54 Worst Performing Nursing Homes**

CMS on November 29, 2007 released the first ever list of the nation's 54 poorest performing nursing homes. Once a facility is selected as a so-called “special focus facility” (SFF), the state survey agency conducts twice the number of standard surveys and will apply progressive enforcement until the nursing home either (a) significantly improves and is no longer identified as an SFF, (b) is granted additional time due to promising developments, or (c) is terminated from Medicare and/or Medicaid, CMS said. As of October 2007, there were 128 SFFs out of about 16,000 active nursing homes, according to CMS. The number of SFFs in each state varies according to the number of nursing homes in the state. In addition to publishing the list of SFFs, CMS noted that it is taking "many other steps to improve the quality of care in the nation's nursing homes including a new program that will make the payment system more sensitive to quality
improvements; developing new, more stringent systems for criminal background checks on facility workers and applicants; unprecedented focus on preventing catastrophic pressure ulcers in nursing home residents; and improving the state survey process."

**Grassley, Kohl Introduce Nursing Home Reform Bill, CMS Posts Expanded List Of Poor Performing Nursing Homes**

Senate Finance Committee Ranking Member Charles Grassley (R-IA) and Senate Special Committee on Aging Chairman Herb Kohl (D-WI) introduced February 14, 2008 legislation aimed at improving the quality of care in nursing homes by providing better public information about staffing and quality, requiring greater accountability and transparency about who owns and operates nursing homes, and strengthening enforcement.

The Nursing Home Transparency and Improvement Act of 2008 would impose new disclosure, accountability, and oversight requirements over nursing home owners and operators, including chains (which would be subject to annual independent audits), according to a U.S. Senate press release. For example, the bill would require CMS to improve its Nursing Home Compare website by including a nursing home’s ownership information, the identity of participants in the agency’s Special Focus Facility (SFF) program, a standardized complaint form, and links to nursing home inspection reports.

To strengthen enforcement, the bill would replace the current penalty provisions authorizing the Department of Health and Human Services (DHHS) Secretary to impose civil money penalties up to $10,000 with provisions authorizing the imposition of a range of penalties (i.e., up to $100,000 for a deficiency resulting in death, and $3,000-$25,000 for actual harm or immediate jeopardy deficiencies). In addition, to address “corporate-level problems in nursing home chains the bill would enable the DHHS Secretary to develop a national independent monitor program specific to multistate and large intrastate nursing home chains.

Meanwhile, the Centers for Medicare and Medicaid Services (CMS) published on its website a list of 136 underperforming nursing homes with poor inspections records. The list adds to a partial list of 54 poor-performing nursing homes (designated as special focus facility or SFF homes) that CMS made available to the public in November 2007. During the three-month interim between the release of the partial and full list, CMS worked with states to add new information enabling consumers to distinguish between those nursing homes that are improving and those that are not, the agency said.

The new list identifies the SFF nursing homes by the following categories: new additions (i.e., added to list within the past six months); not improved (i.e., failed to improve significantly in at least one survey after being placed on list); improving (i.e., significantly improved on the most recent survey); recently graduated (i.e., sustained significant improvement for over one year); no longer in Medicare or Medicaid (i.e., terminated by CMS or voluntarily chose not to continue participation). The list includes 131 active SFF nursing homes, of which 27 are new additions, 52 have showed no improvement, and 52 have demonstrated improvements. In addition, the list indicates
three SFF nursing homes have recently graduated, and two are no longer in Medicare or Medicaid

**Equitable Abstention Doctrine Supports Dismissal Of Consumer Lawsuit Against Healthcare Facilities For Alleged Violations Of Minimum Nurse Staffing Law**

California courts may abstain from considering Unfair Competition Law (UCL) cases that would require them to assume regulatory powers over businesses, ruled the California Court of Appeal August 1, 2007. The Court of Appeal affirmed the dismissal of a UCL action that asked the court to assume the authority of the state executive agency tasked with regulating the defendants and enforcing the nurse staffing law at issue.

Plaintiff Alvaro Alvarado was the son of a former resident of a skilled nursing facility (SNF). Alvarado filed a lawsuit against the SNF and 18 other facilities, which he denominated as a class action, on a theory that the facilities were impermissibly understaffed below the 3.2 aggregate nursing-hours-per-resident-day standard of California Health & Safety Code § 1276.5. Alvarado sought injunctive relief and class-wide restitution under the UCL based on this alleged understaffing. Section 1276.5 requires the California Department of Health Services (DHS) to adopt regulations requiring SNFs to provide an average of at least 3.2 hours of nursing care per patient per day. DHS never issued the requisite regulations, and it was unclear precisely how the 3.2 standard was to be calculated or applied. Alvarado contended that § 1276.5 obligated SNFs to provide 3.2 aggregate hours of care per resident even in the absence of the regulations.

The trial court disagreed, and dismissed the case at the pleading stage. The court held that § 1276.5 is a statute having purely regulatory import, which directs DHS to define and implement a regulatory scheme concerning SNF nurse staffing. The trial court further reasoned that it should not invade the powers of DHS, which it would be forced to do if the action proceeded. Thus, the court invoked the equitable abstention doctrine and abstained from adjudicating Alvarado’s and the putative class’s claims.

The Court of Appeal affirmed in full. The appeals court explained that SNFs already are regulated by DHS, and that regulators like DHS provide “a more effective means of redress” for such claims. Private lawsuits such as Alvarado’s, by contrast, can “interfere with the functions of an administrative agency.” Moreover, explained the court, a healthcare regulatory provision such as § 1276.5 requires expertise to enforce, and, as compared to the judicial system, the executive agency regulator is better equipped to determine compliance with the scheme’s requirements. A court would be inappropriately burdened with complex determinations of liability, and potentially with the further difficulty of ongoing enforcement of any injunction it issued.

The case is a first-impression decision and may affect not only the numerous similar cases pending in California superior courts statewide, but also other private lawsuits that would require courts to make judgments about complex economic policy issues, or to assume the functions of administrative agencies, or to make complex determinations of liability and remedies in regulated industries about which the courts lack expertise.
CMS Issues Guidance To Surveyors Of Long Term Care Facilities
The Centers for Medicare and Medicaid Services (CMS) issued revised guidance to surveyors of long term care facilities containing interpretive guidelines, an investigative protocol, and severity guidance. In Transmittal 27, CMS adds new requirements for accidents, noting the intent of the requirements "is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents." In discussing resident risks and environmental hazards, the guidance states that falls and "unsafe wandering" are of particular concern. The guidance also reviews physical plant hazards. The guidance instructs surveyors on investigative protocol in relation to accidents and supervision. A section on deficiency categorization explains the key elements for severity determination and includes guidelines on determining immediate jeopardy.

Ninth Circuit Upholds DHHS Regulations Allowing Use Of Paid Feeding Assistants In Nursing Homes
Department of Health and Human Services (DHHS) regulations that authorize states to allow the use of paid feeding assistants for nursing home residents without complicated feeding problems do not violate the Nursing Home Reform Law (Reform Law), 42 U.S.C. §§ 1395i-3m, 1396r, a federal appeals court ruled August 31, 2007. The specific provision of the Reform Law at issue in the case provides that a nursing home “must not use on a full-time basis any individual as a nurse aide in the facility . . . for more than 4 months unless the individual . . . has completed a training and competency evaluation program . . . and . . . is competent to provide nursing or nursing-related services.” Affirming a lower court decision in favor of DHHS, the Ninth Circuit concluded nothing in the statutory language of the Reform Law or its legislative history supported plaintiffs’ argument that Congress intended the phrase “nursing or nursing-related services” to include all resident feeding.

In September 2003, DHHS promulgated the regulations at issue (codified at 42 C.F.R. § 483.35(h)), which allow states the option of permitting nursing homes to use paid feeding assistants subject to certain limitations. The regulations require feeding assistants to complete a state-approved training course and to work under the supervision of a registered or licensed practical nurse, the appeals court explained. In addition, the regulations state that feeding assistants may feed only those residents who have no complicated feeding problems (e.g., difficulty swallowing, tube, or IV feedings).

Plaintiffs Resident Councils of Washington and the Washington State Long-Term Care Ombudsman Program challenged the regulations, arguing they violated the Reform Law, and that DHHS’ adoption of the regulations was arbitrary and capricious in violation of the Administrative Procedure Act (APA).
The Ninth Circuit rejected plaintiffs’ argument that the plain language of the Reform Law demonstrated a congressional intent that certified nurse aides perform all resident feeding. According to plaintiffs, the Reform Law’s purpose and structure should be construed broadly, and such construction would include interpreting the phrase “nursing or nursing-related services” to include virtually all hands-on care provided in a nursing home. Congress neither defined the phrase “nursing or nursing-related services” in the Reform Law nor stated that all hands-on care must be performed by nurse aides, the appeals court explained, and therefore Congress did not speak directly to the question at hand, i.e., whether feeding nursing home residents without complicated feeding problems constitute a “nursing or nursing-related service” under the Reform Law.

In finding DHHS’ interpretation to be reasonable, the appeals court rejected plaintiffs’ argument that the agency’s regulations would result in a reduced level of care for nursing home residents. “There can be little debate that a shortage of nurse aides has led to a reduced level of care for all nursing home residents, the appeals court said. “Common sense dictates that easing the burden on nurse aides by delegating non-nursing-related tasks to other workers will enable nurse aides to devote their attention to tasks more important and more difficult than the ‘relatively trivial feeding tasks’ they were previously saddled with.” Residents Council of Washington v. Leavitt, No. 05-36065 (9th Cir. Aug. 31, 2007).

**Baucus, Grassley Ask CMS About Safety, Quality At Nursing Homes Owned By Private Equity Firms**

Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Charles Grassley (R-IA) asked the Centers for Medicare and Medicaid Services (CMS) to provide any information the agency has regarding the effects on care when a nursing home is acquired by private equity investors. In an October 16, 2007 letter to CMS Acting Administrator Kerry Weems, the lawmakers said the inquiry was prompted by a recent report in *The New York Times* that investor-owned homes average fewer clinical registered nurses per resident and a higher number of serious health deficiencies.

The lawmakers also asked CMS to describe the actions it is taking, if any, to address the concerns raised about quality and safety at investor-owned nursing homes. *The New York Times* article indicated that most nursing homes purchased by large investment companies scored worse than the national average on 12 of 14 quality-of-care indicators, the letter said. “This suggests a direct relationship between quality of care and ownership by large investment companies—an unfortunately, not a positive one,” the letter noted.

The lawmakers said they also were “troubled by the legal schemes used by investment firms to shield themselves from liability and, in effect, deny residents and their families legal remedy against nursing homes.” According to the letter, “[t]hese complex legal structures can also result in a lack of transparency regarding who is responsible for resident care and the operation of investor-owned nursing homes."

In addition to requesting the CMS briefing, the lawmakers also sent letters to individual private equity firms asking about their management of nursing homes. Grassley in early
October also asked Government Accountability Office (GAO) Comptroller General David Walker to review the effect of private equity ownership on the quality of care in nursing homes.

**OIG, HCCA Release Roundtable Report On Quality Indicators For Long Term Care**

The Department of Health and Human Services Office of Inspector General (OIG) and the Health Care Compliance Association (HCCA) released January 31, 2008 a report summarizing a recent government-industry roundtable discussion aimed at identifying items for a “Quality of Care Dashboard” for long term care organizations’ boards of directors. The day-long roundtable held December 6, 2007 included over 35 long term care professionals and 10 government representatives who participated in breakout discussion groups on organizational commitment to quality, processes related to monitoring and improving quality, outcome measures related to quality, and benefits of, and challenges to, developing a Quality of Care Dashboard.

A consistent theme in the breakout on commitment to quality, the report said, was that “quality needs to be communicated and demonstrated from the top,” i.e. from the board of directors and management. Key takeaways from this session, according to the report, included whether a board receives regular quality reports, whether board members receive training on quality, and whether quality is part of strategic and capital planning.

With respect to process-related issues to help boards identify risks and understand and track quality measurement, the report noted suggestions such as frequent and focused board-level discussions of quality reports; a coordinated response, with board oversight, to identify quality problems; and investing in staff retention, training, and competence.

The “outcome” breakout group discussed how to provide the board with the actual measurements used to assess performance on quality standards and how to use that information. Among the measures consistently identified by participants to consider when designing a Quality of Care Dashboard were state survey results, resident outcomes and care delivery data, events reporting, complaints, resident and staff satisfaction surveys, and financial indicators.

The final breakout group acknowledged that implementing an effective Quality of Care Dashboard was not without its pitfalls, including information overload and the potential legal exposure for board members overseeing the quality of care delivered at a facility. On the other hand, the report said, participants also noted board members monitoring quality indicators at a facility also would be learning valuable information about the entity’s financial health.

**OIG Issues Draft Supplemental Compliance Program Guidance For Nursing Facilities**

The Department of Health and Human Services Office of Inspector General (OIG) issued April 14, 2008 a draft of supplemental compliance program guidance for nursing facilities. The OIG said the draft is intended to supplement, rather than replace, nursing
facility compliance guidance issued in 2000. The OIG also emphasized that the guidance is not a model compliance program but rather a set of guidelines that nursing facilities should consider when developing and implementing a new compliance program or evaluating an existing one.

In drafting the supplemental guidance, the OIG said it considered, among other things, public comments; relevant OIG and Centers for Medicare and Medicaid Services (CMS) statutory and regulatory authorities; other OIG guidance; experience gained from various federal and state investigations; and OIG audit and evaluation and inspections reports. The OIG also indicated it consulted CMS, the Department of Justice, and nursing facility resident advocates. The draft supplemental guidance includes sections on fraud and abuse risk areas that are particularly relevant to nursing facilities, recommendations for establishing an ethical culture and for assessing and improving an existing compliance program, and actions nursing facilities should take if they discover potential misconduct.

**MEDICAID**

*Legislative Developments*

**President Signs Supplemental War Spending Bill With SCHIP Funding And Moratorium On Medicaid Rule**

Congress passed May 24, 2007 a final Iraq war supplemental spending bill that retains both a one-year moratorium on a controversial Medicaid payment rule and funding to cover shortfalls in the State Children’s Health Insurance Program (SCHIP). President Bush signed the bill into law May 25, 2007. Senate Finance Committee Chairman Max Baucus (D-MT) said the bill provides as much as $650 million to cover SCHIP shortfalls. The legislation also contains a one-year moratorium on a Centers for Medicare and Medicaid Services (CMS) final rule that would limit Medicaid payments to public hospitals and nursing homes. The final rule, issued in the May 29, 2007 Federal Register (72 Fed. Reg. 29748) *(see below)*, addresses so called intergovernmental transfers. Baucus said in the release that he and “other colleagues” believe CMS has not been clear about the propriety of certain Medicaid financing arrangements and “that the currently proposed rule is a too-hasty answer that will result in more confusion.”

**California Governor Signs Bill Slashing Medi-Cal Provider Rates By 10%**

California Governor Arnold Schwarzenegger signed February 16, 2008 special session budget bills, including cuts to Medi-Cal provider rates by 10% beginning July 1, 2008. The scheduled cuts would provide $544 million of ongoing savings in 2008-09, according to a subcommittee report on the special session released February 14, 2008. “The primary purpose of the delay of the reduction until the start of the new fiscal year is to allow time for further review of provider rates during the regular budget process to identify any particularly critical consequences of the reduction and to evaluate the possibility of using a more refined approach to mitigate those consequences while still achieving savings,” the summary said.
The cuts were panned by the California Medical Association (CMA), as “shortsighted.” “These cuts will not only leave millions of Californians stranded with reduced or no access to their critical health care needs, but could break the back of a health care system which is already under serious strain,” CMA President Richard Frankenstein, M.D. said in a statement.

The rate reduction includes distinct-part (hospital-based) nursing facilities, the summary explained, but excludes freestanding nursing homes that pay a quality assurance fee that helps finance their rates. The legislation also reduces provider rates by 10% beginning July 1, 2008 for the non-Medi-Cal components of the California Children's Services (CCS) Program, Child Health and Disability Prevention Program (CHDP), and the Genetically Handicapped Persons Program (GHPP) for a 2008-09 savings of $14.2 million.

**House Clears Bill Delaying Medicaid Rules**

In an overwhelming 349-62 vote, the House cleared April 23, 2008 a bill (H.R. 5613) that would place a one-year moratorium on seven controversial Medicaid regulations issued by the Centers for Medicare and Medicaid Services (CMS). The Protecting the Medicaid Safety Net Act of 2008 would delay, or extend moratoria already in place, through March 2009 Medicaid rules related to rehabilitation services; targeted case management; school-based transportation and outreach; provider taxes; coverage of hospital outpatient services; graduate medical education; and intergovernmental transfers. Critics of the rules have said the rules would reduce federal Medicaid funding to states by nearly $20 billion over five years.

In an April 22, 2008 statement, the administration stressed its strong opposition to the bill, saying it would prevent CMS "from implementing important regulations protecting the fiscal integrity of the Medicaid program, would put billions of dollars of Federal funds at risk, and would turn back progress that has already been made to stop abusive State practices." The Statement of Administrative Policy issued by the Office of Management and Budget also reiterated a threatened veto of the measure. According to the statement, blocking the implementation of the rules “jeopardizes Federal savings of approximately $14 billion over five years and $33 billion over ten years.”

The Senate is considering similar legislation, the Economic Recovery in Health Care Act (S. 2819), which was introduced April 3, 2008 by Senators Jay Rockefeller (D-WV), Olympia Snowe (R-ME), and Edward Kennedy (D-MA). The Senate bill also would delay implementation of an August 17, 2007 CMS directive on the State Children’s Health Insurance Program that set forth stricter requirements for expanding eligibility to children in families with higher incomes.
Regulatory Developments

(1) Proposed Action

CMS Issues Proposal Clarifying Scope Of Medicaid Rehabilitative Services Benefit
The Centers for Medicare and Medicaid Services (CMS) issued in the August 13, 2007 Federal Register (72 Fed. Reg. 45201) a proposed rule that would clarify the types of services states may offer as part of their Medicaid rehabilitative services benefit and still receive federal matching funds. CMS said the proposal addresses concerns that some states may be improperly using the optional rehabilitative services benefit under Medicaid as a “catch-all” category to cover services included in other federal, state, and local programs like foster care. CMS estimates that federal Medicaid spending on rehabilitative services under the proposal would be reduced by roughly $180 million in fiscal year (FY) 2008 and $2.2 billion over five years. Comments on the proposed rule were due October 12, 2007.

CMS Proposes Changes To Medicaid Payments For School-Based Services
Taxpayers are expected to save approximately $635 million in federal funds during the first year and $3.6 billion over five years under proposed changes to Medicaid reimbursement for school-based services, the Centers for Medicare and Medicaid Services (CMS) said August 31, 2007. According to CMS, improper billing by school districts for administrative costs and transportation services under the Medicaid program has been a long-standing concern of the Department of Health and Human Services. The rule, published in the September 6 Federal Register (72Fed. Reg. 51397), proposes to make federal Medicaid payments no longer available for: administrative activities performed by school employees or contractors, or anyone under the control of a public or private educational institution; or transportation from home to school and back for school-aged children with an Individualized Education Program or an Individualized Family Services Plan established pursuant to the Individuals with Disabilities Education Act. Comments on the proposal were due November 6, 2007.

CMS Proposes Clarifications To Medicaid Outpatient Hospital Services Definition
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule in the September 28, 2008 Federal Register (72 Fed. Reg. 55158) that would amend the regulatory definition of outpatient hospital services for Medicaid to align it more closely with the Medicare definition. CMS said the current Medicaid regulatory definition is broader than Medicare’s definition and can overlap with other covered benefit categories that may be reimbursed at lower levels. Moreover, CMS said, the current broad definition “is inconsistent with the applicable UPL [Upper Payment Limit], which is based on the premise of some level of comparability between the Medicare and Medicaid definitions of outpatient hospital and clinic services.” CMS also noted that the revisions would provide more transparency in determining available coverage in any state and generally clarify the scope of services for which federal matching funds are available under the outpatient hospital services benefit category. Comments on the proposed rule were due October 29, 2007.
CMS Issues Rules Giving States More Flexibility In Designing Medicaid Plans, Increasing Cost Sharing

The Centers for Medicare and Medicaid Services (CMS) proposed a pair of rules February 22, 2008 that would give states more flexibility in designing their Medicaid programs (73 Fed. Reg. 9714) and require increased cost-sharing from beneficiaries (73 Fed. Reg. 9727). The rules, which would implement provisions of the Deficit Reduction Act of 2005 and the Tax Relief and Health Care Act of 2006, are the latest in a series of regulations to implement the administration’s goals of aligning Medicaid more closely with private market insurance and giving states more control over their Medicaid benefits packages, CMS said.

Under one rule, states will have the opportunity to offer beneficiaries healthcare that has the same value as plans that are being offered to other populations in the state, through alternative benefit packages called “benchmark plans.” Benchmark coverage includes: the standard Blue Cross/Blue Shield preferred provider option service benefit plan under the Federal Employees Health Benefit Plan; state employee coverage; coverage that is offered by the largest commercial health maintenance organization in the state; or coverage that is approved by the Secretary of the Department of Health and Human Services.

CMS also published a proposed rule on DRA provisions that allow states to change current premiums and cost sharing structures. "These new provisions are similar to what is allowed under SCHIP and will not change existing cost sharing rules for Medicaid beneficiaries with family income below 100 percent of the federal poverty level (FPL)," CMS said.

CMS Issues Proposal For Expanding Availability Of Home And Community Based Care To Medicaid Beneficiaries

The Centers for Medicare and Medicaid Services (CMS) issued April 4, 2008 a proposed rule (73 Fed. Reg. 18676) that would give thousands more Medicaid beneficiaries the option of receiving care in their homes and communities instead of in an institutionalized setting. The proposed rule would implement a provision of the Deficit Reduction Act of 2005 (DRA) allowing states to provide home-and-community based services (HCBS) to Medicaid beneficiaries without obtaining a demonstration waiver. The DRA requires only that states obtain an approved state plan amendment (SPA) satisfying statutory criteria. The SPA does not need to be renewed and is not subject to some of the same requirements of waivers such as budget neutrality, CMS said.

The DRA also eliminates the requirement that beneficiaries seeking to qualify for assistance with personal care, home healthcare, or other services in the home or community setting had to be at imminent risk of institutionalization. Under the DRA, states may cover Medicaid recipients who have incomes no greater than 150% of the federal poverty level, or $15,600 per individual in 2008, and who satisfy the needs-based criteria.
According to CMS, the proposed rule would focus on “person centered” care and would allow states to make available services including case management, homemaker, home health aide, personal care, adult day health, habilitation, and respite care. States also may provide special services to individuals with chronic mental illness, including day treatment or other partial hospitalization, psychosocial rehabilitation, and clinic services.

(2) Final Action

CMS Issues Final Rule On State Medicaid Financing Arrangements
The Centers for Medicare and Medicaid Services (CMS) issued a controversial final rule May 29, 2007 (72 Fed. Reg. 29748) that the agency says is aimed at bringing Medicaid state financing arrangements in line with statutory requirements. At the same time, however, President Bush signed into law May 25, 2007 an Iraq war supplemental spending bill that includes a one-year moratorium on the final rule. The so-called intergovernmental transfer rule drew sharp criticism from hospital groups, the nation’s governors, and some lawmakers when it was proposed in January 2007 (72 Fed. Reg. 2236). According to these opponents, the rule will likely result in higher Medicaid cuts than CMS’ $3.87 billion over five years estimate and could seriously undermine the nation’s healthcare safety net.

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. According to CMS, it found many states make supplemental payments to governmentally operated healthcare providers that are in excess of costs; and these providers often use the excess revenue to subsidize other healthcare operations unrelated to Medicaid. CMS also noted that while “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. The final rule does ask for comments on the definition of “unit of government,” which was modified somewhat from the one appearing in the proposed rule. The comment period on this aspect of the final rule closed July 13, 2007.

In further developments, with the expiration of the one-year moratorium drawing closer, a coalition of hospitals and hospital groups filed a lawsuit March 11, 2008 to prevent the CMS from implementing the cost-based limits on payments to public hospitals. The coalition, which is led by the Alameda County Medical Center (CA), the National Association of Public Hospitals (NAPH), the American Hospital Association (AHA), and the Association of American Medical Colleges (AAMC), filed their lawsuit in the U.S. District Court for the District of Columbia.

In their complaint, plaintiffs asked the court to reject the regulation at issue on three separate grounds. First, plaintiffs argued that CMS overstepped its authority by defining “units of government” far more narrowly than permitted under current federal law. In so doing, plaintiffs claim CMS “usurp[ed] states’ ability to determine the governmental status of entities within their jurisdiction” and “severely restrict[ed] the options available
to states for financing the non-federal share of their Medicaid program expenditures.” Second, plaintiffs asserted that CMS does not have the authority to impose cost-based Medicaid payment limits on public providers while continuing to pay private providers under a different methodology. According to plaintiffs, a cost limit imposed solely on governmental hospitals is counter to clear congressional intent. Third, plaintiffs argued in their complaint that CMS improperly issued its final rule on the same day that the congressional moratorium blocking the rule was signed into law and became effective.

CMS Eases Rules On Proving Citizenship For Medicaid Eligibility
The Centers for Medicare and Medicaid Services (CMS) issued final regulations July 2, 2007 expanding the types of documentation that can be used to establish citizenship for Medicaid eligibility and exempting certain groups from the requirements. The regulations implement a law enacted as part of the Deficit Reduction Act of 2005 that requires individuals applying for Medicaid or renewing their eligibility to document their citizenship. According to CMS, the final rule codifies earlier guidance sent to states that exempts from the citizenship requirements children in foster care, individuals enrolled in Medicare, and individuals who receive Supplemental Security Income or Social Security Disability Insurance. The rule also finalizes an agency policy change that will “extend Medicaid benefits for up to the first year of life to a newborn child whose mother was receiving Medicaid on the date of his or her birth, regardless of the mother’s immigration status,” CMS said.

CMS Issues Final Rule On Medicaid Drug Reimbursements
The Centers for Medicare and Medicaid Services (CMS) issued a final rule July 6, 2007 that changes how the government pays for prescription drugs under the Medicaid program. The changes, which implement provisions in the Deficit Reduction Act of 2005 (DRA), are expected to save $8.4 billion in state and federal funds over five years, the agency said. The DRA changes were prompted by reports from the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General that Medicaid payments to pharmacies for generic drugs were much higher than what pharmacies actually paid for the drugs, CMS said.

Under the DRA, the Federal Upper Limits (FULs)—which caps federal matching payments to states for generic drugs—on multi-source drugs 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. According to CMS, the final rule makes a number of changes from the proposed version aimed at clarifying what should be included and excluded from the AMP calculation. For example, the final rule provides that sales to pharmacy benefit managers and pharmacies serving long term care facilities are excluded from AMP. The final rule also specifically excludes from the list of prices used to determine AMP, manufacturer coupons redeemed by an agent or pharmacy and manufacturer vouchers and drug discount programs. Sales to home infusion and specialty pharmacies, however, are part of the AMP calculation, the final rule provides.
The DRA also requires CMS to disclose AMPs, which the agency says will help introduce transparency in Medicaid prescription drug pricing. “States will now be able to use actual AMP information as the basis for setting drug reimbursement,” CMS said. Drug makers will be required to report AMPs monthly, as well as quarterly. In addition, the final 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 is asking for comments on two aspects of the final rule, which was effective October 1, 2007, regarding (1) an “outlier” policy that eliminates from AMP calculations any drug in an FUL that is priced significantly lower than other drugs in that category and (2) the definition of AMP.

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) filed a joint lawsuit November 7, 2007 to block the new federal regulations affecting Medicaid reimbursements of generic drugs, warning they will spell dire consequences for community pharmacies. The lawsuit, filed in the U.S. District Court for the District of Columbia, allege the regulations will reduce reimbursement rates below the level permitted by law.

NACDS and NCPA announced an initial victory December 14, 2007 in their lawsuit, saying the district court judge issued a preliminary injunction preventing CMS from posting data on the Internet related to generic pharmaceuticals’ average manufacturer price, or from implementing Medicaid reimbursement cuts, until a final decision on the merits of the lawsuit is rendered. “Only new legislation can completely eliminate the severe damage to community pharmacies and ensure that patients continue to have access to their prescription medications,” the groups have said.

Subsequently, on March 14, 2008 (73 Fed. Reg. 13785), CMS issued an interim final rule revising the definition of “multiple source drug” for purposes of the Medicaid drug reimbursement rules. CMS said the change was intended to conform the definition to statutory language and address the concerns raised by NACDS and NCPA in their lawsuit.

CMS had defined a “multiple source drug” as one sold or marketed in the United States, as opposed to a particular state. The NACDS and NCPA lawsuit raised concerns that all drug products are not generally available in every state. Accordingly, CMS said the revised definition indicates that a multiple source drug is one that is sold or marketed in the “state” during the rebate period. “We believe, however, that when an FDA-approved equivalent generic drug is sold or marketed in the United States, at least one generic drug product is sold or marketed in every State,” the interim final rule said. For this reason, CMS expects the effect of the revision to be minimal.

CMS also said it will consider all covered outpatient drugs to be generally available in a state unless there is evidence to the contrary. “When the State confirms that a covered outpatient drug is not a multiple source drug in the State, that drug is not subject to the [Federal upper payment limit] in that State for the applicable rebate period,” the interim
final rule indicated. CMS said the interim final rule, to the extent that it may affect Medicaid reimbursement rates for retail pharmacies, is subject to the district court’s injunction. The interim final rule was effective April 14, 2008, the same day comments were due.

CMS Issues Guidance On Tamper-Proof Rx Pad Requirements; Healthcare Organizations Ask For Implementation Delay
The Centers for Medicare and Medicaid Services (CMS) issued guidance to state Medicaid Directors August 17, 2007 explaining the requirements of a new law requiring Medicaid prescriptions to be written on tamper-proof prescription pads starting October 1, 2007. The tamper resistant pad requirement, § 7002(b) of the U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, applies to all outpatient drugs, including over-the-counter drugs in states that reimburse for prescriptions for such items, the guidance said.

Drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other specified institutional and clinical settings are exempted from the requirements as are prescriptions that are paid for by a managed care entity. CMS also noted that the law “does not restrict emergency fills of non-controlled or controlled dangerous substances for which a prescriber provides the pharmacy with a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.” The guidance also includes a list of characteristics that prescription pads must have to be considered tamper-resistant.

The same day as the guidance was released the National Association of Chain Drug Stores (NACDS) sent a letter signed by 76 healthcare organizations to Department of Health and Human Services Secretary Michael Leavitt asking him to delay implementation of the law for six to 12 months. According to NACDS, compliance with the new mandate would be “very difficult” to achieve by October 1, 2007. The letter noted particular concern over “the potential for delays in Medicaid beneficiaries receiving their prescription medications caused by uncertainty over what action a pharmacist should take if a prescription is written on non-tamper-resistant paper.”

Subsequently, President Bush signed into law September 29, 2008 legislation that, among other things, delayed for six months the “tamper resistant” pad requirement. The legislation the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (H.R. 3668), which also included a number of other healthcare-related “extensions,” was passed by the House September 26, 2007; the Senate followed suit a day later.

CMS Agrees To Renewal Of TennCare Waiver
The Centers for Medicare and Medicaid Services (CMS) has approved TennCare’s Medicaid waiver, allowing Tennessee to continue with the program that covers 1.2 million state residents, including 640,000 children, according to a release posted on the program’s website October 8, 2007. TennCare, Tennessee’s expanded Medicaid program, has been operating under a series of extensions since the program’s waiver expired June 30, 2007. The waiver renewal allows TennCare to pay $115 million more to hospitals
over the next three years to help offset uncompensated care than CMS’ original proposal, although it also places a cap on these supplemental payments. According to the release, over the last three years, TennCare has paid more than $1.7 billion to hospitals to assist with uncompensated care costs related to charity care and Medicaid losses.

**CMS Issues Controversial Interim Final Rule On Targeted Case Management**

The Centers for Medicare and Medicaid Services (CMS) issued an interim final rule December 4 (72 Fed. Reg. 68077) clarifying the Medicaid definition of covered case management and targeted case management (TCM) services and further explaining the situations in which Medicaid will pay for case management activities. The clarifications in the interim final rule aim to stem widespread improper billing by states of the Medicaid program for services mandated by other programs, according to CMS.

Congress required CMS to issue regulations in this area under the Deficit Reduction Act of 2005 (DRA), which also called for redefining the scope of allowable case management services and strengthening state accountability. Prior to including these provisions in the DRA, Congress had received a number of Government Accountability Office (GAO) reports regarding inappropriate Medicaid billing of TCM services, CMS said.

The interim final rule, which became effective March 3, 2008, clarifies the Medicaid definition of covered case management and TCM services and further explains the situations in which Medicaid will pay for referral services to specific (or “targeted”) groups of Medicaid beneficiaries (i.e., those with developmental disabilities or chronic mental illness). Specifically, the rule states that Medicaid coverage will not be available for direct TCM services a Medicaid beneficiary receives that constitute “the administration of foster care programs or other nonmedical programs.” In addition, the rule specifies that Medicaid payment will not be available for direct TCM services that are covered under another Medicaid service category (e.g., counseling services from a case manager, performance of diagnostic tests). The rule also clarifies that Medicaid coverage for TCM services will not be available for certain services to which Medicaid beneficiaries have been referred (e.g., transportation or day care services, and other medical, social, and educational services).

The “refinements and clarifications to Medicaid’s case management benefit, as set forth in the interim final rule, are expected to save the program $1.2 billion over the next five years.”

The interim final rule has been controversial, with interest groups and some lawmakers warning it could unduly restrict the TCM available to Medicaid beneficiaries. The Senate passed February 26, 2008 and Indian health bill that includes an amendment to temporarily delay the TCM rule.

**CMS Finalizes MIP Contractor Liability Limitations**

The Centers for Medicare and Medicaid Services (CMS) published a final rule in the November 30, 2007 Federal Register (72 Fed. Reg. 67653) limiting the liability of Medicaid Integrity Program (MIP) contractors while performing program services.
According to the final rule, a program contractor “will not be held to have violated any criminal law and will not be held liable in any civil action, under any law of the United States or of any State (or political subdivision thereof), by reason of the performance of any duty, function, or activity required” by the MIP program “provided due care was exercised in that performance and the contractor has a contract with CMS.” Under the rule, CMS will reimburse the contractor for expenses incurred in defending a lawsuit if: (1) the suit was brought against the contractor and relates to the contractor’s performance of any duty, function, or activity under a contract entered into with CMS; (2) the funds are available; and (3) the expenses are otherwise allowable under the terms of the contract. The rule was effective December 31, 2007.

CMS Finalizes Changes To Medicaid Payments For School-Based Services
The Centers for Medicare and Medicaid Services (CMS) issued December 28, 2007 a final rule (72 Fed. Reg. 73635) eliminating Medicaid reimbursement for certain school-based administrative and transportation services that is expected to save approximately $635 million in federal funds in fiscal year 2009 and $3.6 billion over five years (2009-2013). According to CMS, improper billing by school districts for administrative costs and transportation services under the Medicaid program has been a long-standing concern of the Department of Health and Human Services.

The final rule adopts without change the proposal CMS issued in September 2007 (72 Fed. Reg. 51937). The final rule also responds to the roughly 1,240 comments CMS received on the proposed rule. Many of those comments, CMS said, focused on concerns that the new rule would reduce funding to already strained state education budgets. But CMS said such comments only confirmed its view that federal Medicaid funds were being used improperly and that the new rule was necessary to ensure the program’s financial integrity. “Constrained local and State funding for education is not the basis for determining whether a cost is properly claimed under Medicaid,” CMS commented.

Case Law

Eighth Circuit Upholds Denial Of State Request For Increase In Medicaid Payments
A federal appeals court upheld July 31, 2007 the Centers for Medicare and Medicaid Services’ (CMS) denial of a state plan amendment (2003 plan amendment) to Minnesota’s Medicaid program, which sought $1,529,000 in additional federal funds to match the state’s decision to increase supplemental Medical Assistance payments to 14 county-owned nursing homes. CMS requested more information on the plan amendment and Minnesota, in its reply, equated Medicaid’s upper payment limit with the Medicaid law’s efficiency requirement. The state opined that if CMS finds the upper payment limit is set so high that payment rates are inefficient, the agency should amend the regulation and not “impose new, burdensome requirements on states to justify payment rates that are below the upper payment limit.” Consistent with its reliance on the upper payment limit, Minnesota also responded that “[n]one of the funds are ‘returned.’ Once the Medical Assistance program pays a provider, the funds are not tracked.”
CMS disapproved of the plan amendment and on reconsideration Presiding Official Kathleen Scully-Hayes rejected the state’s contention that compliance with the upper payment limit alone is sufficient because “CMS is obligated to inquire further to ensure that the SPA [state plan amendment] complies with” statutory requirements.

The Eighth Circuit affirmed the agency’s decision. Minnesota contended that the Secretary departed from its prior practice by substantively limiting the use of intergovernmental transfers. But the appeals court disagreed, finding instead that CMS’ “request for further information did not imply a rejection of intergovernmental transfers and therefore could not be a new substantive rule.” The appeals court also noted that although CMS “may have implemented the upper payment limit to provide some flexibility to states, Minnesota cannot rely on compliance with the upper payment limit to reject every effort of the Secretary to otherwise ensure compliance with the Medicaid statutes.”

The appeals court next found that the Secretary’s decision was not arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law. The appeals court held that to discover abuses of the system, the Secretary’s “review of present state plan amendments necessarily differs from his prior practice,” but this alone does not “constitute ‘[s]udden and unexplained change or change that does not take account of legitimate reliance on prior interpretation.’” Thus, the appeals court rejected the state’s argument that “the decision was arbitrary and capricious simply because it was based on [CMS’] scrutiny of aspects of the 2003 plan amendment that may not have drawn the attention of the Secretary in past adjudications.” Minnesota v. Centers for Medicare and Medicaid Servs., No. 3263 (8th Cir. July 31, 2007).

Fourth Circuit Finds Maryland’s Payment Methods For Compensating Health Centers Violate Medicaid Act

Certain provisions of Maryland’s payment procedures for compensating federally qualified health centers (FQHCs) for service they render to Medicaid patients violate the Medicaid Act, the Fourth Circuit ruled August 24, 2007. Specifically, the federal appeals court found the Maryland payment scheme did not make fully compensatory supplemental payments at least as frequently as every four months to plaintiff-FQHC Three Lower Counties Community Health Services, Inc. (Three Counties), and failed to compensate Three Counties for emergency healthcare services provided to Medicaid patients who were enrolled in a managed care organization (MCO) with which Three Lower Counties did not have a contract.

Maryland's Medicaid managed care program, HealthChoice, contracts on behalf of the state with MCOs to arrange for the delivery of healthcare services to its Medicaid enrollees. The MCO, in turn, contracts with healthcare providers, including FHCQs, to deliver medical services to Medicaid patients. Under the Medicaid Act, 42 U.S.C. §1396a(bb)(5)(A), states must pay FQHCs a supplemental or “wrap-around” payment for any difference between what the MCO paid the FQHC and what the FQHC is entitled to be paid under the Act. The Act, 42 U.S.C. §1396a(bb)(5)(B), requires such supplemental payments be made no less frequently than every four months. Maryland's
Department of Health (DOH) makes an “advance” interim supplemental payment at the beginning of each calendar quarter based on the FQHC’s historical reimbursement data from the preceding year, and then pays a reconciliation payment to account for any shortfall between the interim supplemental payment and full compensation, the appeals court explained.

In bringing its lawsuit against DOH, Three Counties alleged there was usually a substantial shortfall, sometimes reaching up to $500,000, between DOH’s interim supplemental payment and the “full compensation” amount to which Three Counties was entitled under the Medicaid Act. In addition, Three Counties alleged DOH typically made its reconciliation payment between six and nine months after the end of the quarter for which the interim supplemental payment was made.

The appeals court found Maryland’s payment procedures failed to timely and fully provide supplemental Medicaid payments to Three Counties, thereby violating the Medicaid Act. “Maryland’s practice does not accomplish full payment of the supplemental amount until a reconciliation occurs,” the appeals court said, and although “the partial interim payment is made with the frequency required by the statute, it does not fulfill the statutory requirement of full compensation because the reconciliation payment comes a full six to nine months after the end of the applicable quarter.”

The appeals court also found the agency violated another provision of the Medicaid Act, 42 U.S.C. §1396b(m)(2)(A)(vii), by refusing to pay for emergency services that Three Counties provided to Medicaid patients enrolled with an MCO with which Three Counties did not have a contract. The appeals court said DOH essentially required Three Counties to pay for emergency services provided to HealthChoice recipients receiving benefits from an MCO that refused to enter into a contract with Three Counties. “Section 1396b(m)(2)(A)(vii) requires either the State or the managed care organization to compensate a health center for emergency services provided to Medicaid patients, even if the health center is out-of-network,” the appeals court ruled. *Three Lower Counties Community Health Servs., Inc. v. Maryland*, No. 06-1552 (4th Cir. Aug. 24, 2007).

**Texas Supreme Court Finds Medicaid Data Collection Method Invalid Under APA**

The Texas Supreme Court held that a Texas rule setting out its data collection method for determining Medicaid rates was invalid because it was not promulgated properly under the state’s Administrative Procedure Act (APA). Fourteen hospitals in Texas sued the Texas Health and Human Services Commission (HHSC) claiming HHSC’s cut-off date for submitting paid claims data to determine reimbursement rates for inpatient Medicaid services was invalid. According to the hospitals, HHSC’s process did not use 12 consecutive months of claims data in computing rates as its rules require; instead HHSC imposed an arbitrary cut-off that excluded relevant Medicaid claims.

The Supreme Court of Texas agreed with the hospitals that the cut-off provision “falls squarely within the APA’s definition of a rule.” Specifically, the high court noted the rule was generally applicable, amended another rule, and affected the hospitals’ private rights. The high court thus declared the cut-off invalid because HHSC did not follow proper procedures.
rule-making procedures. The high court then noted that, unless good cause existed to invalidate an agency rule, it should remain effective for a reasonable period. “Finding no good reason to invalidate the rule immediately, we remand the rule to the agency for further action,” the high court held. El Paso Hosp. Dist. v. Texas Health and Human Servs. Comm’n, No. 05-0372 (Tex. Aug. 31, 2007).

Fourth Circuit Finds Private Right Of Action Under Medicaid “Reasonable Promptness Provision”

A developmentally disabled plaintiff may bring a private right of action to enforce the Medicaid Act’s “reasonable promptness” requirement with respect to services provided under a waiver program for care in non-institutionalized settings, the Fourth Circuit ruled in a 2-1 decision. Sue Doe, who has developmental disabilities, sued the South Carolina Department of Health and Human Services (DHHS) and the Department of Disabilities and Special Needs (DDSN) alleging she was denied the services she sought under a Medicaid waiver program to provide care to those with mental retardation or related disabilities in alternative settings.

At issue in the instant case was Doe’s claim under 42 U.S.C. § 1983 alleging defendants deprived her of Medicaid services and freedom to choose providers and failed to provide residential habilitation and other Medicaid services with “reasonable promptness” in violation of the Medicaid Act. 42 U.S.C. § 1396a(a)(8). The district court eventually dismissed Doe’s claims as moot after defendants placed her in a group home, the most restrictive setting, as a temporary measure to address a change in her family circumstances.

The Fourth Circuit held Doe’s reasonable promptness claim was not moot, since defendants acknowledged her placement in the group home was temporary. Applying the three-part test under Blessing v. Freeston, 520 U.S. 329 (1997), the appeals court concluded Doe could bring a § 1983 action to enforce § 1396a(a)(8). Specifically, the appeals court found the Medicaid provision at issue was expressly intended to benefit “all” individuals eligible for Medicaid; the “reasonable promptness” requirement was not so “vague and amorphous” to preclude competent enforcement (noting relevant federal and state regulations establishing a 45 – 90 day time period depending on circumstances); and the statute used mandatory rather than precatory terms. Finally, the appeals court noted the Medicaid Act neither expressly nor impliedly barred recourse to § 1983.

The appeals court then turned to Doe’s claim that defendants violated the freedom of choice provision in § 1396a(a)(23) of the Medicaid Act, which in essence “gives recipients the right to choose among a range of qualified providers, without government interference.” The appeals court held the claim was not moot, but lacked merit because Doe’s freedom of choice was not implicated. Doe claimed that although defendants were providing her care under the waiver program, they were not doing so in the setting in which she wanted to receive Medicaid services. According to the appeals court, § 1396a(a)(23) requires freedom of choice only as to the available providers, not to the appropriate setting for the provision of the waiver services, which is determined by DDSN.
A dissenting opinion argued that Doe’s “reasonable promptness” claim was moot, or alternatively, Doe had no private right of action under § 1983. On this “thorny” issue of first impression, the dissent said the majority improperly relied on the Blessing decision and should have instead considered the Supreme Court's more recent opinion in Gonzaga Univ. v. Doe, 536 U.S. 273 (2002), which stated nothing “short of an unambiguously conferred right” will support a § 1983 cause of action. “If Congress had intended to subject the countless Medicaid decisions made by state agencies each day to the scrutiny of the federal judiciary, I would expect to find clear and unmistakable language in the statute stating as much,” the dissent observed. Doe v. Kidd, No. 05-1570 (4th Cir. Sept. 19, 2007).

Missouri High Court Says State Agency’s Medicaid Reimbursement Formula Subject To Rulemaking Procedures

The Missouri Supreme Court held October 30, 2007 that the formula used by the state's Division of Medical Services (DMS) in calculating prospective Medicaid direct payments constitutes an administrative rule that must be promulgated in accordance with rulemaking procedures under Missouri’s Administrative Procedure Act (MAPA). The lawsuit was originally brought by Little Hills Healthcare, L.L.C., d/b/a Centerpointe Hospital, a Missouri psychiatric hospital, challenging how DMS calculated its prospective Medicaid direct payments for state fiscal year (SFY) 2004.

Hospitals in Missouri providing Medicaid services receive direct Medicaid payments as prospective reimbursement for projected estimated expenses. This amount is calculated in part based on "estimated Medicaid patient days" for the state's current fiscal year because actual days are not known until after the fiscal year is over. DMS regulations do not set forth a precise methodology for determining "estimated Medicaid days."

Centerpointe filed a complaint with the state Administrative Hearing Commission (Commission) after it received $1.8 million less in direct Medicaid reimbursements for SFY 2004 than it had received in SFY 2003 based on a different formula for calculating estimated Medicaid days than previously used. Centerpointe argued that the new method DMS used to calculate prospective Medicaid reimbursements for SFY 2004 was unreasonable and that DMS should have promulgated its method as a formal rule in accordance with MAPA.

The Commission agreed, and reversed DMS’ decision. The Commission also ordered that DMS award Centerpointe the additional $1.8 million. The Missouri Court of Appeals reversed, concluding the Commission erred in holding DMS was required to promulgate as a rule its internal guidelines on how to calculate Medicaid estimated days. 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 the method used by DMS involved selecting a time period for estimating Medicaid patient days based on different data each year.

The Missouri Supreme Court, however, rejected DMS' argument that its calculations did not meet the definition of a rule because they were not standards of "general
applicability." According to the high court, DMS applied one method for calculating estimated Medicaid days to Centerpointe and 139 other similar Medicaid-participating providers. “Contrary to DMS’s assertions, its ‘estimated Medicaid days’ calculation does not relate only to a specific set of facts relating to a specific provider[,] and can be considered a standard of ‘general applicability’ for rulemaking purposes,” the high court said.

The high court also found “unpersuasive” DMS’ argument that estimated Medicaid days calculations had no future effect. “DMS determines its 'estimated Medicaid days' calculation method at the start of a SFY and then applies it as that SFY proceeds,” the high court said, “DMS’s choice to annually update or change its calculation methods does not change the fact that its methods could apply indefinitely in the future.”

The high court also found that the Commission’s decision to award Centerpointe the additional $1.8 million was reasonable as it was based on DMS’ estimation method from the previous year (SFY 2003) along with the most current available data. Dep’t of Social Svcs. v. Little Hills Healthcare L.L.C., No. SC88430 (Mo. Oct. 30, 2007).

**U.S. Court In Pennsylvania Finds State’s Medicaid DSH Scheme For Trauma Centers Is Unconstitutional**

A Pennsylvania law that establishes disproportionate share hospital (DSH) payments for in-state trauma centers is unconstitutional because it discriminates against out-of-state providers who serve Pennsylvania Medicaid recipients, a federal trial court in the state ruled November 5, 2007. West Virginia University Hospital Center (WVUH) in Morgantown, West Virginia, sued various Pennsylvania state officials (defendants) alleging their failure to make certain Trauma DSH payments under state law violated the U.S. Constitution’s Commerce and Equal Protection Clauses and the Medicaid Act.

For several years, WVUH, which is located six miles from the Pennsylvania border, has provided emergency services to roughly 1,500 Pennsylvania Medicaid recipients in its Level I trauma center. In March 2004, the state legislature enacted the Pennsylvania Trauma Systems Stabilization Act (Act), which authorizes a new DSH to hospitals accredited as a level I, II, or III trauma center, but limits this definition to hospitals located in Pennsylvania. Nearly $25 million was allocated in 2005 for Level I and II trauma centers, more than half of which was funded by the federal government. Because WVUH is not located in Pennsylvania, defendants concluded it was not entitled to a trauma DSH payment even though it treated a large number of Pennsylvania Medicaid recipients.

The U.S. District Court for the Middle District of Pennsylvania concluded defendants violated the Equal Protection Clause and the Commerce Clause. The court first considered WVUH’s 42 U.S.C. § 1983 claim that the Pennsylvania State Plan violated the Medicaid Act, 42 U.S.C. § 1396(a)(16), because it failed to adequately provide for services to Pennsylvania residents who are absent from the state. The court concluded that, because medical providers are not the intended beneficiaries of § 1396(a)(16), no enforceable federal right was at stake for purposes of § 1983.
Next, applying rational basis review, the court held defendants violated the Equal Protection Clause by discriminating against out-of-state medical providers serving in-state residents. Citing precedent relevant to discriminatory Medicaid plans, the court concluded the state’s proffered justification—improving access to trauma care for Pennsylvania residents—was “not rationally related to the denial of the Trauma DSH payment to all out-of-state hospitals.”

The court also found the Trauma DSH payment scheme violated the dormant Commerce Clause because it discriminated on its face against out-of-state hospitals without serving any legitimate purpose. In so holding, the court rejected defendants’ argument that the Trauma DSH payments are a direct subsidy to in-state hospitals and therefore fall within a “subsidies” exception to the Commerce Clause. Even assuming that a “subsidies” exception exists, defendants’ “characterization of the Trauma DSH payments as a permissible subsidy for domestic industry is untenable,” the court found. Specifically, the court noted the Trauma DSH payments are neither funded purely by state revenue or voluntary; rather, they are part of the state’s Medicaid plan and funded in part by the federal government. *West Virginia Univ. Hosps., Inc. v. Rendell*, Civil No. 1:CV-06-0082 (M.D. Pa. Nov. 5, 2007).

**U.S. Court In Delaware Holds State’s Residency Requirement For Medicaid Eligibility Violated Constitutional Right To Travel**

A federal trial court granted summary judgment to a Medicaid beneficiary in an action alleging Delaware’s residency requirements for Medicaid eligibility unconstitutionally infringed her right to travel. Plaintiff Marianne Duffy, a North Carolina resident who suffers from developmental disabilities, sued Delaware officials (defendants) after they denied her application through the state’s Medicaid program for community residential services in an intermediate care facility for mental retardation (ICF/MR). Her parents relocated to Delaware from North Carolina and applied to defendants for residential placement of their daughter. Defendants determined that Duffy was not a Delaware resident as she was not physically residing in the state and therefore she would not be immediately eligible for Medicaid if she moved there.

The U.S. District Court for the District of Delaware held the residency requirements violated her constitutional right to travel under the Fourteenth Amendment’s Equal Protection Clause. Applying strict scrutiny review, the court found the state’s Medicaid residency policy had the “unconstitutional effect of barring individuals who need ICF/MR services, and who cannot individually afford them, from establishing residency for Medicaid purposes in Delaware.” The court zeroed in on the fact that the state would only determine Medicaid eligibility at the point an individual became a Delaware resident. Here, Duffy’s medical condition warranted intensive supervision requiring her immediate placement in an ICF/MR, which she could not afford absent Medicaid coverage. “While Ms. Duffy may not be literally ‘trapped in North Carolina,’ it is certainly true that the State of Delaware has impeded her ability to relocate to Delaware by refusing to process and approve her application for Medicaid until she physically resides in the State,” the court said. *Duffy v. Meconi*, 508 F. Supp. 2d 399 (D. Del. Sept. 11, 2007).
Fifth Circuit Holds Medicaid’s Equal Access Requirement Does Not Create Private Right Of Action

The Medicaid Act’s so-called “equal access” provision does not confer individual private rights that are enforceable under 42 U.S.C. § 1983, the Fifth Circuit ruled December 10, 2007. The provision at issue, 42 U.S.C. § 1396a(a)(30)(A), requires a states to assure payments under their medical assistance plans “are sufficient to enlist enough providers so that care and services are available” to Medicaid recipients to the extent they are available to the general population in the geographic area.

Plaintiffs in this case, the nonprofit Equal Access for El Paso, several Medicaid recipients, and several healthcare providers, sued the Commissioner of the Texas Health and Human Services Commission (HHSC) under § 1983, alleging the state set deficient Medicaid reimbursement and capitation rates, resulting in inadequate access to medical services for Medicaid recipients in the El Paso area compared to the rest of the state and to individuals with private insurance. The district court refused to dismiss plaintiffs’ claim under the Medicaid Act’s equal access provision.

On interlocutory appeal, HHSC argued the Supreme Court’s decision in Gonzaga v. Doe, 536 U.S. 273 (2002), made clear that the equal access provision did not create a federal right of action enforceable through § 1983. The Fifth Circuit agreed, finding the provision did not “contain sufficient ‘rights-creating’ language critical to showing unambiguously the requisite Congressional intent to create individualized rights for Medicaid recipients and healthcare providers.” Rather, the appeals court noted, the equal access provision “speaks only in terms of institutional policy and practice, has an ‘aggregate’ rather than individualized focus, and is not concerned with whether the needs of any particular person or class of individuals have been satisfied.” Following Gonzaga, the appeals court continued, “[w]e are forced . . . to abjure the notion that anything short of an unambiguously conferred private individual ‘right’ rather than the broader or vaguer ‘benefits’ or ‘interest,’ may be enforced under § 1983.” Equal Access for El Paso, Inc. v. Hawkins, No. 06-50599 (5th Cir. Dec. 10, 2007).

Fourth Circuit Says Rural Healthcare Provider Waived Right To Challenge State's Medicaid Reimbursement In Federal Court

Although a South Carolina healthcare provider that operates rural health clinics (RHCs) has a right, under 42 U.S.C. § 1983, to bring a lawsuit challenging the state’s Medicaid reimbursement methodologies, it voluntarily waived that right by agreeing to a forum selection clause in its contract with the state requiring disputes to proceed through the appropriate state agency first, the Fourth Circuit ruled December 5, 2007.

Plaintiff Pee Dee Health Care, P.A. (Pee Dee) entered into a contract with the South Carolina Department of Health and Human Services (SCDHHS), which administers the state’s Medicaid program. These contracts with the state contain a forum-selection clause that requires provider reimbursement disputes to proceed through SCDHHS and then state court system. In its lawsuit, Pee Dee claimed SCDHHS’ reimbursement formula failed to comply with the Benefits Improvement and Protection Act of 2000 (BIPA), 42 U.S.C. § 1396a(bb), resulting in lower rates. Defendants moved to dismiss, noting Pee
Dee had agreed under its contract with the state to pursue all claims arising under the contract through state administrative and judicial avenues.

The Fourth Circuit first held that Pee Dee had a private right of action under § 1983 to sue the state to enforce reimbursement requirements, finding § 1396a(bb) contained the necessary rights-creating language. Congress intended BIPA to benefit rural health centers (RHCs) such as Pee Dee, the appeals court reasoned, as demonstrated by the statutory language: “the state plan shall provide for payment for services . . . furnished by a [RHC].” (Emphasis added.) In addition, § 1396a(bb) contains “rights-creating language” because it specifically designates the beneficiaries, i.e., the RHCs, and also “mandates action on the part of the states,” the appeals court said.

The appeals court ultimately concluded, however that Pee Dee could not ignore the forum-selection clause in the contract it signed with the state. “[P]rocedural rights under § 1983, like other federal constitutional and statutory rights, are subject to voluntary waiver,” the appeals court noted. The appeals court also emphasized that the contract between Pee Dee and SCDHHS did not completely deprive Pee Dee of a remedy. *Pee Dee Health Care PA v. Sanford*, No. 06-2108 (4th Cir. Dec. 5, 2007).

**North Carolina Appeals Court Finds Medicaid May Recover From Pain And Suffering Settlement Funds**

The North Carolina Court of Appeals found controlling a state supreme court decision that held Medicaid may recover expenses paid from settlement amounts regardless of whether the settlement funds were for pain and suffering or for medical damages. In so holding, the appeals court held a contrary U.S. Supreme Court decision was not applicable in North Carolina.

Katelyn Andrews, who was injured during her birth, sued her doctors and the hospital where she was delivered for medical malpractice. Katelyn’s parents also sued the same parties and on the same allegations in their individual capacities. Katelyn and her parents settled with defendants and a trustee was appointed for the settlement account. Because Katelyn is a Medicaid recipient, North Carolina’s Division of Medical Assistance (DMA) moved to intervene. DMA moved for reimbursement from the settlement account of monies it had paid for her care. The trial court granted the motion and the trustee appealed.

The appeals court first turned to the trustee's argument that the DMA is only entitled to the settlement funds that Katelyn received as compensation for medical expenses and not any settlement funds due to her pain and suffering. The appeals court noted that the state supreme court addressed the issue in *Ezell v. N.C. Dep’t of Health & Human Servs.*, 631 S.E.2d 131 (2006), which held that the DMA was subrogated to the entire amount of the settlement, regardless of whether the funds were for pain and suffering or medical expenses. The trustee argued that the U.S. Supreme Court’s decision in *Arkansas Dep’t of HHS v. Ahlborn*, 547 U.S. 268 (2006), should apply instead. That case held a state’s ability to recover its Medicaid lien was limited to the pro-rata portion of the settlement representing compensation for past medical expenses only, not the entire settlement. The
appeals court agreed, however, with the trial court that Ezell was controlling as it was decided after the Ahlborn case and Ahlborn was interpreting an Arkansas statute, not one from North Carolina. The appeals court further noted that it "has no authority to overrule decisions of our supreme court and we have the responsibility to follow those decisions until otherwise ordered" by the state supreme court.

A lengthy dissent argued that Ahlborn should be controlling because the state supreme court "has not yet squarely answered the question presented to us by this case." The dissent noted that the state supreme court in Ezell adopted a dissent from the state appeals court that had not considered Ahlborn or its effect in North Carolina. Andrews v. Haygood, No. COA06-1670 (N.C. Ct. App. Jan. 15, 2008).

U.S. Court In Maine Rejects Hospital's Unlawful Takings Claim Against Maine’s Medicaid Program

A federal court in Maine rejected January 28, 2008 a hospital’s claim that the state’s failure to pay reasonable reimbursement rates under its Medicaid program, along with a state statute obligating certain hospitals to provide free services to patients eligible for charity care, amounted to an unconstitutional taking. According to the court, the hospital voluntarily participated in the state’s Medicaid program, known as MaineCare, despite its contention that the workings of the free care statute gave it no other viable option.

Franklin Memorial Hospital (FMH) brought the action against Brenda Harvey, the Commissioner of the Maine Department of Health and Human Services (DHHS or defendant), in her official capacity, alleging MaineCare’s low reimbursement rates constituted an unlawful taking without just compensation in violation of the U.S. and Maine Constitutions. The hospital contended that in 2007 FMH would be reimbursed roughly $2,646.95 per discharge for inpatient hospital services under MaineCare, while its historical actual cost per discharge was roughly $4,796. According to FMH, it was compelled to participate in the MaineCare program because of the statutory and regulatory mandates of the state’s Free Care Statute, 22 Me. Rev. Stat. Ann. § 1715 et seq., which require certain hospitals to provide healthcare services “to individuals who are eligible for charity care.”

DHHS guidelines specify the eligibility requirements for free care, including that the individual’s income is not greater than 150% of the federal poverty level; that the individual is not covered by any insurance or state and federal medical assistance; and that the services received were medically necessary. The guidelines also specify that any individual that qualifies for free care shall not be billed for any amount not paid by an insurer or medical assistance program.

Examining relevant Fifth Amendment jurisprudence, the U.S. District Court of the District of Maine rejected FMH’s takings claim. FMH argued that it faced a “Hobson’s choice” in deciding whether to participate in MaineCare—i.e. either participate in the Medicaid program and receive unjustly low compensation or opt out and provide free care without any reimbursement for MaineCare participants. Under FMH’s interpretation of the free care statute and guidelines, hospitals that did not participate in MaineCare...
must consider all services provided to MaineCare participants who otherwise meet income eligibility requirements as free care because the hospital would receive no compensation from the medical assistance program and could not bill the individual for the services rendered.

But defendant contended that under the guidelines, an individual is not eligible for free care if he or she has any insurance or is eligible for a medical assistance program regardless of whether the hospital is a participant in the particular program. A hospital that did not participate in MaineCare would have no obligation to provide free care to the extent the services were covered by the medical assistance program. Instead, the hospital could recommend that the participant obtain services from a participating provider, or bill the participant for any services performed, defendant said.

According “substantial deference” to the agency, the court found while FMH advanced “a colorable reading of the statute and implementing guidelines, Defendant’s interpretation is reasonable in light of the structure and purpose of the free care and MaineCare regulations when considered in their entirety.” Franklin Mem’l Hosp. v. Harvey, No. 07-cv-125-GZS (D. Me. Jan. 28, 2008).

MEDICAL MALPRACTICE

Michigan High Court Finds Malpractice Statute Of Limitations Tolled Regardless Of Defective Affidavit Filed With Complaint
Plaintiffs’ filing of a medical malpractice complaint along with a statutorily defective affidavit of merit tolled the applicable statute of limitations until the validity of the affidavit was successfully challenged in subsequent proceedings, Michigan’s high court ruled July 11, 2007. Mary Kirkaldy and her husband brought a medical malpractice action in a state trial court against neurologist Choon Soo Rim and other physicians. The court entered summary judgment in favor of Rim and the other physicians and dismissed the Kirkaldys’ claims without prejudice. The appeals court affirmed, finding the Kirkaldys had filed a complaint with an affidavit of merit that did not meet the requirements of Mich. Comp. Laws § 600.2912d.

Reversing, the Michigan Supreme Court overruled appeals court precedent holding that filing a defective affidavit of merit is the functional equivalent of failing to file an affidavit of merit for the purpose of tolling the period of limitations. Instead, the high court clarified that the period of limitations remains tolled until the validity of the affidavit is successfully challenged in “subsequent judicial proceedings.” Once an affidavit is successfully challenged, it loses its presumption of validity and triggers the running of the limitations period, the high court noted. Kirkaldy v. Choon Soo Rim, No. 129128 (Mich. July 11, 2007).

California Appeals Court Finds Statute Of Limitations For Malpractice Claims Applies To Medical Students
The statute of limitations provision in California’s Medical Injury Compensation Reform Act of 1975 (MICRA) applies to unlicensed medical students who are lawfully practicing
medicine under a statutory exception to state licensing requirements, a California appeals court ruled July 20, 2007. Enacted to lower medical malpractice insurance premiums by limiting malpractice litigation, MICRA contains a statute of limitations provision (Cal. Civ. Proc. Code § 340.5) that applies to “health care providers,” which is defined as including persons who are licensed or certified by the state to practice medicine. The California Court of Appeal, First Appellate District, Division One, concluded that an unlicensed optometry student at University of California’s School of Optometry who allegedly injured a plaintiff’s ankle during a routine eye exam fell within the definition of “health care provider” set forth in MICRA’s statute-of-limitations provision.

Plaintiff Eve Chosak’s ankle was injured just prior to an eye examination by Lynn Valdez, who was practicing as an intern and was an unlicensed optometry student at the University of California, when her foot became jammed between the chair and the arm of the eye examination device. Nearly two years later, on March 10, 2005, Chosak filed a medical malpractice action against Valdez and others in state trial court. The court dismissed Chosak’s action as barred by MICRA’s statute of limitations provision, which requires a plaintiff to file a medical malpractice claim within one year from the date the plaintiff discovers, “or through reasonable diligence should have discovered,” his or her injury. On appeal, Chosak contended MICRA’s one-year statute of limitations was not applicable to Valdez because she was not a licensed medical professional at the time of the accident.

Rejecting this argument, the appeals court found the public policy underlying MICRA to reduce medical malpractice insurance premiums by lawsuits would be best served by adopting a broad definition of “health care provider” to include those lawfully practicing, but unlicensed or uncertified, to provide medical services. “There is simply no distinction between licensed and exempt professionals that argues for a longer statute of limitations with respect to the latter,” the appeals court said. In addition, the negligent conduct of lawfully practicing unlicensed medical students, who contribute to providing healthcare services, “affects the insurance premiums that health care providers pay, just as the conduct of [licensed] professionals within those entities does,” the appeals court observed. *Chosak v. Alameda County Med. Ctr.*, A113318 (Cal. Ct. App. July 20, 2007).

**Mississippi Supreme Court Affirms Dismissal Of Vicarious Liability, Negligent Supervision Claims**

The Mississippi Supreme Court affirmed the dismissal of vicarious liability and negligent supervision claims against a physician, finding no evidence the physician exerted any control over the staff performing the procedure at issue or that he present in the hospital at the time of the procedure. Kathy Dearman went to Montfort Jones Memorial Hospital for imaging services. The radiology technician, Herbert Hill, injected contrast dye into Dearman’s arm. Dearman’s arm subsequently began to swell and she was treated by Dr. Ron Christian in the x-ray room. Dearman eventually had to undergo surgery to drain the contrast dye. Dearman sued the hospital and Christian in state court pursuant to the Mississippi Tort Claims Act.
Christian moved for partial summary judgment on Dearman’s claims of vicarious liability and negligent supervision. The trial court granted the order and also entered a final judgment of dismissal with prejudice dismissing the vicarious liability and negligent supervision claims against Christian. Dearman appealed.

Pointing to testimony that Christian, as an independent contractor and medical director of the hospital’s radiology department, was not responsible for supervising staff, the Mississippi Supreme Court found the trial court properly held Christian was not vicariously liable for the actions of the hospital employees. After reviewing several other cases on point, the high court concluded “[t]he evidence clearly showed that the radiology staff was not under Dr. Christian’s direction and control at the time of Dearman’s procedure.” Further, the high court found no evidence that Christian was present at the hospital during the time of Dearman’s procedure. *Dearman v. Christian,* No. 2006-CA-01759-SCT (Miss. Aug. 23, 2007).

**Texas High Court Upholds Medical Malpractice Statute's Limitations Provisions As Applied To Incapacitated Plaintiff**

The Texas Supreme Court upheld October 19, 2007 the limitations provision of the Texas Medical Liability Insurance Improvement Act (MLIIA), which prohibits tolling based on incapacity, as applied to a comatose patient whose mother waited more than two years to bring a medical negligence action against various healthcare providers. While the plaintiff argued the MLIIA limitation provision violated the "open courts guarantee" of the Texas Constitution, the high court found the provision was not unconstitutional as applied to the incapacitated patient in this case because her mother failed to exercise due diligence in bringing the action within the applicable medical malpractice statute of limitations.

In May 2000, Carletha Yates underwent surgery to remove kidney stones. During the surgery, she suffered cardiac arrest allegedly caused by the medical personnel’s failure to monitor her oxygen while she was under general anesthesia. As a result, Yates went into a coma and never regained consciousness. In December 2001, Yates’s mother and the guardian of Yates’s estate, Eula Yancy, sued Dr. Manuel Ramirez and Dallas Pain & Anesthesia Associates (DPAA) for negligence. Nearly two years later, Yancy added United Surgical Partners International, Inc. (United Surgical), Valley View Surgical Center, Inc., and June Smith, R.N. (collectively, Valley View) as defendants.

United Surgical and Valley View asserted the applicable two-year statute of limitations barred claims and moved for summary judgment. Yancy contended the statute of limitation had been tolled because Yates was in a continuous comatose state since her surgery. According to Yancy, the MLIIA limitations provision violated the state constitution's open courts guarantee, which provides that “all courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law," as applied to Yates because it prohibited tolling based on minority or incapacity.
The high court first concluded that Yancy had met the burden of presenting evidence to establish Yates’ continuous mental incapacity but went on to conclude applying the MLIIA’s two-year statute of limitations (Tex. Rev. Civ. Stat. art. 4590i, § 10.01) to did not violate the Texas Constitution’s open courts guarantee provision (Tex. Const. art. I, § 13). The high court noted that a plaintiff may not obtain relief under the open courts guarantee if he does not use due diligence and sue within a reasonable time after learning about the alleged wrong. In this case, plaintiff-Yancy “offered no explanation for failing to name Valley View and United Surgical for almost twenty-two months after filing the original petition,” the high court said. The high court therefore found Yancy failed to raise a fact issue establishing that she (on Yates’s behalf) did not have a reasonable opportunity to discover the alleged wrong and bring suit within the limitations period or that she sued within a reasonable time after discovering the alleged wrong. Thus, the “open courts guarantee” provision did not save Yates’ time-barred negligence claims. Because the high court found the MLIIA limitations provision constitutional as applied to Yates, it found "no need to strike it down because it might operate unconstitutionally in another case."  


**Louisiana Appeals Court Says Patient Compensation Fund Had No Authority To Deny Medical Review Panel Requests**

The Louisiana Patients’ Compensation Fund (PCF) Oversight Board has no statutory authority to decline a request for a medical review panel based on its unilateral determination that the claim did not meet the definition of medical malpractice under state law, a Louisiana appeals court ruled November 2, 2007. The case at issue stemmed from various medical review panel requests asserting issues of negligent care and failure to evacuate at several hospitals and a nursing home in the wake of Hurricane Katrina. The PCF denied the requests, concluding the complaints did not fall within the scope of the Louisiana Medical Malpractice Act (LMMA). Plaintiffs sought a writ of mandamus ordering PCF to perform its statutory ministerial duties under the LMMA by accepting their medical review panel requests. The trial court issued the mandamus order. 

Affirming, the Louisiana Court of Appeal, First Circuit, held the PCF overstepped its statutory authority. In a September 2007 decision, the Louisiana Supreme Court held a lawsuit following the death of a hospital patient in the aftermath of Hurricane Katrina sounded in general negligence and not medical malpractice. Thus, the high court held the action did not have to be submitted to a medical review panel before proceeding in court.  

_Lacoste v. Pendleton Methodist Hosp.,_ L.L.C., No. 07-0008 (La. 2007). But the court here noted no jurisprudence indicating that PCF has actual or implied authority to determine in the first instance whether a claim constituted medical malpractice. The court found support for its conclusion in the _Lacoste_ decision, which indicated that whether a case is one of medical malpractice or negligence is ultimately a decision for the fact finder. Moreover, the statute outlining the PCF’s affirmative and mandatory duties does not give it discretion to determine whether a claim falls under the LMMA. Thus, the PCF lacked any adjudicatory authority and its duties following a request to invoke a medical review panel are clerical or ministerial in nature, the court held.  

Nevada Supreme Court Finds Physician May Testify As Expert Against Nurse
The Nevada Supreme Court reversed November 8, 2007 a district court’s directed verdict for a hospital in a medical malpractice action, finding a physician qualified to testify as to the accepted standard of care for a procedure even though it was performed by a nurse. Plaintiff Nicolaus Staccato was admitted to Valley Hospital’s emergency room after seeking treatment for back pain. The attending physician ordered a pain reliever to be administered by injection. Staccato alleges that he protested because of his fear of needles, but a nurse nonetheless instructed him to stand and administered the shot. The nurse then left Staccato unattended, at which point he passed out and fell resulting in a laceration to his head and a brain injury.

Staccato sued the hospital and the nurse for medical malpractice. He designated Paul Fischer, M.D., an emergency room physician, as a standard-of-care expert witness. The hospital moved to preclude Fischer from testifying about the “nursing standard of care.” The district court granted the motion and subsequently directed a verdict in the hospital’s favor. Staccato argued on appeal that Fischer is qualified to both administer intramuscular injections and to attest to the acceptable standard of care for that procedure, regardless of whether a nurse administered the injection at issue.

The state supreme court agreed, noting that in Nevada, expert witness assessment turns on whether the proposed witness' special knowledge, skill, experience, training, or education will assist the jury. In distinguishing an Illinois case relied on by the hospital, the high court stated that in “states like Nevada, where the focus of expert witness qualifications is directed at the scope of the witness's practical knowledge in light of the particular circumstances of the case, courts have routinely allowed physicians to testify against nurses with respect to the accepted standard of care.” Staccato v. Valley Hosp., No 42297 (Nev. Nov. 8, 2007).

Mississippi High Court Finds Statutory Cap Limits Total Noneconomic Damages In Wrongful Death Case Involving Multiple Plaintiffs
A Mississippi trial court correctly concluded the total noneconomic damages that can be awarded to multiple plaintiffs in a wrongful death lawsuit brought against a hospital is limited to $500,000 under Mississippi’s statutory cap, the state high court ruled November 29, 2007. Stacey Kay Klaus died following surgery at River Region Hospital (River Region). Stacey’s mother, Alta Klaus (Mrs. Klaus), subsequently filed a wrongful death suit against Vicksburg Healthcare LLC d/b/a/ River Region Health Systems and an individual physician and nurse on River Region’s staff (collectively, defendants). Mrs. Klaus filed her complaint as administratrix of Stacey’s estate and as personal representative of Stacey’s wrongful death beneficiaries (her father and mother, and her half-sister; collectively, plaintiffs).

Plaintiffs later filed a motion in the trial court for a declaratory judgment addressing the question of whether the $500,000 statutory cap on noneconomic damages contained in Miss. Code Ann. § 11-1-60(2)(a) limits noneconomic damages for each of the three plaintiff-wrongful death beneficiaries in the case to $500,000, or limits noneconomic damages to $500,000 for all three plaintiffs in the aggregate. The trial court entered a
declaratory judgment finding “the limitation on non-economic damages in Section 11-1-60(2)(a) to $500,000 applies to this cause of action regardless of the number of beneficiaries.” On appeal, plaintiffs argued that § 11-1-60(2)(a) is ambiguous when read together with Mississippi’s wrongful death statute, Miss. Code Ann. § 11-7-13.

The Mississippi Supreme Court disagreed and concluded the cap on noneconomic damages in § 11-1-60(2)(a) “applies to all plaintiffs who bring a wrongful death-action pursuant to Miss. Code Ann. §11-7-13,” limiting recover to an aggregate of $500,000.

A dissenting opinion argued §11-1-60(2)(a) was ambiguous, saying it could be interpreted “to mean either that plaintiffs cannot recover more than a total of $500,000 in noneconomic damages in a wrongful death action or that each plaintiff in a wrongful death action cannot recover more than $500,000 in noneconomic damages.” In re-examining the statutes at issue to ascertain the legislative intent behind §11-1-60(2)(a), the dissent concluded the provision should be construed to apply the cap to each wrongful death beneficiary individually. In addition, the dissent noted that, in other statutes, “[w]hen the Legislature has intended to place a cap on plaintiffs’ damages in the aggregate . . . it has done so explicitly.” Estate of Klaus ex rel. Klaus v. Vicksburg Healthcare, LLC, No. 2006-IA-00675-SCT (Miss. Nov. 29, 2007).

Wisconsin Appeals Court Finds Medical Resident Not A “Borrowed Employee” Of Hospital

The Wisconsin Court of Appeals held December 4, 2007 that a first-year resident working in a hospital pursuant to a medical resident program was not a “borrowed employee” of the hospital such that the state's non-economic damages cap would apply regarding his negligence. Marlene and Gregory Phelps sued St. Joseph's Hospital, Dr. Matthew Lindemann, and his insurer, Physicians Insurance Company of Wisconsin, Inc. (collectively, PIC) in state trial court for medical malpractice following the death of one of the twin babies Marlene had been carrying. Marlene was under Lindemann's care while on bed rest at St. Joseph’s. Lindemann at the time of the delivery was an unlicensed first-year resident and an employee of the Medical College of Wisconsin (MCWAH).

The trial court ultimately found Lindemann negligent under both the standard of care applicable to a first-year resident and the standard of care of a physician treating an obstetrical patient. The court apportioned liability 20% to St. Joseph's Hospital and 80% to Lindemann. As a result of the trial court’s findings, the court awarded Gregory and Marlene $500,000 for the wrongful death of their son. In addition, the trial court awarded $200,000 each to Gregory and Marlene for their emotional distress and permanent injuries.

PIC appealed, and the Wisconsin Supreme Court found Lindemann should be held to the standard of care applicable to a first-year resident. The high court then remanded to the trial court after concluding the state's non-economic damages cap did not apply against Lindemann because he was not a "health care provider" as defined by statute, but could apply if on remand he was found to be the "borrowed employee" of the hospital where he was working. On remand, the trial court determined that Lindemann was a “borrowed
employee” of St. Joseph’s Hospital, bringing him under the statutory protection of Wis. Stat. ch. 655, which provides a compensation fund for victims of medical malpractice and caps the recoverable amount of damages that can be awarded to victims of medical malpractice.

The appeals court disagreed with the trial court's ruling that Lindemann was a borrowed employee. The appeals court noted evidence in the record showing that Lindemann did not consider St. Joseph’s his employer, nor did St. Joseph’s consider itself to be Lindemann’s employer. “In order to consent to become the employee of another there must be something more than an agreement to assist in the work of another,” the appeals court held. The appeals court also noted that the practice of local hospitals was to contract with MCWAH and its program directors to pay, assign, control, and evaluate first-year residents. Thus, the appeals court held that, “[b]ecause Dr. Lindemann was not a ‘borrowed employee’ of a health care provider, the WIS. STAT. ch. 655 caps are irrelevant to this case.” Phelps v. Physicians Ins. Co. of Wis., Inc., No. 2006AP2599 (Wis. Ct. App. Dec. 4, 2007).

Texas Appeals Court Finds Optometrist May Not Author Expert Report In Malpractice Action Against Ophthalmologist

An optometrist may not serve as the author of an expert report in a medical malpractice case against an ophthalmologist, the Texas Court of Appeals held January 22, 2008. Because an ophthalmologist is a physician and an optometrist is not, an optometrist is not qualified to testify regarding whether a physician departed from accepted standards of medical care, the appeals court said.

Plaintiff William Davis underwent cataract surgery performed by defendant John Q. A. Webb, Jr., M.D., an ophthalmologist. Davis subsequently sued defendant for medical malpractice alleging his post-operative care was deficient and resulted in injuries to him. Before the trial court, Davis timely filed an expert report authored by Anastis Pass, O.D., M.S., J.D., FAAO, who is a doctor of optometry, but not a physician. Defendant moved to dismiss, alleging Davis failed to timely file an expert report because Pass did not meet the statutory qualifications for an expert. The trial court granted the motion.

According to Davis, § 74.402 of the Texas Civil Practice and Remedies Code (Code) should apply when determining the statutory qualifications of an expert in this case because Davis’ post-operative treatment, although provided by a physician, could have been provided by an optometrist. Defendant countered that § 74.401 of the Code was the applicable statute as it establishes the necessary qualifications for an expert providing an expert report regarding the care rendered by a physician.

Affirming the dismissal of the case, the appeals court noted Davis cited “no cases in which an expert report by a health care provider such as an optometrist concerning the standard of care required of and allegedly breached by a physician has been determined to constitute a good faith effort to comply with the statutory scheme.” Here, Davis’ expert was “barred by statute from offering an expert opinion regarding medical causation or the alleged breach of the standard of care applicable to a physician.” See § 74.351(r)(5)(A)
and (C). Moreover, the appeals court noted, “nothing in section 74.351(c) indicates that a report authored by an individual who is not statutorily qualified to offer an expert opinion is a deficient report curable by a discretionary 30-day extension.” *Davis v. Webb*, No. 14-07-00331-CV (Tex. Ct. App. Jan. 22, 2008).

**Utah High Court Holds Expert Testimony Not Always Required To Prove Proximate Cause In Malpractice Action**

The Utah Supreme Court held February 5, 2008 that proximate cause in a medical malpractice lawsuit does not always require the support of expert evidence. According to the high court, in cases where the causal connection between the alleged negligence and the harm caused is a matter of common knowledge, expert testimony is not required.

Ann Davis Menlove was under the care of psychiatrist Dr. Michael A. Kalm for anorexia, depression, and anxiety, when Kalm prescribed the sleeping pill amitriptyline. Menlove filled the prescription and was found dead the next day pinned under a bedroom dresser. Thirteen of the thirty sleeping pills were missing. Menlove’s ex-husband, plaintiff Kim Bowman, sued Kalm for medical malpractice and wrongful death. Kalm moved for summary judgment. Plaintiff presented some expert testimony, but failed to provide any expert testimony on the issue of whether Kalm’s alleged malpractice was the proximate cause of Menlove’s death. The district court granted summary judgment to Kalm.

The high court first noted that because “the standard of care and the causal link between the negligence and the injury are usually not within the common knowledge of the lay juror, testimony from relevant experts is generally required in order to ensure that factfinders have adequate knowledge upon which to base their decisions.” The high court explained, however, that a limited “common knowledge” exception to the requirement exists “when the causal link between the negligence and the injury would be clear to a lay juror who has no medical training.” Here, the high court found plaintiff’s assertion that Kalm failed to meet the standard of care by prescribing sleeping pills to Menlove when he should have known both that she would abuse them and that the prescription would make her clumsy fell within the common knowledge exception. *Bowman v. Kalm*, No. 20060986 (Utah Feb. 5, 2008).

**Virginia Supreme Court Denies Medical Foundation Charitable Immunity**

The Virginia Supreme Court held February 29, 2007 that the Virginia Health Services Foundation (HSF) was not entitled to charitable immunity in various tort actions against it and the physicians the group employs. In so holding, the high court found HSF “operates like a profitable commercial business with extensive revenue and assets,” despite its stated charitable purpose in its articles of incorporation.

The consolidated action arose as various separate lawsuits against HSF for the alleged medical negligence of several physicians employed by the foundation. While the court in one case granted HSF charitable immunity under state law, two other courts refused to do so. According to the opinion, HSF, which was created to improve patient billing and collection processes, is a “non-profit group practice health care provider organization” that employs physicians who work at the University of Virginia School of Medicine.
HSF’s articles of incorporation state it was formed for “exclusively charitable, scientific and educational” purposes. HSF is exempt from federal income tax under § 501(c)(3).

In addition to judicial limitations, the high court noted that state statute, Va. Code § 8.01-38, denies charitable immunity to most hospitals unless they render exclusively charitable medical services. But the high court determined HSF was not a “hospital” under § 8.01-38 as it was never licensed as such. Therefore, the high court continued, this was not a viable basis for denying HSF charitable immunity as one lower court had.

The high court next considered whether HSF was eligible for common law charitable immunity from tort liability. The high court found HSF established a rebuttable presumption that it was organized with a charitable purpose, citing the foundation’s bylaws. Applying a ten-factor test articulated in previous case law, however, the high court concluded that HSF did not in fact operate with a charitable purpose.

Specifically, the high court noted that “(a) HSF was created to correct billing and collection problems; (b) the ratio of HSF’s revenue compared to the cost of its charitable work is substantially disproportionate; (c) HSF’s incentive payment structure is functionally a profit-based bonus system, much like a for-profit enterprise; and (d) HSF does not accept charitable gifts.” According to the high court, “HSF was created to increase the amount of revenue received by the Medical Center and aggressively pursues legal collections. The magnitude of these practices suggests that HSF operates more like a for-profit business with a financial purpose of earning a profit than a charitable organization.”

The high court also noted HSF had revenue in 2005 of $216,780,000, while its shortfall for charity care was roughly $1.5 million (after taking into account reimbursement from the state and the typical discounts provided to insured patients)—a ratio of 0.66%. In addition, the high court said, HSF spends an average of $12 to $17 million annually in incentive payments. This revenue is distributed by HSF to medical departments based on revenues generated, not indigent care provided, research performed, or hours spent teaching. “The HSF incentive payment structure is functionally a profit-based bonus system,” the high court concluded. “In this respect, HSF follows the model of a profitable commercial business, not a charitable institution,” the high court said. The high court also found it significant that HSF receives no charitable gifts, noting that, as a result, tort awards would not undermine any “philanthropic-minded intentions.” Given these factors, the high court said it was clear that HSF in fact did not conduct its affairs with a charitable purpose. University of Va. Health Servs. Found. v. Morris, Nos. 070214, 070217, and 070475 (Va. Feb. 29, 2008).

**Oregon Supreme Court Upholds Non-Economic Damages Cap In Wrongful Death Action Against Medical Group**

The Oregon Supreme Court held February 22, 2007 that the application of the state’s $500,000 statutory cap on non-economic damages in a wrongful death suit against a medical group was not unconstitutional. Plaintiff Lori Gayle Hughes, as the personal representative of her deceased daughter’s estate, sued PeaceHealth Medical Group for
wrongful death, seeking damages for her daughter’s physical and mental suffering and
the loss of her society, services, love, and companionship. A jury returned a verdict in
plaintiff’s favor and awarded $1 million in non-economic damages.

Pursuant to Or. Rev. Code § 31.710, the trial court reduced the award to the $500,000
statutory cap applicable to medical malpractice actions. The trial court also applied a
lower interest rate under Or. Rev. Code. § 82.010(2)(f) for judgments against medical
providers in malpractice actions. Plaintiff appealed, arguing the statutory cap violated the
Oregon Constitution’s “remedy” guarantee and right to a jury trial. An appeals court
affirmed.

In a 5-2 decision, the Oregon Supreme Court upheld the application of the statutory cap
and reduced interest rate to plaintiff’s wrongful death action. The high court rejected
plaintiff’s argument that the statutory cap violated the “remedy” clause, which provides
that “every man shall have remedy by due course of law for injury done him in his
person, property or reputation.” According to the high court, because wrongful death is
an entirely statutory cause of action, plaintiff could not meet the threshold inquiry for
applying the remedy clause, i.e. that the cause of action existed in Oregon’s common law
when the constitution was adopted in 1857. Moreover, “there is no basis . . . to conclude
that the common law would have recognized the particular cause of action that plaintiff
now asserts—an action seeking damages for all injuries occasioned by the wrongful death
of a family member.”

For similar reasons, the high court rejected plaintiff’s contention that, as applied to her
wrongful death action, the statutory cap violated the right to a jury trial. The high court
noted it had addressed this precise issue in a previous case and declined to deviate from
that ruling. Specifically, the high court said because no wrongful death action existed—
under the common law or by statute—when the constitution was adopted, no right to a
jury trial of such an action could have existed at that time. Instead, the legislature,
subsequent to the constitution’s adoption, created a wrongful death cause of action by
statute, and therefore could place limits on the parameters of such actions. Finally, the
high court concluded the special, reduced interest rate was properly applied to the
judgment, rejecting plaintiff’s argument that it applied only to actions for injuries, not
death, resulting from professional negligence.

One dissenting opinion argued that the majority improperly focused on the narrow issue
of whether the common law, at statehood, recognized a particular claim or cause of

**Florida High Court Rules Patient Right To Know Amendment Applies
Retroactively To Existing Medical Records**

A constitutional amendment passed by Florida voters that gives patients the right to
access information from healthcare providers about adverse medical incidents applies
retroactively to existing medical records, trumping any previous statutory protections
limiting discovery during litigation, the Florida Supreme Court held March 6, 2008.
Resolving a split among the lower courts, the Florida Supreme Court concluded the self-
executing amendment is prospective in operation, but retrospective as to extant records created before the provision’s November 2, 2004 effective date.

The “Patients’ Right To Know Amendment,” or Amendment 7, was approved by Florida voters in 2004. Amendment 7 provides that “patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.” The consolidated action before the high court arose from two appeals court cases interpreting the amendment’s application in medical malpractice actions seeking discovery of documents relating to adverse medical incidents. In both cases, the defendant hospitals asserted the information sought was confidential pursuant to various statutory privileges existing before Amendment 7 was passed.

In *Florida Hospital Waterman, Inc. v. Buster*, 932 So. 2d 344 (Fla. Dist. Ct. App. 2006), the Fifth District Court of Appeal held Amendment 7 was self-executing and allowed for discovery, but concluded that it could not be applied to existing records. The First District Court of Appeal, in *Notami Hospital of Florida Inc. v. Bowen*, 927 So. 2d 139 (Fla. Dist. Ct. App. 2006), held the amendment was self-executing, that it could be applied to existing records, and that provisions enacted by the legislature to implement the amendment (Fla. Stat § 381.028) were unconstitutional because they impermissibly restricted explicit rights set forth in the amendment.

The Florida Supreme Court first held the amendment was self-executing and required no further legislative enactments. Specifically, the high court noted the amendment stated it was effective upon passage and provided a “sufficient rule” to allow patients to access records of a healthcare provider’s adverse medical incidents under existing law.

The high court next agreed with the First District Court of Appeal that the amendment mandated access to medical records that existed at the time of its effective date even though those records were previously protected under statutory privileges. According to the high court, the amendment’s use of the word “any” to define the scope of discoverable records relating to adverse medical incidents, and the broad definition of “patient” to include those who “previously” received treatment expressed a clear intent that the records subject to disclosure include those created before the amendment’s effective date.

The high court also found the amendment’s retrospective application did not violate medical providers’ constitutional due process rights. According to the high court, for a statute to be unconstitutionally retrospective it must impair a vested right. But the high court concluded that such a vested right was not created by the statutory guarantee of confidentiality previously in effect. Instead, the high court found the “hospitals’ claim rests on a mere expectation of the continuance of the legislative policy of limited access to the proceedings of peer review committees.”

Finally, the high court held certain aspects of the legislative provisions implementing the amendment were unconstitutional. For example, the statute allows only for final reports
to be discoverable, not “any records” as the amendment specifies; limits production to only those records generated after November 2, 2004; and states that it will have no effect on existing privilege statutes. The high court declined, however, to invalidate the entire statute and instead severed the offending provisions while leaving intact other aspects of the legislation that, for example, defined important terms, dictated that patient privacy restrictions be upheld, and indicted the party responsible for identifying records of adverse incidents.

A dissenting opinion argued the majority’s decision regarding the retrospective application of the amendment to existing records was “contrary to the law and fundamental fairness.” According to the dissent, statutory protections, in place for over 20 years, established vested rights that the investigations, proceedings, and records of a peer review panel were not discoverable in civil actions. Florida Hosp. Waterman, Inc. v. Buster, Nos. SC06-688, SC06-912 (Fla. Mar. 6, 2008).

**Oklahoma High Court Finds State Law Affords Cause Of Action For Wrongful Death Of Nonviable, Stillborn Fetus**

On a certified question from the Tenth Circuit, the Oklahoma Supreme Court held April 1, 2008 that the state wrongful death statute applicable in plaintiff parents' medical malpractice action afforded a cause of action for the wrongful death of a nonviable, stillborn fetus. The underlying case commenced after Amy Pino gave birth, in September 2003, to a 20-week stillborn fetus at the Carl Albert Indian Health Care Facility (hospital). Amy and her husband (the Pinos) went to the hospital when Amy began experiencing severe cramping and vaginal bleeding. After receiving a urinary tract infection diagnosis, the Pinos returned home. Only hours later, Amy arrived back at the hospital by ambulance and was diagnosed with a placental abruption. The treating physician ruptured the amniotic sac and delivered a stillborn fetus.

The Pinos brought a medical malpractice action, alleging the medical care provided by the hospital and the treating physician deviated from acceptable standards. More specifically, the Pinos alleged the treating physician’s diagnosis was erroneous, and that the fetus was alive with a detectable heartbeat when the physician ruptured the amniotic sac.

The federal trial court granted summary judgment in defendants' favor, concluding that Oklahoma law does not recognize a wrongful death action for a stillborn, nonviable fetus. The Tenth Circuit then certified the following question to the Oklahoma Supreme Court: As of September 2003, “did the Oklahoma Wrongful Death Statute, Okla. Stat. tit. 12 § 1053, afford a cause of action for the wrongful death of a nonviable stillborn fetus?”

After summarizing relevant state case law on wrongful death actions where death occurs as a result of prenatal injury, the high court ultimately concluded that such actions are clearly recognized under Oklahoma’s wrongful death statute. The Oklahoma Wrongful Death Statute, Okla. Stat. tit. 12 § 1053, in effect in 2003, provided that “[w]hen the death of one is caused by the wrongful act or omission of another, the personal representative of the former may maintain an action . . . against the latter.” The
legislature in 2005 amended the statute to explicitly state § 1053 applied to "the death of an unborn child," which is defined as "the unborn offspring of human beings from the moment of conception . . ." Defendant argued that the legislature was making a change in Oklahoma's law, while the Pinos characterized the amendment as merely a clarification of existing law.

Citing Nealis v. Baird, 996 P.2d 438 (Okla. 1999), the high court noted it previously allowed a cause of action under the Oklahoma wrongful death statute in effect at the time on behalf of a nonviable fetus born alive that died shortly thereafter as a result of alleged prenatal injury. The high court saw no “logical reason” to impose a criterion of live birth to prevent the Pinos from bringing their cause of action alleging that the death of their nonviable fetus was caused by prenatal injury. “To allow a tortfeasor to escape liability merely because of the fortuitous circumstances of a fetus dying moments before delivery rather than moments after birth would derogate section 1053’s purpose,” the high court continued. Thus, the high court determined that the 2005 amendment was a clarification of the law, not a substantive change.

The high court acknowledged that its conclusion in this case is not the “prevailing view” among jurisdictions ruling on the issue, noting its finding that only one other state (West Virginia) has allowed a wrongful death action for a stillborn, nonviable fetus without express legislative direction. Pino v. United States, No. 105223 (Okla. Apr. 1, 2008).

Seventh Circuit Finds Resident And Supervising Physician Liable For Malpractice But Vacates $7 Million Award For Loss Of Consortium

A federal district court did not err in finding both the resident, who misdiagnosed a patient’s hip muscle infection as a muscle strain, and her supervising physician, who failed to examine the patient separately, were jointly and severally liable for the patient’s subsequent death from septic shock, the Seventh Circuit held April 8, 2008. The appeals court vacated, however, the district court’s award to the patient’s family of $7 million for loss of consortium, concluding the calculation for this portion of the damages award was not sufficiently explained.

The patient, Ronald Arpin, fell while working at his job as a welder and injured his right hip. Arpin went to St. Elizabeth’s Hospital (St. Elizabeth’s) in Belleville, Illinois, but was discharged with prescription painkillers after x-rays came back negative. Over the next three days Arpin’s pain worsened, and he developed other symptoms including sweating, shortness of breath, and loss of appetite. Arpin then went to Belleville Family Practice Clinic (Clinic), where he was seen by a second-year resident, Dr. Asra Khan. The Clinic is jointly operated by the U.S. Air Force and St. Louis University. After a brief examination, Khan, who was an employee of St. Louis University, refused the family’s request for an MRI, and sent the Arpins home without prescribing any further medication or asking her supervising physician, Dr. Janes Haynes, to examine Arpin. Prior to sending Arpin home, Khan provided a brief description of the case to Haynes, who agreed with Khan’s diagnosis of severe muscle strain. Haynes is an officer of the U.S. Air Force.
At home, Arpin’s condition continued to worsen, and two days later, Arpin was re-admitted to St. Elizabeth’s with symptoms of septic shock and multi-organ failure. He died two weeks later. Arpin’s wife sued the U.S. government and St. Louis University (collectively, defendants), as employers of Haynes and Khan, respectively, for wrongful death arising from alleged medical malpractice. During the subsequent malpractice trial, Khan and Haynes disputed whether Khan had told Haynes about Arpin's increasing pain. According to Haynes, had he known this symptom, he probably would have ordered a CAT scan or MRI, which would have revealed the deadly infection and prompted him to immediately start antibiotic treatment.

After a three-day bench trial, the U.S. District Court for the Southern District of Illinois found defendants jointly and severally liable, and awarded plaintiff damages in excess of $8 million. Of that damages award, $7 million was designated for the loss of consortium with the remainder for medical care, lost wages, and pain and suffering. The government appealed.

The Seventh Circuit agreed with the district court’s finding that a resident’s supervising physician has a duty to personally examine a patient who already has been examined by a resident, and to assess the resident’s medical knowledge and experience before giving any weight to the resident’s diagnosis. In reaching its conclusions regarding Haynes’ joint liability, the district court relied on simple findings of fact (i.e., that Arpin was exhibiting symptoms of infection such as increased pain), and a credibility determination in Khan’s favor on her testimony that she had told Haynes about Arpin’s increasing pain.

However, while affirming Kahn and Haynes' joint and several liability, the appeals court refused to sustain the lower court’s award of $7 million in damages for loss of consortium. The appeals court noted that, pursuant to Fed R. Civ. P. 52(a), a federal judge who acts as trier of fact is required to explain the grounds of his decision. In this case, “the figures [for loss of consortium] were plucked out of the air,” and therefore this award “cannot be squared with the duty of reasoned, articulate adjudication imposed by Rule 52(a),” the appeals court concluded. “We suspect that such an analysis would lead to the conclusion that the award in this case was excessive, but it is not our place to undertake the analysis,” the appeals court said in remanding the action for further proceedings. *Arpin v. United States*, Nos. 07-1079, 07-1106 (7th Cir. Apr. 8, 2008).

**MEDICARE**

*Regulatory Developments*

(1) Proposed Actions

**CMS Proposes 9.9% Reduction In Medicare Physician Payment Rates For 2008**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule July 2, 2007 providing a negative 9.9% update in the Medicare physician fee schedule for 2008 under the Sustainable Growth Rate (SGR) formula. Under the proposed rule, CMS expects payments of roughly $58.9 billion to 900,000 physicians and other healthcare
professionals in 2008. CMS has been projecting negative updates in the physician fee schedule 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. Congress over the last several years has stepped in to avoid planned payment cuts, most recently delaying a 5% reduction in 2007 and instead freezing payments at 2006 levels. At the same time, Congress has not adjusted the spending target, causing a further gap between actual spending and the targets.

Significantly, CMS also proposed “[m]odifying a number of physician self-referral provisions to close loopholes that have made the Medicare program vulnerable to abuse,” according to the agency’s press release. For example, the proposed rule would impose an anti-markup provision on the technical component (TC) and the professional component (PC) of diagnostic tests, irrespective of whether the billing physician or medical group purchases the PC or TC outright or whether the physician or other supplier or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity). CMS said it declined at this time to issue a specific proposal for amending the in-office ancillary services exception. Comments on the proposed rule were due August 31.

**CMS Proposes “Revisit” User Fees For Healthcare Facilities Cited For Quality Deficiencies**

The Centers for Medicare and Medicaid Services (CMS) issued June 29, 2007 (72 Fed. Reg. 35673) a proposed rule to establish user fees for healthcare providers and suppliers cited for deficiencies with federal quality of care requirements that require a "revisit" to ensure appropriate corrective action. The fees are expected to generate an estimated $37.3 million annually. Comments on the proposed rule were due August 27, 2007.

The fees would be assessed for revisits required because of deficiencies cited during initial certification, recertification, or substantiated complaint surveys, CMS said. The administration’s fiscal year 2007 budget request for the Department of Health and Human Services included the new user fees to finance the costs associated with the Medicare survey and certification program’s revisit surveys. CMS is proposing to calculate the user fees based on the type of revisit (onsite or offsite); the average number of hours that a revisit requires; and the average per hour cost of a revisit. Under the proposed rule, exceptions to the assessment of a user fee would include a “state monitoring visit” (unless the visit also met the definition of a revisit) and visits regarding Medicare provider or supplier compliance with Life Safety Code requirements, which relate to fire protection. In addition, CMS proposes to adjust revisit user fees to account for the provider or supplier’s size, the number of follow-up revisits resulting from uncorrected deficiencies, and/or the seriousness and number of deficiencies.

**CMS Issues Proposed ASC Rule**

The Centers for Medicare and Medicaid Services (CMS) published in the August 31, 2007 Federal Register (72 Fed. Reg. 50470) a proposed rule revising the requirements ambulatory surgical centers (ASCs) must meet in order to be reimbursed by Medicare.
According to CMS, its proposal would update the existing ASC Conditions for Coverage to reflect contemporary standards of practice in the ASC community, and includes recommendations made by the Department of Health and Human Services Office of Inspector General.

The rule contains a more comprehensive quality assessment and performance improvement condition (QAPI) and requires an ASC’s governing body to be responsible for the oversight and accountability for the updated QAPI program, CMS said. The rule also would add new requirements for radiologic services provided in an ASC to ensure they are parallel to the requirements for furnishing laboratory services. In addition, CMS noted that “the specific types of procedures that will be covered when performed in an ASC, and the payment rates that will apply, have been dramatically changed as a result of a final ASC payment methodology rule that was issued” in July 2007. CMS also issued in July a proposed rule setting payment rates and adding procedures to the ASC-covered list, effective for ASC services performed on or after January 1, 2008, the agency said.

Meanwhile, CMS posted August 29, 2007 updated ASC payment information. According to CMS, "the information is being displayed in the same format as last year, updated with calendar year (CY) 2006 data." The posted information includes charge and Medicare payment data for ASC facility costs for a limited set of services and charge and payment data for facility costs related to services of high utilization.

CMS Proposes Rule Allowing Part D Plans To Offer Lower Premiums
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule January 8, 2008 (73 Fed. Reg. 1301) that would allow prescription drug plan sponsors to offer a reduced premium amount for certain individuals eligible for the low-income subsidy (LIS) under Medicare Part D. Currently, premiums for Medicare prescription drug coverage are based on plan bids projecting the cost for providing coverage for the following year. Based on these bids, the agency calculates the amount of the premium that will be paid by Medicare for low-income beneficiaries in each region. As a result of premium and subsidy changes, the premium for any individual Part D plan can be fully covered by the subsidy in one year and not the following year. Therefore, during the annual election period each fall, CMS randomly reassigns certain LIS-eligible beneficiaries to another Part D plan if they would otherwise have to begin paying a premium because their plan’s premium will be higher than the amount subsidized by the federal government.

“Through this proposed rule, we are seeking comment on a means of reducing the number of beneficiaries subject to random reassignment while maintaining the integrity of the annual bid process,” said CMS acting Administrator Kerry Weems. “We expect changes adopted in the final rule to be effective in the 2009 benefit year.” CMS’ proposal would apply in regions where there otherwise would be fewer than five prescription drug plan sponsors with a “zero-premium” plan option for limited income beneficiaries.

Accordingly, the proposed rule would “help to ensure there are a sufficient number of organizations offering such plans and increase the number of LIS-eligible enrollees in
those regions who could remain with their current plan without having to pay a premium.”

**CMS Proposes 2.6% Update For LTCHs In Rate Year 2009**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule January 22, 2008 that would update the long term care hospital (LTCH) prospective payment system (PPS) by 2.6% to a standard federal rate of $39,076.28 for the 2009 rate year (RY). Under the proposed rule, LTCH PPS payments for RY 2009 are pegged at roughly $4.44 billion, an increase of approximately $124 million over estimated payments in RY 2008. The update reflects a market basket of 3.5% less a 0.9% adjustment to account for changes in coding practices in RY 2006 rather than the treatment of more resource intensive patients, CMS said.

CMS said the proposed update complies with provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Act), which President Bush signed into law December 29, 2007. The Act provided regulatory relief for three years from certain LTCH payment changes. The legislation also froze the market basket update for LTCHs in the last quarter of RY 2008.

The update is effective for discharges on or after July 1, 2008. CMS also is proposing to synch the annual update schedule for the LTCH PPS with the annual update of the Medicare Severity Long Term Care Diagnosis Related Groups classifications, which are effective beginning each October 1. Thus, the rates for RY 2009 would be effective from July 1, 2008 through September 30, 2009 under the proposed rule. The proposed rule also would raise the outlier fixed-loss amount, the threshold at which LTCHs treating high-cost cases are eligible for additional Medicare payments, to $21,199 from $20,738 in RY 2008. Comments on the proposed rule were due March 24, 2008.

**CMS Proposes New Standards For DMEPOS Suppliers Participating In Medicare**
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule January 25, 2008 (73 Fed. Reg. 4503) that would expand existing enrollment requirements Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers must meet to establish and maintain participation in the Medicare program.

Among the proposed standards are requirements that the DMEPOS supplier obtain oxygen from a state-licensed oxygen supplier; maintain ordering and referring documentation, including the National Provider Identifier, received from a physician, nurse practitioner, physician assistant, clinical social worker, or certified nurse midwife, for seven years after a claim has been paid; and open to the public at least 30 hours per week (except for those DMEPOS suppliers that work with custom-made or fitted orthotics and prosthetics). Another new standard would prohibit a supplier from sharing a practice location with another Medicare supplier.

Under the proposed rule, suppliers also would have to state that they do “not have an Internal Revenue Service (IRS) or a State taxing authority tax delinquency.” According to the rule, this provision was prompted by a recent Government Accountability Office
CMS Issues Proposed Rule On Medicare Part D Appeals
The Centers for Medicare and Medicaid Services (CMS) issued in the March 17 Federal Register (73 Fed. Reg. 14342) a proposed rule to further elaborate on procedures at the Administrative Law Judge and Medicare Appeals Council levels in deciding appeals brought by Medicare Part D enrollees. The proposal also includes the reopening procedures that would be followed at all levels of appeal, CMS said.

While Part D appeals generally follow the same procedures as those for Parts A, B, and C, the proposed rule aims to further clarify and detail appeals procedures specific to Part D enrollees. “We believe that these changes will maintain or clarify our original intent, making the revised regulation easier to read and understand,” CMS said. CMS characterized the proposal as making conforming changes rather than substantive changes to underlying policy. Comments on the proposed rule were due May 16, 2008.

CMS Issues Proposed FY 2009 IPPS Rule, Includes New Quality Measures, Stark Changes
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule April 30, 2008 (73 Fed. Reg. 23528) that would increase Medicare inpatient rates for hospitals in fiscal year (FY) 2009 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 $4 billion under the proposed inpatient prospective payment system (IPPS) rule. CMS estimates that total FY 2009 operating payments will increase 4.1% compared to FY 2008, largely due to a 3.0% inflationary update. Hospitals failing to report on certain specified quality measures would see their inflationary updates reduced 2.0 percentage points to 1%, CMS said. In accordance with legislation enacted at the end of last year, CMS will reduce payment rates by 0.9% in FY 2009 to account for certain anticipated changes in hospital documentation and coding practices.

The proposed rule, which would apply to services provided to patients who are discharged from the hospital beginning October 1, 2008, would add 43 quality measures to the current list hospitals must report on to receive the full inflationary update for FY 2010, bringing the total number of measures in FY 2009 to 73. The additions include measures involving hospital readmissions, nursing care, patient safety indicators developed by the Agency for Healthcare Research and Quality, stroke, and cardiac surgery.

The proposal also would expand an initiative mandated by the Deficit Reduction Act of 2005 to ensure Medicare no longer pays hospitals for the additional costs of hospital-acquired conditions (including infections). CMS is proposing to add a number of conditions to the list of those that would not be assigned to a higher paying diagnosis related group (DRG) unless they were present on admission. These conditions include...
surgical site infections following certain elective procedures, Legionnaires’ disease, extreme blood sugar derangement, delirium, and ventilator-associated pneumonia.

In addition, the IPPS proposed rule included a number of provisions relevant to the physician self-referral, or Stark, rules. Specifically, the proposed rule would modify the so-called “stand in the shoes” provisions in the definition of indirect compensation arrangement to address certain financial transactions involving academic medical centers or integrated healthcare delivery systems and to require a designated health services entity to stand in the shoes of an organization in which it has a 100% ownership interest. The proposed rule also would revise the definitions of “physician” and “physician organization” and clarify the “period of disallowance” for relationships subject to the Stark law prohibition. CMS also is soliciting comment on gainsharing arrangements and physician-owned implant companies.

Other changes in the proposed rule include amending Emergency Medical Treatment and Labor Act (EMTALA) regulations to allow hospitals to comply with the on-call list requirement by participating in a formal community call plan and clarifying requirements for hospitals with specialized capabilities. CMS also is soliciting comments on a mandatory “Disclosure of Financial Relationships Report” to collect information about hospital-physician financial arrangements. Comments on the proposed rule were due June 13, 2008 with a final rule expected before August 1.

CMS Proposes Updates To IRF Payment, Implements 60% Compliance Threshold
The Centers for Medicare and Medicaid Services (CMS) issued in the April 25, 2008 Federal Register (73 Fed. Reg. 22674) a proposed Inpatient Rehabilitation Facility (IRF) payment rule, which would result in an estimated decrease in aggregate IRF payments of $20 million for fiscal year (FY) 2009, the agency said in announcing the rule. According to a CMS fact sheet, the decrease in payments is due to the decrease in the outlier threshold amount from 3.5% in FY 2008 to 3% in FY 2009.

The proposed rule also would implement provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) that require only 60% of a facility’s patient population to have one of 13 specified qualifying conditions and allowing facilities to count patients whose principal reason for needing inpatient rehabilitation services is not one of the specified conditions, but whose treatment is complicated by the presence of one of the 13 conditions as a secondary diagnosis, according to the agency. This compliance rate had previously been scheduled to increase to 75% for cost reporting periods beginning on or after July 1, 2008. In addition, as required under the MMSEA, CMS is updating IRF prospective payment system payment rates by zero percent for FY 2009.

CMS Proposes FY 2009 SNF PPS Rates That Result In Net 0.3% Cut In Payments
The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule May 1, 2008 for the fiscal year (FY) 2009 Skilled Nursing Facility Prospective Payment System (SNF PPS). CMS uses Resource Utilization Groups (RUGs) to help determine a daily payment rate for SNFs. The RUGs reflect a patient’s severity of illness and the kind of
services that a person requires—also known as “case-mix.” In 2006, CMS made refinements to the case-mix indices that had the unintended effect of increased Medicare expenditures, according to the agency.

Under the proposal, CMS would recalibrate the case-mix weights in order to reestablish budget neutrality on a prospective basis. “The proposed FY 2009 recalibration of these adjustments to better reflect the resources used by beneficiaries would result in a reduction in payments to nursing homes of $770 million, or 3.3 percent,” the CMS said. The agency added that the decrease would be largely offset by the FY 2009 market basket increase of 3.1%. “Taken together with the proposed recalibration of the CMI, skilled nursing facilities could expect to see a slight decrease in payments of $60 million, or 0.3 percent,”

In an April 30, 2008 to Department of Health and Human Services Secretary Michael Leavitt, Senator Ron Wyden (D-OR) asked the agency to withhold implementation of the proposal. According to Wyden, CMS in making its proposal “fails to recognize other changes in Medicare policy that have resulted in an increased number of high acuity patients receiving care in SNFs since the RUGs were revised in 2005 and coincided with a separate policy initiative (known as the 75% rule) to shift certain categories of Medicare patients who needed rehabilitation care from higher cost settings to SNFs.”

**CMS Proposal Aims To Further Curb Abusive Marketing Tactics By Medicare Advantage, Part D Plans**

The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule May 8, 2008 intended to tighten restrictions on the marketing activities of Medicare Advantage (MA) and Medicare prescription drug plans. Specifically, the proposal would implement new prohibitions on door-to-door marketing and cold-calling and add requirements related to broker/agent commissions. Medicare private plan marketing activities have come under increasing scrutiny of late with reports of “hard sell” tactics and concerns about the adequacy of federal oversight.

The proposed rule would codify a number of requirements that CMS previously imposed through operational guidance in addition to adding several new provisions to enhance consumer protections, the agency said. Among other things, the proposed plan marketing standards would prohibit sales activities at educational events; require MA organizations that use independent agents to market MA and Part D plans using state-licensed agents; and require commission structures for sales agents and brokers that are level across all years and across all MA plan product types.

In addition, the rule would provide CMS with greater flexibility in determining penalty amounts and levying fines on MA or Part D plans that violate Medicare rules. Under the proposal, CMS would have clear authority to levy a penalty of up to $25,000 for each enrollee affected, or likely to be affected, by the violation, the agency said.

The proposed rule also contains provisions to streamline eligibility for the low-income subsidy and prevent unnecessary cost sharing, as well as new protections for beneficiaries
enrolled in special needs plans (SNPs), including requiring that 90% of new enrollees in SNPs be special needs individuals; more clearly establishing and clarifying delivery of care standards for SNPs; and protecting beneficiaries from being billed for cost-sharing that is not their responsibility, CMS said.

In a statement, Senate Finance Committee Chairman Max Baucus (D-MT), who has been leading the investigation into abusive Medicare private plan marketing tactics, applauded the new proposed regulations, pledging “to get these bans into the law to insure aggressive marketing tactics are quashed once and for all.” America’s Health Insurance Plans, which has supported increasing federal regulation and oversight of MA and Part D marketing activities, said it was reviewing the proposal and developing detailed comments.

(2) Final Actions

**CMS Releases Measures For Evaluating Financial Health Of Suppliers Participating In New DMEPOS Competitive Bidding Program**

The Centers for Medicare and Medicaid Services (CMS) posted on its website May 25, 2007 the measures that will be used to evaluate the financial stability of suppliers submitting bids under the new competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). CMS issued a final rule April 10, 2007 establishing the new competitive bidding program (72 Fed. Reg. 17992).

The posting on CMS’ website states that all bids for the program must include certain financial documentation for the supplier to be considered for a contract. The financial measures that CMS and the Competitive Bidding Implementation Contractor (CBIC) will use in evaluating financial health are standard accounting ratios including, for example, current assets to current liabilities, accounts payable to sales, current liabilities to net worth, sales to inventory, and working capital (i.e., current assets-current liabilities). In addition, CMS and the CBIC will take into account the supplier’s credit history in evaluating the overall financial health of the supplier.

**Health Insurers Agree To Suspend Marketing Of Medicare PFFS Plans**

Seven major healthcare sponsors have agreed to suspend voluntarily the marketing of Medicare private-fee-for-service (PFFS) plans after questions surfaced about potentially deceptive practices, the Centers for Medicare and Medicaid Services (CMS) announced June 15, 2007. The health insurers, which represent the vast majority of PFFS enrollees, are United Healthcare, Humana, Wellcare, Universal American Financial Corporation (Pyramid), Coventry, Sterling, and Blue Cross/Blue Shield of Tennessee. The marketing suspension applies to individual, non-group Medicare Advantage PFFS plans.

Under the agreement, plans will refrain from marketing activities until they show CMS they have the management and internal controls in place to comply with new consumer protection requirements, as described in the 2008 call letter, which went into effect for all plans October 1, 2007. Among the key marketing requirements that PFFS must meet are including model disclaimer language in all marketing materials; requiring sales staff to
pass a written test about Medicare requirements; and conducting outbound education and verification calls to all beneficiaries requesting enrollment to ensure they understand plan rules.

In September 2007, CMS announced that the seven health plan sponsors could resume marketing of their PFFS plans. After a comprehensive marketing review, the agency found the plans were compliant with Medicare requirements. Still skeptical of "whether CMS is sufficiently protecting seniors," Senate Finance Committee Chairman Max Baucus (D-MT) sent a letter September 26, 2007 to CMS Administrator Kerry Weems questioning how the agency plans to oversee and monitor the marketing practices of Medicare Advantage plans and PFFS in particular. Baucus asked Weems to provide detailed information about CMS' ongoing efforts to monitor PFFS marketing.

CMS Announces First-Year Results Of Its Physician Group Practice Pay-For-Performance Demonstration

The Centers for Medicare and Medicaid Services (CMS) announced July 11, 2007 that two of ten large physician group practices (PGPs) participating in the Medicare Physician Group Practice Demonstration were eligible to receive $7.3 million in pay-for-performance payments for redesigning care to improve clinical quality and efficiency. The three-year demonstration program rewards providers for coordinating and managing the overall healthcare needs of Medicare patients with chronic conditions.

PGPs performance is measured by comparing healthcare spending for patients assigned to the group with a population of Medicare patients from their local market areas. During the first year of the demonstration, which ended March 2006, a total of 224,893 Medicare patients were assigned to the ten participating PGPs.

Marshfield Clinic and University of Michigan Faculty Group Practice (U of M Group Practice) earned the $7.3 million in performance payments for quality and efficiency as their share of the $9.5 million in savings to the Medicare program during the first year of the project, according to CMS. The Marshfield Clinic will receive about $4.57 million in performance payments for savings of roughly $6 million to the Medicare program over the first year of the demonstration. CMS assigned the Clinic approximately 42,000 beneficiaries, representing the largest group of beneficiaries in the demonstration. U of M Group Practice will receive about $2.7 million in performance payments for first-year savings of approximately $3.5 million to the Medicare program. The Practice was assigned 20,505 beneficiaries through the demonstration. Both PGPs indicated they were pleased with their performance, but acknowledged only data from beneficiaries with diabetes was used in the calculation of quality. “In coming years, heart failure, coronary artery disease, hypertension and preventative services quality measures will be added,” a U of M Group Practice’s press release said.

CMS Issues Final Decision Memorandum On Clinical Trial Policy

The Centers for Medicare and Medicaid Services (CMS) released July 9, 2007 a final decision memorandum that makes two modifications to its 2000 policy statement addressing Medicare coverage of items and services used by beneficiaries participating in
clinical research trials. In the decision memorandum, CMS clarifies that any items or services is covered for participating beneficiaries if they are covered outside of the clinical research trial. CMS said the change addresses comments from several hospitals on the agency's proposed decision memorandum in April 2007 suggesting that Medicare contractors had been paying claims for hospital services involving patients in various types of clinical trials outside the terms of the 2000 clinical trial policy. “[H]ospitals and others have sought assurances that coverage will continue for the usual patient care associated with research in a hospital,” CMS said in its final decision memorandum.

The second revision modifies the former clinical trial policy by adding CMS’ Coverage with Evidence Development (CED) policy. As explained in the memorandum, CED allows for coverage of items and services in clinical research trials for which there is insufficient evidence to support a “reasonable and necessary” determination. CED, which is determined through the NCD process, is conditioned upon “meeting standards for clinical research that ensure patient protection and development of evidence to evaluate coverage,” according to the decision memorandum. In addition, CMS said that it would propose changes to the regulations pertaining to clinical trials and Medicare payment and implement changes to claims processing instructions.

Based on the public comments received in response to the proposed decision memorandum, CMS “became aware of differing views regarding the existing and proposed clinical trial policy.” For this reason, CMS said it was issuing the final decision memorandum to clarify its intent to “preserve the status quo” with the exception of the two revisions outlined in the memorandum. CMS explained, however, that it would reopen for consideration the Clinical Trial Policy NCD and post a new proposed decision memorandum to allow the public an adequate opportunity to comment on any additional proposed revisions.

CMS subsequently announced July 19, 2007 that it was reopening its clinical trial policy national coverage determination and, to that end, released a proposed decision memorandum for 30 days of public comment to “address ambiguities about Medicare coverage in research studies and what items and services are reasonable and necessary for beneficiaries participating in clinical research studies.” CMS then issued a final decision October 17, 2007 opting not to change the clinical policy. According to an agency press release, “[t]he decision to make no change is based on a thorough review and consideration of comments from the public, and the enactment of the Food and Drug Administration Amendments Act of 2007.”

**CMS Finalizes Rules On Exclusions, Waiver Requirements Based On Hardship To Medicare Beneficiaries**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the July 20, 2007 Federal Register (72 Fed. Reg. 39746) on imposing exclusions for certain Medicare program violations. CMS said the final rule is based on the procedures the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) has published for civil money penalties, assessments, and exclusions under their delegated authority. The rule also finalizes procedures and requirements for certain healthcare providers to request
a waiver of their exclusion from the Medicare program on a showing that the exclusion would result in a hardship on Medicare beneficiaries.

The final rule implements § 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which allows for a waiver of an exclusion from Medicare “in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in the community.” The DHHS Secretary has delegated the authority to exclude providers from Medicare and Medicaid to CMS and OIG. Under the final rule, an excluded provider could request that CMS recommend to the OIG that it waive an exclusion imposed under its authority. CMS stressed, however, that the final decision whether to grant a waiver is left to the OIG.

CMS Issues Final ASC Payment Rule, Proposes 3.3% Update To OPPS
The Centers for Medicare and Medicaid Services (CMS) issued July 16, 2007 a final rule aimed at better aligning payments for surgical procedures provided in ambulatory surgical centers (ASCs) with those performed in the hospital outpatient or physician office setting. At the same time, CMS also released a proposed rule that would provide a 3.3% inflation update in Medicare payment rates for services paid under the hospital outpatient prospective payment system (OPPS) and set ASC final rates for Calendar Year (CY) 2008. According to an agency press release, CMS expects to make payments of nearly $3 billion in CY 2008 to the roughly 4,600 ASCs that participate in Medicare. “[T]his revised system will take a major step toward eliminating financial incentives for choosing one care setting over another, thus assuring the patient’s needs come first,” said then Acting CMS Administrator Leslie V. Norwalk.

The final rule allows payment to an ASC for any surgical procedure that “does not pose a significant safety risk,” adding about 790 procedures for ASC payment beginning in CY 2008, CMS said. Payments in the ASC setting are generally considered to be less costly than those performed in the hospital outpatient department. Accordingly, the proposed ASC payment rates for CY 2008 are estimated to be set at 65% of the OPPS rates for the corresponding procedure, CMS explained. Payment for certain surgical procedures identified as “office-based” (i.e. that could be performed at less cost in a physician’s office) is capped at the “nonfacility practice expense component” of the Medicare physician fee schedule. CMS added that the final CY 2008 payment rates will be published in the November 2007 OPPS/ASC final rule, some of which will be phased in over four years. CMS also will apply a geographic wage index to 50% of the ASC payment.

CMS is projecting that hospitals would receive $34.9 billion in CY 2008 under the OPPS proposed rule, with expenditures projected to be roughly 10.5% higher than in CY 2007. In the release, CMS said the rate of increase was of “great concern” given its impact on taxpayers and Medicare beneficiaries who must pay for 25% of Part B expenditures. Beginning in CY 2009, hospitals must report on 10 quality measures; those that fail to do so will see their annual payment update reduced by two percentage points. CMS sought public comment on 30 additional measures for future reporting. The proposed rule also would increase the size of the OPPS payment bundles to help encourage hospital
efficiency, the agency said. Comments on the proposed rule were due September 14, 2007.

CMS Issues IPPS Rule With So-Called “Behavioral Offset” Provision
The Centers for Medicare and Medicaid Services (CMS) issued August 1, 2007 the final hospital inpatient prospective payment system (IPPS) rule, which retains a controversial provision (sometimes referred to as a “behavioral offset”) that will prospectively reduce payments based on the assumption that changes implemented by the rule will result in hospitals modifying their coding practices to receive higher payments.

The final rule creates 745 new severity-adjusted diagnosis-related groups (MS-DRGs) to replace the current 538 DRGs to better account for severity of illness. However, in response to comments received on the April 2007 proposed rule, CMS said the new severity-adjusted DRGs will be phased-in over two years, rather than one year, as had been proposed. The changes will result in payment increases to hospitals treating more severely ill and costlier patients while decreasing payments to hospitals treating less severely ill patients, CMS said in a fact sheet.

Because the DRG changes are expected to result in an increase in aggregate payments for inpatient services without a corresponding increase in actual patient severity, CMS is adopting a -1.2% adjustment for fiscal year (FY) 2008, the fact sheet said. By more accurately recognizing the costs of caring for a patient, the new MS-DRGs should help reduce the potential for abusive practices, CMS said.

The final rule aims to increase accuracy of payments by setting the DRG relative weights based on costs instead of charges, CMS said. The final rule implements the cost weights over a three-year transition period from FY 2007 to FY 2009. Altogether, CMS maintains that payments to all hospitals will increase by an estimated average of 3.5% for FY 2008 when all provisions of the rule are taken into account, primarily as a result of the 3.3% market basket increase. In addition, the rule sets out new quality reporting requirements for hospitals to receive the full market basket update. For hospitals that do not report on the required 27 quality measures, the annual percentage increase amount will be reduced by 2.0 percentage points, CMS said.

The final rule was published in the August 22, 2007 Federal Register (72 Fed. Reg. 47568).

In further developments on the “behavioral offset” in the IPPS final rule, President Bush signed into law September 29, 2007 legislation preventing CMS from fully implementing the estimated $20 billion in prospective payment cuts to hospitals under the provision. The House passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (H.R. 3668) September 26, 2007; the Senate followed suit a day later.

The “behavioral offset” provision established a –1.2% adjustment to total payments for services provided to Medicare patients in FY 2008, and a –1.8% adjustment in each of FYs 2009 and 2010. Over the next five years, the “behavioral offset” was estimated to
result in a $20.3 billion cut in operating and capital payments to hospitals. Under the legislation, the adjustments are halved in FYs 2008 and 2009, to 0.6% and 0.9%, respectively.

**CMS Increases Medicare Payments To SNFs By 3.3%**
Medicare payments to skilled nursing facilities (SNFs) and hospitals that furnish certain skilled nursing and rehabilitation care to Medicare beneficiaries will increase 3.3% in 2008, according to a final rule published in the August 3, 2007 *Federal Register* (72 Fed. Reg. 43412). The SNF prospective payment system (PPS) final rule also revises and rebases the SNF market basket, which currently reflects data from fiscal year 1997, to reflect data from fiscal year 2004. The rule also finalizes the use of hospital wage data in developing a wage index to be applied to SNFs. According to the rule, CMS "continue[s] to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage data is appropriate and reasonable for the SNF PPS."

**CMS Releases IRF PPS Final Rule With 3.2% Payment Update**
The Centers for Medicare and Medicaid Services (CMS) issued a final rule updating Medicare payment rates under the Inpatient Rehabilitation Facility (IRF) prospective payment system (PPS) by 3.2% in fiscal year (FY) 2008. The increase is based on the rehabilitation, psychiatric, and long term care hospital market basket and is expected to amount to additional payments of approximately $150 million to IRFs in FY 2008.

The final rule, published in the August 7, 2007 *Federal Register* (72 Fed. Reg. 44284), applies to discharges occurring from October 1, 2007 through September 30, 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. CMS also said that for cost reporting periods beginning July 1, 2008, IRFs may no longer use comorbidities to determine whether they meet the requirements of the 75% rule. Current policy allows the use of comorbidities in addition to a patient’s principal diagnosis.

The final rule also increases the high cost outlier threshold from $5,534 to $7,362, based on an analysis of 2006 data indicating this threshold will maintain estimated outlier payments at 3% of total payments under the IRF PPS. CMS noted that although the higher threshold will mean fewer cases will qualify for outlier payments, it is necessary to maintain budget neutrality and avoid an across-the-board reduction in the base payment for an IRF stay.

In further developments, Congress passed legislation in December 2007 (see discussion under “Legislative Action”) that would permanently block implementation of the controversial 75%, which critics have charged could severely hamper beneficiary access to these types of facilities. The legislation freezes the compliance threshold at 60% and allows comorbid conditions to count toward this percentage. The legislation also freezes the annual IRF payment update from April 1, 2008 through fiscal year 2009. Bush signed the legislation December 29, 2007.
The Centers for Medicare and Medicaid Services (CMS) announced July 20, 2007 a new policy for monitoring dosing amounts of anemia drugs, known as erythropoiesis stimulating agents (ESAs), for beneficiaries with end stage renal disease (ESRD) receiving dialysis. The more stringent monitoring policy was triggered by recent “black box” warnings issued by the Food and Drug Administration (FDA) emphasizing the risks facing ESRD patients who receive large doses of ESAs and have hemoglobin levels above 12 g/dL. ESAs are anti-anemia biologics, distributed as Epogen and Aranesp, which is manufactured by Amgen Inc., and Procrit, which is manufactured by Ortho Biotech LLC.

The changes are intended to provide greater restrictions on the dosage amounts of ESAs for which payment is made for patients with levels that rise above 13 g/dL, CMS said. The revised policy requires a 50% reduction, compared to the current 25%, in the reported ESA dosage for which payment will be made if the facility reports the beneficiary’s hemoglobin has exceeded 13 g/dL for three consecutive months, including the billing month. In addition, CMS lowered dosage limits above which Medicare will not pay for the anti-anemia drugs from 500,000 IU per month for Epogen to 400,000 IU and 1500 mcg per month for Aranesp to 1200 mcg per month.

In related developments, CMS issued July 30, 2007 a final national coverage decision (NCD) to limit Medicare coverage of ESAs for beneficiaries with certain cancers and related neoplastic conditions. The NCD was effective immediately.

The proposed NCD issued in May 2007 stated that Medicare coverage of ESA treatment in beneficiaries with cancer should be limited to circumstances in which the treatment is not likely to worsen the cancer and in cases where the beneficiary’s anemia is responsive to the ESA. CMS said the final NCD contains a number of modifications to the proposal based on over 2,600 public comments and additional evidence.

The NCD, which restricts coverage whenever a patient’s hemoglobin goes above 10g/dl, has been controversial. The Senate passed by unanimous consent a resolution (S. Res. 305) pressing CMS to reconsider the NCD. The resolution, which was introduced by Senator Arlen Specter (R-PA) on August 3, 2007, asks CMS to consult with the clinical oncology community to determine appropriate revisions to the NCD. According to the resolution, physicians and patients have continued to express concerns about the potential impact of the NCD on the treatment of cancer patients in the U.S.

The resolution also noted that the American Society of Clinical Oncology has urged CMS to reconsider the provision of the NCD that would restrict coverage whenever a patient’s hemoglobin goes above 10g/dl, noting such a restriction is inconsistent with the labeling approved by the FDA and national guidelines. CMS has said it will need to see new evidence before it will consider reopening the NCD.
In continuing coverage on this development, the FDA approved November 8, 2007 strengthened boxed warnings and other safety-related product labeling changes for ESAs. These new statements address the risks that the drugs pose to patients with cancer and patients with chronic kidney failure, FDA said.

According to FDA, for patients with cancer, the new boxed warnings emphasize that ESAs caused tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid, and non-small cell lung cancer when they received a dose that attempted to achieve a hemoglobin level of 12 grams per deciliter (g/dL) or greater. The boxed warnings also emphasize that no clinical data are available to determine whether there is a similar risk of shortened survival or increased tumor growth for patients with cancer who receive an ESA dose that attempts to achieve a hemoglobin level of less than 12 g/dL, FDA said.

For patients with chronic kidney failure, the revised boxed warning states that ESAs should be used to maintain a hemoglobin level between 10 g/dL to 12 g/dL, as maintaining higher hemoglobin levels increases the risk for death and for serious cardiovascular reactions such as stroke, heart attack, or heart failure. In addition, the new warnings emphasize that there are no data from controlled trials demonstrating that ESAs improve symptoms of anemia, quality of life, fatigue, or patient well-being for patients with cancer or for patients with HIV undergoing AZT therapy.

**CMS Finalizes Medicare Integrity Program Requirements**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the August 24, 2007 Federal Register (72 Fed. Reg. 48869) establishing the Medicare Integrity Program (MIP) and finalizing the types of entities that are eligible to become MIP contractors. The rule also identifies program integrity functions a MIP contractor may perform, describes procedures for awarding and renewing contracts; establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest; prescribes responsibilities for fiscal intermediaries and carriers; and sets forth limitations on MIP contractor liability.

According to the rule, in order to qualify as an entity eligible to enter a MIP contract, an entity must: demonstrate the capability to perform MIP contractor functions, agree to cooperate with the Office of Inspector General and the Department of Justice in fraud investigations, and comply with conflict of interest and integrity standards, among other things. The rule also carves out an exception to its contract competition requirements that allows a successor in interest to a fiscal intermediary agreement or carrier contract “to be awarded a contract for MIP functions without competition if its predecessor performed program integrity functions under the transferred agreement or contract and the resources, including personnel, which were involved in performing those functions, were transferred to the successor.”

**CMS Issues Final Medicare Home Health Payment Rule**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule August 22, 2007 to refine and update the Medicare home health prospective payment system (HH
However, the final rule also maintains a reduction in certain home health payments that was outlined in the proposed version of the rule published in May (72 Fed. Reg. 25356). “To account for the changes in case mix that are not related to home health patients’ actual clinical conditions,” the final rule implements a reduction in the national standardized 60-day episode payment rate by 2.75% per year for three years beginning in CY 2008, and by 2.71% for the fourth year (i.e., CY 2011). CMS said that it was seeking public comments only on the 2.71% reduction in the payment rates for CY 2011, and that it may adjust the percentage reductions for any of these years or implement other case-mix change adjustments in the future.

The final rule also implements an improved case-mix model “that accounts for comorbidities and the differing health characteristics of longer-stay patients.” CMS explained that, under current regulations, HHAs are paid prospectively for 60-day episodes of care, with a therapy threshold of ten visits per episode. Under the revised case-mix model implemented in the final rule, the ten-visit-per-episode threshold will be replaced with three new therapy thresholds at six, 14, and 20 therapy visits, in combination with graduated payment levels between thresholds.

Under the final rule, HHAs that submit certain quality data will receive payments based on the full home health market basket update of 3.0% for CY 2008, while those that fail to do so will only receive a 1.0% update. CMS noted that the final rule also adds two new National Quality Forum-endorsed quality measures to the existing ten measures that HHAs must report in CY 2008.

Final OPPS Rule Includes Overall 3.8% Update
The Centers for Medicare and Medicaid Services (CMS) released November 1, 2007 a final rule with comment period that provides an overall average increase of 3.8% in Medicare payment rates for services paid under the hospital outpatient prospective payment system (OPPS) in Calendar Year (CY) 2008. The final rule also sets ambulatory surgical center (ASC) rates for CY 2008.

CMS is projecting that hospitals will receive $36 billion in CY 2008 under the OPPS, with expenditures projected to be roughly 10% higher than in CY 2007. In a July proposed rule, CMS had pegged the OPPS update at 3.3%. According to an agency press release, the final OPPS rule with comment period, which appeared in the November 27, 2007 Federal Register (72 Fed. Reg. 66580), better focuses on value-based purchasing and promotes efficiencies within the payment structure by providing larger payment bundles for certain outpatient services.

Pursuant to the Tax Relief Health Care Act of 2006, Pub. L. No. 109-432, CMS is requiring hospitals to report seven consensus quality measures, including five emergency
department acute myocardial infarction transfer measures and two surgical care improvement measures, in CY 2008. Those hospitals that fail to report the applicable hospital outpatient quality measures will see their CY 2009 update reduced by 2.0 percentage points. CMS also is extending the current packaging of payments to include guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast agents, and observations services.

In addition, the final rule introduces composite ambulatory payment classification groups to encourage efficiencies by providing one bundled payment for several major services. In July, CMS issued a final rule aimed at better aligning payments for surgical procedures provided in ASCs with those performed in the hospital outpatient or physician-office setting. Payments in the ASC setting generally are considered to be less costly than those performed in the hospital outpatient department. CMS included the final CY 2008 payment rates for ASCs in the OPPS final rule.

CMS Issues Final Physician Payment Rule With 10.1% Cut

Medicare payments to physicians would have been cut by 10.1% under the final 2008 physician payment rule issued by the Centers for Medicare and Medicaid Services (CMS) November 1, 2007. In year-end legislation, however, Congress stepped in and offered a temporary reprieve from the substantial cut, implementing a 0.5% positive update in Medicare reimbursement rates through June 30, 2008. (See section on “Legislative Action.”)

CMS noted in the release that it had “no choice but to implement this negative update” because the update is mandated by a statutory formula, known as the sustainable growth rate (SGR) formula, which compares the actual rate of growth in spending to a target rate. This year, as in the past several years, because payment for physician services increased faster than projections, the SGR dictated payment cuts, CMS said.

The 2008 rule also continues CMS’ voluntary reporting program under the Physician Quality Reporting Initiative (PQRI). In the rule, CMS outlines PQRI measures that were endorsed by the National Quality Forum, and other sources completing development for upcoming PQRI implementation, according to the release. “These structural measures, which focus on whether a health care professional uses electronic health records and/or electronic prescribing, emphasize the importance of this technology for delivery of high-quality health care services,” the release said. The rule also implements improvements to the process for determining payment for new clinical laboratory tests and modifies enrollment standards for Independent Diagnostic Testing Facilities.

Notably, the rule did not finalize most of the proposed changes relating to the Stark regulations included in the proposed physician fee schedule. CMS did, however, finalize the anti-markup provisions of the proposed rule. Specifically, the final rule imposed an anti-markup restriction on the technical component (TC) or professional component (PC) of diagnostic tests (other than clinical lab tests) that are ordered by the billing supplier, if the TC or PC is purchased by the billing supplier, or the TC or PC is performed outside
of the office of the billing supplier. But given strong industry reaction and confusion about the restriction’s application, CMS on January 3, 2008 decided to delay implementation of the new anti-markup provisions until January 1, 2009, with two exceptions. First, the anti-markup prohibition, as of January 1, 2008, continues to apply to the technical component of a “purchased diagnostic test” in the manner it had been prior to the recently promulgated rule. Second, effective January 1, 2008, the new anti-markup provisions is applicable to anatomic pathology diagnostic testing services if those services are furnished in space that: (1) is utilized by a physician group practice as a “centralized building” for purposes of complying with the physician self-referral rules; and (2) does not qualify as a “same building” as defined in CMS regulation.

CMS Issues Final E-Prescribing Standards
The Centers for Medicare and Medicaid Services (CMS) proposed November 16, 2007 final uniform standards for an electronic prescription drug program. The rule (72 Fed. Reg. 64900) also proposes the adoption of a standard identifier for providers and dispensers to use in e-prescribing transactions.

The proposed standards were required under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The rule includes a standard for electronic medication history transactions among plan sponsors, prescribers, and dispensers when e-prescribing for covered Medicare Part D drugs. CMS said before the propose rule, it was "unaware of any standard for these transactions that clearly met the criteria for adequate industry experience."

The proposed rule also would adopt the National Provider Identifier as a standard for use in e-prescribing transactions among plan sponsors, prescribers, and dispensers and would add a standard for the transaction of communicating formulary and benefit information between the prescriber and the plan sponsor. According to CMS the proposed standards "represent an ongoing approach to adopting standards that are consistent with [the MMA's] objectives of patient safety, quality of care, and efficiencies and cost saving in the delivery of care." Comments on the proposal were due January 15, 2008.

CMS Final Rule Does Not Include Mandatory Self-Reporting For Medicare Advantage And Part D Drug Plans
The Centers for Medicare and Medicaid Services (CMS) opted not to include a mandatory self-reporting requirement in a final rule (72 Fed. Reg. 68700) aimed at strengthening current oversight requirements and penalties for Medicare Advantage (MA) and Part D prescription drug plans. The proposed rule, published May 25, 2007 (72 Fed. Reg. 2938), set forth new steps for organizations and sponsors to help them expose potential fraud or misconduct through mandatory self-reporting. The final rule with comment period, published in the December 5 Federal Register (72 Fed. Reg. 68700), instead retains a voluntary self-reporting recommendation, although CMS emphasized its commitment to adopting mandatory self-reporting in the future.

CMS said comments on the proposal revealed the need to better define what constitutes “potential” fraud and misconduct, to flesh out further the actual reporting process, and to
ensure consistency with other agency guidance on self-reporting. To that end, CMS is sought additional comments on mandatory self-reporting issues by February 4, 2008.

The rule also finalizes clarifications to Medicare program provisions on contract determinations involving MA organizations and Medicare Part D prescription drug plan sponsors. In addition, the final rule includes clarifications to the intermediate sanction and civil money penalty provisions that apply to MA organizations and Medicare Part D prescription drug sponsors, modifications to elements of their compliance plans, and revisions to ensure the Department of Health and Human Services has access to the books and records of their first tier, downstream, and related entities.

Most provisions of the final rule were effective January 4, 2008, but a number, including those requiring compliance plan training and communication to first tier, downstream, and related entities and those requiring access to these entities’ books through contractual arrangements, do not go into effect until January 1, 2009.

Expansion Of Medicare DMEPOS Competitive Bidding Announced
On January 8, 2008, the Centers for Medicare and Medicaid Services (CMS) announced the second phase of Medicare competitive bidding for durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). In this second round, competitive bidding will be implemented in 70 areas, including the nation’s largest cities. With very limited exception, only suppliers who are successful bidders in these regions and who meet program standards (including accreditation) will be eligible to furnish eight categories of DMEPOS to Medicare beneficiaries beginning next year. Successful bidders will be paid based on the median of the winning suppliers’ bids for each of the selected items in the region, rather than the Medicare fee schedule or supplier bid amount. This expanded bidding program builds on the first phase of competitive bidding affecting 10 geographic regions and 10 product categories, which goes into effect July 1, 2008. This summary is an excerpt from an article by Carol Loepere, Elizabeth Carder-Thompson, and Debra McCurdy, Reed Smith LLP.

CMS Announces New Contract Terms For QIOs In Effort To Address Performance Concerns
Moving to address concerns about the effectiveness of Medicare Quality Improvement Organizations (QIOs), the Centers for Medicare and Medicaid Services (CMS) issued a 9th Statement of Work (SOW) that the agency said would better link QIO work to measurable outcomes and improve oversight and transparency of the program. The SOW for QIOs focuses improvement efforts on four main areas—protecting beneficiaries, care transitions, patient safety, and prevention—with each subject to measurable criteria, close monitoring, and performance improvement plans.

CMS said the 9th SOW responds to recommendations by the Institute of Medicine (IOM) and the Government Accountability Office (GAO), both of which have questioned whether QIOs are performing as they should. In a report issued last year, GAO said most QIOs failed to focus their quality improvement efforts on low-performing nursing homes. The IOM in a 2006 report suggested QIOs concentrate more on helping providers
improve their delivery of care and their organizational cultures and information systems, instead of handling beneficiary complaints, appeals, and other case reviews.

The latest contract cycle will begin August 1, 2008 for all QIOs. CMS said QIOs also will have to meet periodic milestones, help Medicare promote value-driven healthcare, support the adoption and use of interoperable health information technology, and reduce health disparities in their communities. The 9th SOW calls for QIOs to develop quality improvement activities focused on system-wide changes and help improve coordination across the continuum of care. CMS also wants QIOs to focus on facilities that could stand to improve the most on certain specific quality measures. To this end, CMS has identified a group of hospitals and nursing homes that fall into this category, but also will allow QIOs to choose 15% of the facilities they work with based on their own criteria.

CMS said it evaluated the 53 QIOs based on the 8th SOW contract requirements and determined that QIOs from eight states—California, Minnesota, Mississippi, North Carolina, Nevada, New York, Oklahoma, and South Carolina—will need to compete for new contract awards as they did not meet criteria for automatic renewal.

**CMS Issues Final Rule On Prior Coverage Determinations For Certain Physicians’ Services**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the February 22, 2008 *Federal Register* (73 Fed. Reg. 9672) that establishes a process for Medicare contractors to provide physicians and beneficiaries with a medical necessity determination for certain physicians' services before the services are furnished. CMS issued a proposed rule August 30, 2005 (70 Fed. Reg. 51321), implementing § 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, to establish the reasonable limits on physicians' services for which a prior determination could be requested.

In the rule, CMS noted that currently no process exists by which physicians and beneficiaries can confirm whether an item or service will be considered reasonable and necessary, and therefore covered under Medicare. Instead, physicians that believe a particular service may not be covered by Medicare must give their patient an Advanced Beneficiary Notice (ABN), allowing the beneficiary to decide whether to incur potential financial liability.

Based on its analysis, CMS said it was establishing an initial pool of physicians’ services that are eligible for the prior determination with the highest average allowed charges that are performed at least 50 times annually. CMS also is establishing a list of plastic and dental surgeries that may be covered by Medicare and that have an amount of at least $1,000 in the Medicare physician fee schedule.

According to the final rule, CMS plans to issue detailed procedures for the prior determination process through instructions to contractors in the agency’s manuals. CMS estimated it would receive 5,000 requests for prior determinations on an annual
basis, which would take 15 minutes per request for an annual burden of 1,250 hours. The final rule was effective March 24, 2008.

**CMS Issues Final Rule On Medicare Secondary Payer Amendments**

The Centers for Medicare and Medicaid Services (CMS) published in the February 22, 2008 *Federal Register* (73 Fed. Reg. 9679) a final rule implementing amendments to the Medicare Secondary Payer (MSP) provisions as required by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). Under the MSP provisions of the Social Security Act, Congress made Medicare the secondary rather than a primary payer of healthcare services when other types of coverage are available. Congress in the MMA sought to clarify erroneous interpretations of the MSP statute that limited the application of the provisions, the final rule said.

CMS said the final rule, which was effective March 24, 2008, incorporates the provisions of the interim final rule, except that two sections were amended further to clarify the reimbursement obligations and notice requirements of primary payers. And another section was amended to replace the word “capacity” with “incapacity” so the language used in the regulation is generally consistent.

**CMS Delays Final Rule On Medicare Claims Appeals Procedures**

The Centers for Medicare and Medicaid Services (CMS) announced February 29, 2008 in the *Federal Register* (73 Fed. Reg. 11043) that it is extending an interim final rule on changes to Medicare claims appeal procedures. The notice extends the timeline for publication of a final rule one year until March 1, 2009. The interim final rule, published in March 2005 (70 Fed. Reg. 11420), will remain in effect until that time unless a final rule is issued before then. CMS said it was not able to meet the initial three-year timeline for publishing the final rule “due to the complexity of the rule and the need to ensure coordination with other government agencies.” In particular, developing the final rule requires the collaboration of the Department of Health and Human Services (HHS) Office of Medicare Hearings Appeals, the Departmental Appeals Board, and the Office of the General Counsel. In addition, CMS said the final rule requires significant coordination with other HHS policy-related regulations—i.e. the provider reimbursement determinations and appeals final rule and the Medicare prescription drug appeals process proposed rule—that are currently under development.

**CMS Issues Final E-Prescribing Rule**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule April 2, 2008 establishing Part D e-prescribing standards for formulary and benefits, medication history, fill status notification, and identification of individual healthcare providers. The new standards apply to all Part D sponsors, as well as to prescribers and dispensers that electronically transmit prescriptions and prescription-related information about Part D covered drugs prescribed for Part D eligible individuals. E-prescribing remains voluntary, but those who do implement it must comply with the new standards when using e-prescribing, the agency said in a press release. The new e-prescribing standards supplement a set of “foundation” standards published in November 2005, which took
effect with the start of Part D on January 1, 2006. The new e-prescribing standards were effective April 1, 2009.

**CMS Final Rule Aims To Reduce Part D Plan Reassignments For Low-Income Beneficiaries**

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the April 3, 2008 *Federal Register* (73 Fed. Reg. 18176) that changes the way that Medicare will calculate the regional low-income subsidy (LIS) benchmarks under Medicare Part D. The rule will allow many beneficiaries to remain in the Medicare prescription drug plan in which they are enrolled without having to pay a premium, the agency said. Under the final rule, LIS benchmarks will be weighted based on each plan’s share of enrollees receiving the low-income subsidy, rather than their share of total Part D enrollment, CMS said. “This will result in fewer LIS beneficiaries seeing their drug coverage disrupted by having to change prescription drug plans in order to avoid paying a premium,” according CMS. The final rule is effective May 31, 2008.

**CMS Issues Final Rule On Medicare Conditions For Coverage For Dialysis Centers**

The Centers for Medicare and Medicaid Services (CMS) issued in the April 4, 2008 *Federal Register* (73 Fed. Reg. 18676) a final rule setting forth new minimum standards that dialysis facilities must meet to be certified under the Medicare program. The final rule updates conditions for coverage that were first published in 1976 for the more than 4,700 Medicare-approved renal dialysis centers across the country, CMS said. More than 336,000 Medicare beneficiaries have End-Stage Renal Disease (ESRD) and require regular dialysis treatment.

According to CMS, the final rule focuses on the patient and the quality of care provided to the patient; requires facilities to develop a quality assessment and performance improvement (QAPI) program to track its performance in patient health outcomes; encourages patients to participate in their plan of care and treatment; and eliminates many outdated procedural requirements. CMS said the final rule also adopts updated Centers for Disease Control and Prevention guidelines for hemodialysis facilities to increase infection control procedures; requires defibrillators in every dialysis facility; upgrades fire safety standards; sets forth minimum qualifications and training requirements for patient care technicians; and implements new patient rights protections such as a facility-level grievance process and a policy that requires a 30-day written notice to patients before a facility can involuntary discharge them.

**CY 2009 MA Capitation Rates Will Increase An Average 3.6%, CMS Says**

The aged and disabled Medicare Advantage (MA) capitation rates will increase on average about 3.6% in calendar year (CY) 2009, the Centers for Medicare and Medicaid Services (CMS) announced April 7, 2008. CMS explained in a fact sheet that the MA Growth Percentage—which is used to determine the minimum percentage increase rate—is an estimated 4.24% for aged and disabled beneficiaries, which includes 3.74% for the 2009 underlying trend change and approximately 0.5% due to corrections to prior years’ estimates, as required by law.
Along with the new rates, CMS also announced “a new audit initiative to determine the accuracy of the diagnosis code information submitted to CMS by MA plans.” According to the fact sheet, CMS will audit the medical records from a sample of plans. Then, as coding errors are identified, CMS will reconcile payments to correct for these errors at the plan level. The fact sheet noted that the “results of these audits will also help CMS to establish whether differences in risk scores between MA plans and fee-for-service (FFS) Medicare are attributable to differences in coding patterns, and therefore, to determine whether an adjustment to rates would be appropriate for 2010.”

**CMS Issues Rule Implementing Legislative Changes To LTCH PPS, Finalizes 2009 Payment Rates**

The Centers for Medicare and Medicaid Services (CMS) issued May 1, 2008 an interim final rule with comment period to incorporate legislatively mandated changes to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) into existing regulations, according to the agency. The interim final rule implements the Medicare, Medicaid, and SCHIP Extensions Act of 2007 (MMSEA), which was enacted at the end of last year and included provisions affecting certain payment changes that CMS had adopted in the LTCH PPS final rule for rate year (RY) 2008.

In the LTCH PPS final rule for RY 2008, CMS revised its short stay outlier (SSO) policy to adjust LTCH payments for cases that, based on the patient’s length of stay, appeared to be similar to those treated in acute care hospitals under the Inpatient Prospective Payment System (IPPS). The MMSEA required CMS to delay application of the “IPPS comparable” option and to restore the previous policy for three years, effective for LTCH discharges on or after December 29, 2007, the date the legislation was signed into law.

The LTCH PPS final rule for RY 2008 also adopted the controversial proposal to extend the “25 percent threshold” restriction to virtually all LTCHs. Specifically, the new policy would have extended the restriction 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. The MMSEA instructed CMS to delay extending the 25% threshold policy to freestanding LTCHs and to grandfathered LTCH hospital-within-hospital for three years. CMS said this provision would be implemented in a forthcoming regulation.

CMS also said it would implement a three-year moratorium under the MMSEA on the construction of new LTCHs and satellites, and the expansion of beds in existing LTCHs and satellites, in a forthcoming regulation. The interim final rule was effective June 5, 2008, with comments due July 7.

Meanwhile, on May 2, 2008 CMS issued a final payment rule for RY 2009 that increases the standard federal rate for LTCHs by 2.7% from the 2008 rate established by the MMSEA. Under the final rule, the standard federal rate for RY 2009 will be $39,114.36 and is applicable for discharges from July 1, 2008 through September 30, 2009. CMS
estimated that aggregate LTCH PPS payments for RY 2009 will be roughly $4.47 billion, a $110 million increase over RY 2008 estimated payments.

**CMS Expands Medicare Coverage For Artificial Heart Devices In Certain FDA-Approved Studies**

The Centers for Medicare and Medicaid Services (CMS) issued May 1, 2008 a final National Coverage Determination (NCD) expanding Medicare coverage of artificial hearts implanted as part of clinical studies approved by the Food and Drug Administration (FDA) that meet Coverage with Evidence Development (CED) criteria. Under a 1986 non-coverage policy, artificial heart technology was not available to Medicare beneficiaries. “CMS believes there is now sufficient scientific evidence on the use of artificial hearts to allow coverage of these devices for beneficiaries in the carefully controlled clinical environment of an FDA-approved study,” the agency said. Under its CED framework, CMS may determine that a technology will be covered when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise available to the beneficiary. The final coverage decision specifies the questions that studies must address and the standards those studies must meet for Medicare coverage, CMS said.

**Legislative Developments**

**CMS Issues Report To Congress On Medicare Hospital Value-Based Purchasing**

The Centers for Medicare and Medicaid Services (CMS) issued a statutorily required report to Congress November 21, 2007 outlining its plan to implement value-based purchasing (VBP) beginning in fiscal year (FY) 2009 for hospitals paid under the Medicare Inpatient Prospective Payment System (IPPS).

In March 2007, CMS released a VBP Options Paper that described the agency’s plans to phase out the Medicare’s Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program, under which hospitals currently must meet certain requirements, including reporting on a defined set of inpatient quality measures, to receive their full IPPS annual payment update. RHQDAPU would be replaced by a new VBP program, which would include both public reporting and financial incentives to encourage better performance. After receiving over 100 comments on the Options Paper, CMS missed its August deadline under the Deficit Reduction Act of 2005 for submitting its report to Congress.

In the new report, CMS explains that the VBP program will make “a portion of hospital payment contingent on actual performance on specified measures, rather than simply on a hospital’s reporting data for these measures.” Hospitals would receive incentive payments based on their performance on a specific set of measures. These payments would be funded by making a 2%-5% reduction in hospitals’ base diagnosis-related group (DRG) rate. The report also noted that the VBP program would be implemented in a manner that does not increase Medicare spending; instead, through performance, hospitals would essentially earn back the incentive payment.
The report noted that a range options for the components that could provide an appropriate basis for the incentive payment. “[T]he incentive could be a percentage of the base operating DRG payment only . . . [which] would link the incentive payment most directly to the clinical services provided during a patient stay,” the report said, or it could be based on additional components, including capital costs, disproportionate share hospital payments, and indirect medical education payments.

With regard to how hospital performance would be measured, the report said that each hospital’s performance would be assessed annually using the Performance Assessment Model, a methodology for scoring hospital performance. The model would combine “scores on individual measures across different performance domains . . . to compute a hospital’s VBP Total Performance Score, which [would then be] used to determine the percentage of the VBP incentive payment earned by the hospital,” the report said. In addition, the model would evaluate a hospital’s performance on each measure based both on “attainment,” which would compare the hospital’s performance with national thresholds and benchmarks, and “improvement,” which would assess the extent to which a hospital improved as compared to performance in the previous 12-month baseline period. By factoring both “attainment” and “improvement” into the calculation of the VBP Total Performance Scores, this model aims to “mobiliz[e] all hospitals to improve quality,” the report said, even those that begin with a “low absolute level of performance.”

CMS proposes a phased three-year transition from RHQDAPU to VBP. Under this approach, the entire incentive payment could be based on reporting alone in the first year, and then progress to payment based half on reporting and half on performance in the second year, and payment based entirely on performance in the third year. “Now that the plan is set, Congress needs to get the job done and pass additional legislation to start implementing value-based purchasing,” Senate Finance Committee Ranking Member Charles Grassley (R-IA) said after the report’s release.

**Congress Clears Increases Physician Pay Rates For Six-Months, Extends SCHIP**

Unable to reach a broader consensus on a Medicare reform package, the Senate cleared December 18, 2007 by unanimous consent a bill (S. 2499) that provides a temporary, six-month reprieve from a scheduled 10.1% cut in Medicare reimbursement rates for physicians in 2008. Under the legislative package, physicians would see a 0.5% positive update in Medicare reimbursement rates through June 30, 2008. The House, which earlier in 2007 passed a far-reaching Medicare reform measure, cleared the bill a day later in a 411-3 vote, with the President signing the measure into law December 29, 2008.

The bill, which Senate Finance Committee Ranking Member Charles Grassley (R-IA) characterized as an interim measure, also reauthorizes the popular State Children’s Health Insurance Program (SCHIP) until March 31, 2009. SCHIP expired October 1 and the program has been operating under stop-gap measures since the President vetoed two reauthorization bills passed by Congress in the fall. Those measures would have added $35 billion in funding to SCHIP for the next five years over baseline levels. In a statement, Senate Finance Committee Chairman Max Baucus (D-MT) said the longer
SCHIP extension would allow “Congress to enter the new year with a renewed focus on reauthorization while also providing funding certainty to the states.”

Seniors group AARP called the short-term fixes "woefully inadequate," saying the legislation does little to protect millions of Medicare beneficiaries from higher monthly premiums and only temporarily averts the physician payment problem. The American Medical Association (AMA) also weighed in saying the six-month delay in physician payment cuts “creates great uncertainty for Medicare patients and physicians.” In a floor statement, Grassley said he favored a two-year update for physicians, but ultimately such a fix was not achievable at this time.

The positive physician payment update under Medicare will be funded, in part, by removing $1.5 billion from the Medicare Advantage stabilization fund that was to be available in 2012. Grassley emphasized in a floor statement, however, that the bill does not repeal the fund so Congress can add more funds in future years if needed.

The bill also includes a number of other Medicare provisions, including a one-year extension to Medicare Advantage special needs plans through 2009. Medicare special needs plans are intended to help tailor services for certain vulnerable beneficiary populations. At the same time, Grassley said, the legislation puts a moratorium on new special needs plans so Congress and CMS can monitor their performance and determine if any changes are needed. "While these plans have proliferated, it is unclear how well they are meeting their mission of specialized care," Grassley said.

The legislation also would permanently block the implementation of the so-called 75% rule for inpatient rehabilitation facilities (IRFs). Under the rule, to be designated as a Medicare IRF, 75% of the facility's Medicare patients must have at least one of 13 medical conditions. The rule currently is being phased in, with the compliance threshold this year set at 65%. The legislation would freeze the compliance threshold at 60% and allow comorbid conditions to count toward this percentage. The legislation also would freeze the annual IRF payment update from April 1, 2008 through fiscal year 2009.

For long term care hospitals (LTCHs), the bill would provide regulatory relief for three years to ensure continued access to the services these facilities offer. The legislation also would impose a limited moratorium on the development of new LTCHs and would establish new facility and medical review requirements to ensure patients are receiving appropriate levels of care. In addition, the legislation would freeze the market basket update for LTCHs in the last quarter of rate year 2008, the summary indicated. Among the bill's other provisions are:

- An extension that allows independent laboratories to continue to bill Medicare directly for the technical component of certain physician pathology services provided to hospitals as authorized by the Balanced Budget Act of 1997 through June 30, 2008.
• An extension of the exceptions process for therapy caps to ensure Medicare beneficiaries have access to therapy services through June 30, 2008.
• A six-month extension of an incentive payment program providing a 5% bonus payment to physicians practicing in scarcity areas.

President Signs Bill Blocking Full Implementation Of So-Called “Behavioral Offset,” Delaying Tamper-Proof Pad Requirement

President Bush signed into law September 29, 2007 legislation preventing the Centers for Medicare and Medicaid Services (CMS) from fully implementing an estimated $20 billion in prospective payment cuts to hospitals under Medicare called for by the so-called “behavioral offset” in the inpatient prospective payment system (IPPS) final rule published on August 22, 2007. The legislation, among other things, also delays for six months a provision requiring all Medicaid prescriptions to be written on "tamper resistant" pads in order to be eligible for federal reimbursement. The House passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (H.R. 3668) September 26, 2007; the Senate followed suit a day later.

The final IPPS rule (72 Fed. Reg. 47129), which became effective October 1, 2007 included the controversial “behavioral offset” provision, which the agency said was designed to prospectively reduce payments based on the assumption IPPS reforms would result in hospitals changing their coding practices to receive greater payments. The provision established a –1.2% adjustment to total payments for services provided to Medicare patients in fiscal year (FY) 2008, and a –1.8% adjustment in each of FYs 2009 and 2010. Over the next five years, the “behavioral offset” was estimated to result in a $20.3 billion cut in operating and capital payments to hospitals. Under the legislation, the adjustments are halved in FYs 2008 and 2009, to 0.6% and 0.9%, respectively.

The legislation also provided a number of other healthcare-related “extensions,” including an increase in funding for the Medicare Physician Assistance and Quality Reporting Initiative to $325 million in 2009 and $60 million during or after 2013 and an extension to December 31 for the transitional medical assistance program, which was set to expire September 30.

Medicare “Trigger” Legislation To Curb Spending Introduced In House, Senate

As required by statute, key congressional leaders introduced February 25, 2008 in the House and Senate the Bush administration’s legislative proposal for curbing Medicare program spending. In the Senate, Finance Committee Chairman Max Baucus (D-MT) and Ranking Member of the Budget Committee Judd Gregg (R-NH) introduced the so-called Medicare “trigger legislation (S. 2662), which the administration proposed a week earlier. Majority Leader Steny Hoyer (D-MD) and Minority Leader John Boehner (R-OH) sponsored the bill (H.R. 5480) in the House.

Baucus emphasized that while he was required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to introduce the White House legislation, the bill did not have his support. Baucus added that he plans to introduce his
own Medicare reform package later in 2008 and his committee also will tackle the broader issue of system-wide healthcare reform.

The President’s proposals contained in the bill are “not the answer to the Medicare program’s problems,” Baucus said. But Gregg urged Congress “to consider this reasonable proposal and for the Senate leadership to grant it a final vote as the House is required to do.” Boehner agreed, saying he hoped the legislation “can act as a catalyst for Congress to pass long-overdue legislation to bring stability to the Medicare program.”

Under the MMA, the Medicare Trustees must issue a formal warning if two consecutive annual reports show general revenues exceed 45% of total Medicare spending within the current or next six years. The Trustees triggered the warning in 2006 and 2007, which in turn required the administration to propose legislation to curb program spending. Value-based purchasing, medical liability reform, and means-testing for Part D are the Bush administration’s key proposals contained in the bill.

**Litigation Developments**

**Ninth Circuit Finds PRRB May Modify Final Determination Based On Evidence Not Considered By Intermediary**

The Ninth Circuit found July 9, 2007 that the Provider Reimbursement Review Board (PRRB) has jurisdiction under 42 U.S.C. § 1395oo(a) to consider an issue on appeal that is related to a cost report even though the issue was not considered by the fiscal intermediary. Plaintiff Loma Linda University Medical Center inadvertently zeroed out reimbursable interest expenses in its cost report for the 1985 fiscal year, which it timely filed with its fiscal intermediary Blue Cross of California. The intermediary issued a notice of program reimbursement and Loma Linda appealed to the PRRB identifying six issues not including interest expense. Once Loma Linda realized its error, it filed a request with the PRRB to add the interest expense issue to its pending appeal. Blue Cross contested the PRRB’s jurisdiction on the interest expense issue because there had been no intermediary determination concerning the issue and it was untimely.

The PRRB accepted jurisdiction, finding the error was clear and obvious, and should have been corrected by the intermediary. The PRRB concluded that jurisdiction was appropriate under 42 U.S.C. § 1395oo(a) and 42 C.F.R. § 405.1841(a)(1), as well as under § 1395oo(d) because both the offset amount and the incurred expense were covered by the cost report even if the intermediary had not considered the matter. The Centers for Medicare and Medicaid Services Administrator reversed and Loma Linda sought review in district court. The court held that the Administrator’s interpretation of the Medicare Act was arbitrary and capricious and contrary to the language and intent of § 1395oo(a). Thus, the court ordered the PRRB’s last decision be reinstated, subject to the Secretary reviewing the merits. Both parties appealed.

The Ninth Circuit rejected the Department of Health Human Services Secretary’s position that a provider cannot be “dissatisfied” with respect to costs for which it could have claimed reimbursement from its intermediary but did not. The appeals court found
instead that § 1395oo(a) “plainly says that a provider, such as Loma Linda, may obtain a Board hearing with respect to the cost report when it is dissatisfied with the intermediary’s final determination of the amount of total reimbursement.” According to the appeals court, “§ 1395oo(d) squarely allows the Board to modify a final determination based on evidence that was not considered by the intermediary, and to make revisions on a cost or expense incurred during the year being reported even though the cost wasn’t claimed and the matter wasn’t considered by the intermediary.”

Turning to Loma Linda’s cross appeal, the appeals court found as a threshold matter that the Administrator had authority to reverse the PRRB’s decision. The appeals court then found no error in the district court’s decision to limit its review to the jurisdictional issue and not reach the merits of Loma Linda’s appeal. According to the appeals court, “the critical predicate for judicial review—a final decision of the Board or a reversal, affirmance, or modification by the Secretary—is missing” with respect to the merits of Loma Linda’s appeal and its request for interest. Loma Linda Univ. Med. Ctr. v. Leavitt, Nos. 05-56341, 56497 (9th Cir. July 9, 2007).

Fourth Circuit Affirms Finding That Nursing Home Violation Was Immediate Jeopardy Level
The Fourth Circuit affirmed the Department of Health and Human Services Secretary’s decision that a nursing home’s violation of Medicare regulations rose to the “immediate jeopardy” level. During an annual survey at Liberty Commons in North Carolina, state surveyors found the facility had neglected to provide proper care to residents, including using latex gloves on a patient with a known latex allergy. The surveyors ranked the violation at the “immediate jeopardy” level. Liberty Commons challenged the finding, which was upheld by an Administrative Law Judge (ALJ) and the Departmental Appeals Board (DAB).

Affirming the agency’s decision, the Fourth Circuit rejected the facility’s contention that an actual resident must have been harmed for the violation to rise to the immediate jeopardy level. The appeals court noted the relevant regulation requires only that the nursing home’s noncompliance be likely to cause harm to “a resident.” 42 C.F.R. § 488.301. The appeals court also agreed with the agency that “a resident” has a broader meaning and does not require establishing harm from “a particular, identifiable compliance violation to a particular, identifiable, resident” to be a reasonable interpretation of the statute. In addition, the appeals court found substantial evidence supported the ALJ’s determination that the facility's noncompliance problem was “systemic.” Liberty Commons Nursing and Rehab. Ctr.-Johnston v. Leavitt, No. 06-1868 (4th Cir. July 20, 2007).

U.S. Court In District Of Columbia Finds Pharmacy Associations Lacked Standing To Bring Lawsuit On Behalf Of Their Member Pharmacies
The Long Term Care Pharmacy Alliance (LTCPA) and the American Society of Consultant Pharmacists (ASCP) lacked standing to seek a declaration that UnitedHealth Group, Inc. (United) violated contracts and federal law by failing to reimburse their member pharmacies for copayments they erroneously made under the Medicare Part D
prescription drug program on behalf of dual-eligible beneficiaries, the U.S. District Court for the District of Columbia held July 30, 2007. The federal district court therefore granted United’s motion to dismiss for lack of standing and dismissed the case with prejudice.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, those beneficiaries who qualify as “institutionalized full-benefit dual eligibles” are not required to make any copayments for covered medications obtained through their prescription drug plans (PDPs). The LTCPA and ASCP alleged in a July 2006 complaint that United’s subsidiary PDPs, along with most other PDPs, failed to recognize that a number of institutionalized full-benefit dual eligibles were not required to make copayments to the pharmacies, and therefore improperly reduced the reimbursement to the pharmacies by the standard copayment amount. As a result, according to LTCPA and ASCP, the PDPs accumulated millions of dollars of erroneously withheld copayments, while the pharmacies incurred a corresponding amount of debt.

United argued that its PDPs were authorized to process claims only in accordance with Centers for Medicare and Medicaid Services (CMS) data. If that data indicated a particular beneficiary owed a copayment, then the PDP had no choice but to reduce the reimbursement to the pharmacy by the amount of the copayment. LTCPA and ASCP said they attempted to work with CMS and United’s subsidiary PDPs, but were unable to resolve the problem. United then notified LTCPA in June 2006 that its PDPs were preparing to send individual reimbursement checks for each of the improperly held copayments directly to the individual Medicare Part D beneficiaries, rather than to the pharmacies.

LTCPA and ASCP sought a temporary restraining order (TRO) and preliminary injunction barring United from sending the checks. After United agreed to delay distributing the checks, the parties informed the district court they had settled the case. The court dismissed the case without prejudice so the parties could finalize the terms of their settlement agreement. When the settlement negotiations failed, LTCPA and ASCP renewed their motion for a TRO and preliminary injunction, which the district court dismissed, concluding the pharmacy associations had not made the requisite showing of irreparable injury because any of the alleged injuries could be addressed by money damages. LTCPA and ASCP filed an amended complaint, and United moved to dismiss, arguing that the associations lacked to standing to bring the lawsuit.

In granting United’s motion, the district court rejected the associations’ argument they had standing to sue on their own behalf because of the injury they suffered as a result of United’s conduct. According to the associations, they were forced to divert resources from other priorities, such as advocating for the improvement of federal statutes, in order to focus on their member pharmacies’ reimbursement conflict with United. The district court noted that LTCPA and ASCP had not alleged their activities were impeded in any way, aside from contending an “abstract conflict” between their advocacy goals and United’s activities. “Were an association able to gain standing merely by choosing to fight a policy that is contrary to its mission, the courthouse door would be open to all
associations,” the court said. "[I]t is clear that if a cognizable injury exists at all, it belongs to the pharmacies, not to the organizations that represent them."

The district court next rejected the associations’ argument they had standing to bring their lawsuit on behalf of their member pharmacies. The court noted that an association can sue on behalf of its members when: its members would otherwise have standing to sue in their own right; the interests at stake are germane to the association’s purpose; and neither the claim asserted nor the relief requested requires the participation of individual association members. The district court determined the associations failed to meet this test’s third requirement because the participation of their members would be necessary to provide the relief sought, i.e., a declaration requiring United’s PDPs to pay erroneously withheld copayment amounts directly to pharmacies rather than to individual beneficiaries. The court said it was “unable to adjudicate the pharmacies’ entitlement to money without their participation in the suit.” Long Term Care Pharmacy Alliance v. UnitedHealth Group, No. 06-01221 (ESH) (D.D.C. July 30, 2007).

Ninth Circuit Upholds DHHS’ Effective Medicare Certification Date For Psychiatric Hospital
The Ninth Circuit upheld the effective Medicare certification date (ECD) of a psychiatric hospital, finding certain low-level deficiencies precluded the Department of Health and Human Services (DHHS) Secretary from granting an earlier date. County of Pierce, doing business as Puget Sound Behavioral Health (PSBH), sought Medicare certification as a psychiatric hospital. The Secretary ultimately granted PSBH an ECD of April 4, 2002—the date on which it submitted a plan of correction for certain lower-level deficiencies. PSBH argued the ECD should have been earlier under 42 C.F.R. § 489.13(d)(1)(i) because it was previously accredited by the Joint Commission as an acute care facility. A federal district court refused to overturn the DHHS Secretary’s ECD decision. In an unpublished decision, the Ninth Circuit affirmed.

As a threshold issue, the appeals court held the Secretary’s decision was properly reviewed under 42 U.S.C. 405(g)’s “substantial evidence” standard, rather than under the Administrative Procedure Act’s “arbitrary and capricious” standard as PSBH argued. The appeals court said PSBH’s accreditation by the Joint Commission as an acute care facility was insufficient to establish its certification as a psychiatric hospital. Even if its accreditation was sufficient to trigger § 489.13(d)(1)(i), PSBH would still have to satisfy “all requirements” for certification before it could be granted an ECD, the appeals court noted. “It is undisputed that although PSBH had satisfied the two additional requirements for certification as a psychiatric hospital when the Centers for Medicare and Medicaid Services completed its survey, eleven lower-level deficiencies remained,” the appeals court said. County of Pierce v. Leavitt, No. 05-36176 (9th Cir. Aug. 1, 2007).

U.S. Court In California Says Hospital Entitled To Medicare Reimbursement For “Bad Debt”
The Department of Health and Human Services (DHHS) Secretary improperly disallowed a hospital’s claim for Medicare reimbursement of $38,000 for uncollected beneficiary deductible and co-insurance obligations, a federal court in California ruled August 8,
2007. Reversing a final DHHS decision, the court found no evidence to refute Dameron Hospital Association’s (plaintiff’s) contention that the fiscal intermediary had previously accepted plaintiff’s practice of writing off “bad debt” while it was still in collection at an outside agency and therefore was barred under the Omnibus Budget Reconciliation Act of 1989 (OBRA) from denying the hospital’s reimbursement claim.

Under § 6023 of OBRA, the Secretary may not impose “new or different bad debt criteria on a provider after August 1, 1987 if the intermediary ‘accepted’ the provider’s policies before that date in accordance with the rules then in effect.” University Health Servs., Inc. v. Health & Human Servs., 120 F.3d 1145, 1151 (11th Cir. 1997). At issue, was $38,000 plaintiff wrote off as bad debt for its 1999 cost year. Plaintiff’s ongoing policy was to attempt to collect the debt internally and then refer unpaid accounts to a collection agency. Usually between 30 and 60 days from the date the accounts were turned over to the collection agency, plaintiff considered the uncollected amounts reimbursable “bad debt” under Medicare.

In a 2003 Notice of Program Reimbursement (NPR), the fiscal intermediary disallowed plaintiff’s “bad debt” reimbursement claim for the fiscal year ending (FYE) 1999 because the debts had, at that time, still been in “active” status with an outside collection agency. The Provider Reimbursement Review Board (PRRB) reversed the intermediary’s decision, holding the “active” status of the account with an outside collection agency was not conclusive on the issue of collectibility and that the statutory bar in OBRA applied. The DHHS Secretary reversed the PRRB’s decision, finding no amount of evidence could overcome the presumption of collectibility arising from the active status of a bad debt account still pending at a collection agency and that the record failed to show the intermediary “accepted” plaintiff’s policy under OBRA.

The U.S. District Court for the Eastern District of California reversed, finding plaintiff provided sufficient evidence that its bad debt policy was in effect since before 1987 and that the intermediary had annually audited its accounts and never objected until the FYE 1999 audit in 2003. The intermediary neither provided any evidence in rebuttal nor challenged the reliability or admissibility of plaintiff’s evidence, the court noted. The court rejected the Secretary’s contention that plaintiff had to produce previous audits to prove the intermediary had accepted plaintiff’s pre-August 1, 1987 bad debt policy. Because the court found the OBRA statutory bar to the denial of plaintiff’s reimbursement claim applied, it did not address whether the “active status” of the accounts with an outside collection agency prevented a provider from claiming them as bad debt. Dameron Hosp. Ass’n v. Leavitt, No. CIV S-06-136 FCD/KJM (E.D. Cal. Aug. 8, 2007).

Sixth Circuit Affirms Denial Of Reimbursement For Bad Debt Still Subject To Collection Efforts

The Sixth Circuit held August 14, 2007 that the Department of Health and Human Services Secretary’s decision to disallow bad debt that was still the subject of collection efforts was reasonable and was not arbitrary and capricious. Plaintiffs Battle Creek Health System (Battle Creek) and Trinity Health-Michigan (Trinity Health) are non-
profit, tax-exempt, acute care hospitals. Their Medicare fiscal intermediary audited plaintiffs' fiscal year 1999 cost reports and disallowed $155,822 and $327,829 in bad debts claimed by Battle Creek and Trinity Health, respectively. The intermediary concluded the debts were sent to a collection agency, but not returned to plaintiffs as uncollectible and therefore did not meet the requirements of 42 C.F.R. § 413.89(e)(3) and (4) because the debts had never been determined to be uncollectible and collection efforts could be expected to continue after the accounts were written off.

Plaintiffs appealed to the Provider Reimbursement Review Board (PRRB), which held the intermediary's determination was erroneous and plaintiffs were entitled to reimbursement for the bad debts. The Centers for Medicare and Medicaid Services (CMS) Administrator reversed. The district court granted the Department of Health and Human Services Secretary’s motion for summary judgment.

Affirming, the appeals court first addressed plaintiffs’ argument that “[t]he Secretary's newly-imposed requirement that providers discontinue collection agency efforts before seeking reimbursement of debts outstanding for more than 120 days is inconsistent with the § 310.2 presumption and with Medicare's requirement that its beneficiaries bear the costs of deductibles and co-insurance [set forth in] 42 U.S.C. § 1395x(v)(1)(A).” The appeals court rejected plaintiffs’ contention that they were entitled to rely upon the presumption of noncollectibility set forth in PRM § 310.2. Instead, the appeals court found “eminently reasonable” the Secretary’s opinion that the presumption of noncollectibility is discretionary in nature and should not be applied automatically in this case despite the passage of 120 days, because the accounts in question had been referred to a collection agency and were not yet returned to the provider as uncollectible. The appeals court also rejected plaintiffs’ public policy arguments, finding the policy “does not deprive plaintiffs or other providers of reimbursement for Medicare bad debts; rather, it merely requires them to engage in the same sound business practices that they use when pursuing non-Medicare debt.” Battle Creek Health Sys. v. Leavitt, No. 06-1775 (6th Cir. Aug. 14, 2007).

U.S. Court In D.C. Holds Finds Hospital Properly Denied Sole Community Hospital Status Based On Original Rural Requirement
The Department of Health and Human Services (DHHS) properly cured procedural deficiencies in how it defined urban areas for purposes of determining sole community hospital (SCH) status, the U.S. District Court for the District of Columbia ruled September 4, 2007. Because it considered alternative definitions as previously directed by the court, DHHS was now free to reinstate its decision to deny a hospital SCH status based on the regulation as originally promulgated, the court said.

A SCH is exempt from the Medicare prospective payment system and therefore eligible for higher payments based on its historic costs. Before 1999, the Medicare statute defined a SCH as a hospital (1) located more than 35 miles from another hospital or (2) that met certain other qualifying factors such as time required for travel, location, weather, and travel conditions, and the absence of other like hospitals. Under regulations promulgated by DHHS, a hospital that was fewer than 35 miles from another hospital could only
obtain SCH status under the second definition if it was located in a rural area, which is defined as any area outside an urban area, or Metropolitan Statistical Area (MSA). Congress in 1999 amended the Medicare law to provide that an urban hospital could be treated as being located in a rural area for purposes of determining SCH status. Heartland was granted SCH status in 2000.

Heartland Regional Medical Center (Heartland), located in St. Joseph, Missouri, is less than 35 miles from other hospitals. In May 1992, its Medicare fiscal intermediary denied its application for SCH status on the ground that it was located in an urban area. Heartland eventually challenged the regulatory rural location requirement in federal district court. The court initially remanded the case to DHHS, concluding that the regulation was invalid because DHHS failed to consider other alternatives to the way it chose to define an "urban area." See Heartland Hosp. v. Shalala (Heartland I), No. 95-951 (D.D.C. 1998). On remand, DHHS considered alternative definitions but rejected them in favor of its original definition. Heartland again sought relief in court moving to enforce the Heartland I judgment and filing a separate action against the agency challenging the regulations under the Administrative Procedure Act (APA).

The case eventually went up to the D.C. Circuit, which concluded that DHHS by re-examining the urban area definition complied with Heartland I. According to the appeals court, the case only invalidated the regulations to the extent that the agency failed to consider alternatives to its urban area definition. Thus, the only issue remaining before the district court was the viability of Heartland’s separate action under the APA that the agency arbitrarily rejected the alternative definitions in its post-Heartland I review.

Affording substantial deference to the agency’s interpretation of the applicable statute, the U.S. District Court for the District of Columbia held DHHS was entitled to summary judgment. The court found DHHS had not arbitrarily rejected alternatives to an MSA-based definition of urban area in its subsequent reevaluation. On remand and in compliance with the court’s order, DHHS considered the two proposed alternatives to the MSA-based definition advanced during the rulemaking process and rejected them with adequate explanation of its reason for doing so. Finally, the court held DHHS did not engage in impermissible retroactive rulemaking, emphasizing that an agency that cures a problem identified by a court is free to reinstate the original result on remand. Heartland Reg’l Med. Ctr. v. Leavitt, No. 00-2802 (RMU) (D.D.C. Sept. 4, 2007).

U.S. Court In Alabama Remands Plaintiffs’ State Law Claims Alleging Health Insurer Fraudulently Sold Medicare Advantage Plan

A federal district court in Alabama remanded to state court an action against a health insurer by individuals asserting they were fraudulently induced to enroll in the insurer's Medicare Advantage (MA) plan. The court found applicable Medicare statutes did not "completely preempt" plaintiffs’ state common law claims.

Plaintiffs were seven individuals who alleged Pacificare Life and Health Insurance Co. (Pacificare) and its agents used fraudulent tactics to persuade them to enroll in its MA plan, Secure Horizons Direct. Filing an action in state court, plaintiffs accused Pacificare
and its agents of “acting in concert” in misrepresenting to Medicare recipients that they had to enroll in Secure Horizons Direct under the federal government’s new prescription drug program. Plaintiffs also alleged Pacificare and its agents misrepresented their actions by failing to adequately explain that they were disenrolling plaintiffs from their existing Medicare coverage and enrolling them in Secure Horizons Direct, a private MA plan. As a result, according to the complaint, plaintiffs’ benefits and healthcare coverage through Medicare was drastically reduced, causing them "to suffer physical injury and mental distress and to incur large medical bills."

Plaintiffs asserted state common law causes of action for fraud and unjust enrichment, as well as other state law causes of action for negligent infliction of emotional distress, wantonness, and outrage. In moving for removal to federal court, Pacificare argued that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003's (MMA's) preemption clause, 42 U.S.C. §1395w-26(b)(3), applied. That provision states the “standards established [under the MMA] . . . shall supersede any State law or regulation . . . with respect to plans which are offered by [Medicare Advantage] organizations.” Plaintiffs moved for remand, arguing against complete preemption.

Agreeing with plaintiffs’ argument, the U.S. District Court for the Middle District of Alabama noted federal courts have applied the complete preemption doctrine sparingly, with the U.S. Supreme Court confirming its application to only three statutes, i.e., the Labor Management Relations Act, the Employee Retirement Income Security Act, and the National Bank Act. The district court also noted an important distinction between “complete preemption” and “ordinary preemption.” The court pointed out that “complete preemption” is a narrowly drawn jurisdictional rule for assessing federal removal jurisdiction when a complaint purports to raise only state law claims, while “ordinary preemption” may be invoked in both state and federal court as an affirmative defense to allegations in a plaintiff’s complaint. “The issue in this case is whether federal court, not federal law is appropriate,” the district court continued, “In other words, ordinary preemption is not at issue, only complete preemption.”

The district court then explained that, in this case, Pacificare erroneously commingled ordinary and complete preemption principles by assuming the preemption clause at issue, 42 U.S.C. §1395w-26(b)(3), supports complete preemption of state common law claims and proceeding directly to the issue of whether plaintiffs’ state common law claims are preempted because they fall within the scope of §1395w-26(b)(3). “In making this assumption, however, Pacificare . . . ignores the threshold question of whether . . . § 1395w-26(b)(3) is a complete preemption statute at all,” the district court said. On this question, the district court found Pacificare failed to demonstrate that the clause at issue supported “complete preemption,” noting it failed to highlight any language in the MMA’s legislative history establishing Congress intended either “that the MMA would provide an ‘exclusive cause of action’ to redress rights," or that "state-law claims falling within §1395w-26(b)(3)’s scope would be regarded as arising under the laws of the United States.” Harris v. Pacificare Life & Health Ins. Co., Civ. Act. No. 2:06cv956-ID (M.D. Ala. Sept. 28, 2007).
Meanwhile, in a case with similar allegations and facts but reaching a different result on the preemption issue, the U.S. District Court for the Southern District of Alabama granted a motion for interlocutory appeal on the question of whether § 1395w-26(b)(3) is a complete preemption statute. The court previously ruled that at least some of the state law claims plaintiffs had asserted were completely preempted under the MMA. In the instant case, the court denied plaintiffs' motion for remand, finding some of plaintiffs' state law claims, "those for fraud based on misrepresentations regarding marketing, enrollment, filing of claims, benefits, and coverage under the plan, unjust enrichment and breach of contract to the extent these claims result from a failure to pay benefits as promised," were completely preempted pursuant to § 1395w-26(b)(3). Plaintiffs then moved to certify interlocutory appeal from the order denying remand and defendants joined in the motion.

The court explained that at least two other district courts have ruled differently in substantially similar cases and entered orders granting remand upon a finding that plaintiffs' claims were not subject to complete preemption under the MMA. See Bolden v. Healthspring of Alabama, Inc., Nos. 07-413-CG-B, 07-414-CG-M (S.D. Ala. 2007); and Harris v. Pacificare Life & Health Ins. Co., No. 2:06-956-ID (M.D. Ala. 2007). The court determined that all requirements for interlocutory appeal were met here—namely, a controlling question of law, a "substantial ground for difference of opinion," and the appeal would "materially advance the termination of the litigation." Dial v. HealthSpring of Ala., Inc., No. 2:07-0412-KD-C (S.D. Ala. Oct. 15, 2007).

U.S. Court In New York Finds Medicare Managed Care Rates Do Not Violate Equal Protection

The fact that some Medicare beneficiaries located in suburban counties pay more for services provided by health maintenance organizations (HMOs) than seniors located in other nearby urban counties does not amount to an equal protection violation, a federal trial court in New York ruled September 27, 2007. Plaintiffs are Medicare beneficiaries located in the New York “suburban counties” of Nassau, Rockland, Suffolk, and Westchester who participate in the Medicare Advantage (MA) program. In challenging how the Medicare managed care program sets rates, plaintiffs alleged discrimination in violation of their Fifth Amendment rights to equal protection because they pay more for services under MA than do beneficiaries located in the borough counties of New York City.

Applying rational basis review, the U.S. District Court for the Eastern District of New York granted defendants’ motion to dismiss, finding the MA program’s payment formula was rationally related to the government’s legitimate interest of containing healthcare costs while expanding healthcare options. The court noted that the Centers for Medicare and Medicaid Services set capitation rates based on congressionally mandated formulas. The court rejected plaintiffs’ assertion that CMS must calculate capitation rates on “whatever ‘information and data’” was available to it. Instead, the relevant statute requires only that CMS consider “other information and data.” “While the Court empathizes with the Plaintiffs’ frustration over the cost differential of the program provided by organizations within the borough counties versus that provided by organizations with the Plaintiffs’ counties, such difference is not sufficient to render the
program unconstitutional,” the opinion said. The court acknowledged plaintiffs made “compelling arguments” that the process for setting capitation rates could be improved to reduce these differences, but any such reform should be undertaken by Congress. *Andersen v. Leavitt*, No. 03-6115 (DRH) (E.D.N.Y. Sept. 27, 2007).

**Fourth Circuit Upholds Finding Of Overpayments For Power Wheelchairs**
The Fourth Circuit upheld October 31, 2007 the government’s determination that Medicare overpaid a power wheelchair supplier over a half of a million dollars because the medical necessity for some chairs was not sufficiently established. Affirming a lower court’s decision, the appeals court rejected the supplier’s argument that under the Medicare Act only a certificate of medical necessity (CMN) signed by a physician is necessary to establish appropriate reimbursement for power wheelchairs.

Between September 1, 1998, and February 28, 1999, plaintiff MacKenzie Medical Supply sold 135 power wheelchairs and submitted claims to its Medicare Durable Medical Equipment (DME) Regional carrier, Palmetto Government Benefits Administrators. The carrier initially approved and paid the claims, but alerted by the high volume of power wheelchair claims, eventually conducted a post-payment audit. The carrier determined that MacKenzie was overpaid $508,747.57 for claims that failed to satisfy medical necessity requirements. MacKenzie sought administrative review, arguing the CMNs it submitted with each claim established medical necessity under the Medicare Act without the need for any additional documentation.

The Fourth Circuit held the plain language of the Medicare Act did not mandate reimbursement of a DME claim supported solely on the submission of a completed CMN form. Quoting the Eleventh Circuit’s recent decision in *Gulfcoast Med. Supply, Inc. v. Secretary, HHS*, 463 F.3d 1347 (2006), the Fourth Circuit noted that the CMN is best viewed as “an optional pre-payment tool designed primarily to reduce paperwork and to streamline the processing of claims,” not as a complete standardization of the DME-claim-process that eliminates the Secretary’s flexibility to require additional support for DME claims initially made with a CMN. Moreover, the appeals court continued, even if the Medicare Act were ambiguous, the Secretary’s interpretation was reasonable and entitled to deference.

The appeals court also rejected MacKenzie’s contention that it was entitled to a waiver of the overpayment because it could not have known reimbursement would be denied for lack of medical documentation, given its reasonable interpretation that a completed CMN was always sufficient. The plain language of the Medicare Act “in no way states that a CMN alone is sufficient to establish medical reasonableness and necessity under Part B,” and a Medicare Advisory Manual issued before the submission of the claims at issue “explicitly put MacKenzie on notice” that additional medical documentation beyond a CMN may be required to support a DME claim, the appeals court found. *MacKenzie Med. Supply, Inc. v. Leavitt*, No. 06-1630 (4th Cir. Oct. 31, 2007).

In another federal appeals court ruling on the issue, the Ninth Circuit agreed that the Department of Health and Human Services (DHHS) could require the submission of
additional documentation beyond a CMN to prove that a particular item of DME was reasonable and medically necessary. In this case, an audit contacted by a Medicare carrier revealed that DME supplier Maximum Comfort Inc. (Maximum) failed to substantiate the medical necessity of power-operated wheelchairs provided to 22 of 30 randomly selected Medicare beneficiaries in 1998 and early 1999. From this sample (30 out of a total of 236 claims), the carrier concluded Maximum had been overpaid roughly $548,500, and a second audit revealed further documentation problems, and an additional overpayment of over $237,000.

Ruling in favor of Maximum’s motion for summary judgment, the U.S. District Court for the Eastern District of California held the DHHS Secretary could not require DME suppliers to obtain additional information beyond the CMN to prove that the wheelchairs were reasonable and medically necessary. The Ninth Circuit disagreed, found the relevant statutory language set forth in 42 U.S.C. §1395m(j)(2)(A)&(B) describing the use of a CMN “permits (but does not require) the supplier to distribute certificates to physicians or patients,” and does not state the certificate "is the sole vehicle for claims reimbursement, nor does it state that a completed certificate establishes, by itself, a right to reimbursement.”

As in the MacKenzie decision, the appeals court rejected the DME supplier’s argument that it should be excluded from liability for repayment because it “did not know, and could not reasonably have been expected to know, that payment would not be made” for the DME it supplied. Citing 42 C.F.R. § 411.406(e), the appeals determined that Maximum had “constructive notice” that certain items of DME might not be covered by Medicare, and that the Secretary might require additional documentation. Maximum Comfort Inc. v. Leavitt, No. 05-15832 (9th Cir. Dec. 21, 2007).

Third Circuit Says Nonprofit Hospital Not Entitled To Medicare Reimbursement For Loss On Sale
A transaction in which a nonprofit hospital sold its assets to a larger community hospital below actual market value was not a bona fide sale for Medicare purposes, the Third Circuit concluded October 30, 2007 in a non-precedential ruling. Affirming a lower court decision, the appeals court held the hospital was not entitled to reimbursement from Medicare for the loss.

The case arose following 110-bed acute care Muhlenberg Hospital Center’s (MHC’s) sale of its assets to Lehigh Valley Health Services Organization (Lehigh) in October 1997. According to the opinion, nonprofit MHC chose to enter into the transaction with Lehigh primarily because of its ability to improve the quality of care and access to services in the community. Pursuant to the agreement, MHC sold all of its assets, including cash, to Lehigh and, in return, Lehigh paid all costs associated with the transaction and assumed MHC’s liabilities of over $43 million. Lehigh also agreed to contribute up to $20 million to the Muhlenberg Foundation and to expand the hospital’s campus.

MHC claimed a loss of more than $30 million on the sale of its assets and sought to recover excess depreciation of $4,277,421 for Medicare’s share of the loss. At the time of
the sale, the opinion said, MHC’s net book value was over $104 million and a consultant had determined that the fair market value of Muhlenberg’s fixed and intangible assets was over $62 million. Because the “purchase price was significantly less than the market value of the Provider’s assets,” the fiscal intermediary determined the transaction was not a bona fide sale and therefore MHC was not entitled to a loss on the sale. The Provider Reimbursement Review Board affirmed and the Centers for Medicare and Medicaid Services Administrator declined to review the Board’s decision.

The Third Circuit affirmed, finding the Board’s decision was supported by substantial evidence. The appeals court rejected Lehigh’s argument that the Board erroneously relied on Program Memorandum A-00-76, which was issued several years after the sale at issue. The Program Memorandum, which was specifically addressed to transactions involving nonprofits, merely explained an existing rule and therefore the Board’s reliance on it did not raise retroactivity concerns, the appeals court found.

The appeals court also disputed that the Board should have considered Lehigh’s promises of future services to the community and the development of the MHC campus in examining whether a bona fide sale took place. “Testimony before the PRRB makes clear that the hospital’s leadership was more concerned with maintaining quality health care in the community than obtaining the highest price,” the appeals court observed. Citing case law and the Program Memorandum, the appeals court found substantial evidence to support the Board’s decision not to include the promise of future services in analyzing whether the transaction was a bona fide sale. Lehigh Valley Hosp. – Muhlenberg v. Leavitt, No. 06-4194 (3d Cir. Oct. 30, 2007).

Eighth Circuit Rejects MSP Action By Individual Claiming Standing As Qui Tam Relator
The Eighth Circuit upheld November 27, 2007 the dismissal of a consolidated action against two health systems 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 appeals court found the MSP does not permit a private qui tam action on behalf of the government.

Douglas B. Stalley sued Catholic Health Initiatives and Triad Hospitals, Inc. and various insurance defendants, alleging the hospitals negligently injured Medicare patients triggering 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. 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 like the False Claims Act in that it relies on private persons with superior knowledge to discover the
government’s claim, increases damages to motivate action by private individuals, and involves the government recouping part of the private party’s recovery.

The appeals court acknowledged these similarities to a qui tam statute but found Congress intended plaintiffs under the MSP to assert their own injuries rather than the government’s injury as a realtor does. Stalley argued a Medicare beneficiary could never have a personal injury to vindicate because Medicare in most instances already has made conditional payments for the services rendered. Therefore, according to Stalley, the only way the “private right of action” under the MSP could help the government recoup money from primary payors is if it functioned as a qui tam statute. But the Eighth Circuit found this reasoning flawed, concluding Congress in the MSP contemplated allowing individuals to vindicate their private rights against primary payors even if Medicare had already made a conditional payment of the beneficiaries’ expense. Thus, Stalley lacked any injury in fact and did not have standing to pursue his action, the appeals court held. *Stalley v. Catholic Health Initiatives*, No. 06-3884 (8th Cir. Nov. 27, 2007).

In a February 28, 2008, another federal appeals court reached the same result, dismissing Stalley’s claims under the MSP against various Tennessee health systems. The Sixth Circuit agreed with the Eighth Circuit’s decision that the MSP is not a qui tam statute and therefore Stalley lacked standing to bring his claims. The Sixth Circuit also entered an order instructing Stalley and his counsel to show cause as to why sanctions should not be imposed against them for pursuing “unreasonable and vexatious” appeals. “Stalley cited no legal authority for his contention that the MSP is a qui tam statute, and he has failed to persuade a single one of the many other courts in which he has raised this claim,” the appeals court said. *Stolley v. Methodist Healthcare*, No. 07-5077 (6th Cir. Feb. 28, 2008).

**Lawsuit Seeks Medicare Part D Coverage Of Drugs For Medically Necessary Off-Label Uses**

Advocacy group the Medicare Rights Center (MRC) filed a lawsuit November 26, 2007 challenging federal regulations it says unlawfully prevent Medicare Part D drug plans from covering medically necessary prescriptions for “off-label” uses. The complaint was filed in the U.S. District Court for the Southern District of New York against Department of Health and Human Services Secretary Michael Leavitt in his official capacity.

Federal regulations prohibit Part D coverage of off-label prescriptions unless the prescribed use is supported in one of three specific medical compendia, the complaint notes. But these rules, according to the complaint, fail to take into account other published research and whether the off-label use of the drug is medically necessary for the particular patient. Over 20% of prescriptions written for the 500 most commonly used drugs are for off-label uses, the complaint says.

MRC brought the lawsuit on behalf of Judith M. Layzer, a 66-year-old Medicare beneficiary with ovarian cancer. According to the complaint, Layzer had been taking Cetrotide to treat and limit her cancer at a monthly cost of about $40 before Medicare Part D was implemented in January 2006. Because Cetrotide has not been approved by the Food and Drug Administration (FDA) to treat ovarian cancer, although it is a
“covered Part D drug” for other purposes, her monthly copayments under Medicare Part D are over $7,000 per month, the complaint notes. “Many people with Medicare were actually better off before the drug benefit was introduced,” the complaint charges.

The action seeks to enjoin the Secretary “from denying coverage of a prescription that is indisputably medically necessary” to treat Layzer’s cancer and a declaration that the administration’s interpretation of the Medicare statute is unlawful. The suit also seeks reimbursement of the more than $100,000 Layzer has paid out of pocket to date for the drug.

On November 15, 2007 MRC along with a number of other organizations sent a letter to Senate Finance Committee Chairman Max Baucus (D-MT) arguing that recent expansions to the list of information used to make coverage determinations for the off-label uses of prescription drugs under Part B should be extended to Part D. "The undersigned organizations, which serve Medicare beneficiaries, have found that this exclusive reliance on FDA indications and a limited number of compendia can prevent access to medically necessary, life-sustaining prescriptions," the letter says. The groups are asking for legislative action to ensure access to "off-label" prescription drug treatment under Medicare Part D.

**U.S. Court In Missouri Says Medicare Entitled To Reimbursement From Wrongful Death Settlement**

Medicare was entitled to reimbursement for the medical expenses it paid on behalf of a now deceased beneficiary from the settlement proceeds following a wrongful death action against the alleged third-party tortfeasor, a federal trial court in Missouri ruled. David Gerald Mathis died after receiving medical treatment for injuries he sustained at a Kansas City restaurant. Medicare paid North Kansas City Hospital $77,403.67 for the medical care Mathis received there. Mathis’ wife and children (plaintiffs) subsequently reached a settlement with the alleged tortfeasors for proceeds in excess of the amount Medicare paid for Mathis’ medical care. Plaintiffs asked Medicare to acknowledge that they had no lien against the settlement proceeds but Medicare refused.

In the subsequent federal court action, the U.S. District Court for the Western District of Missouri found Medicare had a right to reimbursement from plaintiffs’ wrongful death settlement for the payments made on Mathis’ behalf. Citing the Medicare Secondary Payer (MSP) provisions, the court said Medicare made a conditional payment for Mathis’ medical expenses and that the subsequent wrongful death settlement constituted a payment from a responsible party (the third-party tortfeasor). The court noted that, under Missouri’s Wrongful Death Statute, the decedent’s medical expenses and pain and suffering damages are recoverable as part of the wrongful death claim.

The court found plaintiffs’ argument that Medicare may only seek reimbursement from Medicare beneficiaries was belied by the broad scope of the MSP statute and its implementing regulations, which allow recovery from “an individual or any other entity.” Because plaintiffs’ settlement proceeds included an award of damages for medical expenses and constituted a payment by a responsible party, “Medicare is entitled to

**Tenth Circuit Finds Hospital Consolidation Did Not Trigger Medicare “Loss” On Depreciable Assets**

The Tenth Circuit held in a December 7, 2007 decision that a hospital comprised of two previously unrelated entities was not entitled to reimbursement from Medicare on a $9.7 million loss claim. Although the appeals court found the consolidation involving two nonprofit hospitals was not a transaction between related parties, it held the deal did not amount to a “bona fide sale” and therefore no Medicare reimbursement for a depreciation adjustment was due.

Two nonprofit healthcare providers in Kansas affiliated with the Catholic Church, St. Joseph's Medical Center (St. Joseph) and St. Francis Regional Medical Center (St. Francis) consolidated to create a new corporation, Via Christi Regional Medical Center (Via Christi). One day after the consolidation, St. Joseph’s sole member consolidated with St. Francis' sole member to create Via Christi Health System. Ultimately, seven members of St. Joseph’s old board and six members of St. Francis’ old board became members of the new Via Christi board. Via Christi sought Medicare reimbursement of $9.7 million as a “loss” on the assets it acquired as the surviving entity in the consolidation.

Under 42 C.F.R. § 413.134(f), relating to “disposals” of depreciable assets, a provider may claim a “loss” and receive reimbursement for Medicare’s share of that loss if the transaction is a “bona fide sale” in which the consideration received is worth less than the asset’s net book value. Pursuant to the consolidation regulation, specifically 42 C.F.R. § 413.134(l)(3), a provider may claim a “loss” on the disposal of depreciable assets so long as the transaction is not between related parties.

The fiscal intermediary denied the loss claim, concluding the consolidation was between related parties. The Provider Reimbursement Review Board (PRRB) found undisputed that the consolidating providers were not related parties prior to the consolidation and that the related party concept was to be applied only to the pre-transaction relationship. The PRRB also determined the transaction was a bona fide sale.

The CMS Administrator reversed the PRRB, holding the consolidation involved related parties based on the “continuity of control” between the consolidating entities and Via Christi. Specifically, the Administrator noted that St. Joseph’s sponsoring corporation was one of two voting members of the post-consolidation hospital and that seven of Via Christi’s 23-member board were former St. Joseph's board members. The CMS Administrator also noted a continuity of business enterprise and mission between St. Joseph's and the post-consolidation entity. Finally, the CMS Administrator concluded the transaction did not meet the § 413.134(f) requirement for a bona fide sale to allow the calculation of a loss on consolidation.
The Tenth Circuit held the Secretary’s “related party” interpretation—i.e. that the determination is based on the parties’ relationship post- instead of pre-consolidation—contradicted the plain language of the regulation. The appeals court nonetheless affirmed the denial of Via Christi’s loss claim, concluding the “bona fide sale” requirement had not been met.

The appeals court found it arbitrary and capricious for the Secretary to apply the “continuity of control” doctrine to determine whether the parties were related. According to the court, the consolidation regulation (§ 413.134(l)(3)) clearly focuses on “whether the parties to the consolidation were related prior to the transaction—not whether they were related to the newly created entity.”

The appeals court did agree, however, that consolidating Medicare providers had to meet the “bona fide sale” requirements of § 413.134(f) to obtain reimbursement for a depreciation adjustment. To hold otherwise, the appeals court said “would make depreciation adjustments easier for providers attempting consolidations than for providers undergoing asset sales or statutory merges—a strange result to say the least.”

The appeals court also found substantial evidence that the consolidation here was not a “bona fide sale.” Specifically, the appeals court noted that this was not an arm’s length transaction, citing St. Joseph’s own admission that it was not attempting to get the full value of its assets, but rather seeking to advance its ministry. The appeals court also found reasonable consideration was “notably absent from the transaction.” Although the parties had not conducted an appraisal of the assets’ fair market value, the appeals court declined to remand for such a determination. St. Joseph's had the burden of showing the transaction was a bona fide sale, but it made no effort to show the assets’ fair market value in earlier proceedings. Via Christi Reg’l Med. Ctr. v. Leavitt, No. 06-3402 (10th Cir. Dec. 7, 2007).

D.C. Circuit Finds DHHS Secretary Required To Publish Reimbursement Standard For Dialysis Providers

The Department of Health and Human Services Secretary was required to publish in the Federal Register its standard for determining atypical patient mix for reimbursement of dialysis providers, the D.C. Circuit has held. Accordingly, the appeals court reversed a lower court's grant of summary judgment to the Secretary as to one provider who challenged the standard. However, the appeals court affirmed the decision as to the other two providers who also challenged the standard, holding the agency's finding that the providers failed to prove an atypical patient mix provided an independent ground to uphold the Secretary's decision.

Three Michigan dialysis providers—Alpena Dialysis Services, Northern Michigan Hospital, and Chippewa Dialysis Services—applied to the Centers for Medicare and Medicaid Services (CMS) for an exception to the Medicare composite rate under which the agency generally reimburses facilities providing dialysis services. All three providers based their exception requests on atypical patient mix—specifically, higher than average percentages of aged and diabetic patients. CMS denied the request, finding national data
showed average direct patient care hours were 3.0 hours per treatment and because the per treatment hours of all three providers fell below that level they were ineligible for the exception. All three providers appealed to the Provider Reimbursement Review Board (Board), which affirmed CMS' determination. The three providers then sought review in district court. The court granted summary judgment to the Secretary. On appeal, the providers challenged the Board’s use of the 3.0 hours per treatment standard, arguing that the Medicare Act required the Secretary to publish it in the Federal Register. See 42 U.S.C. § 1395hh(c)(1).

The D.C. Circuit found the 3.0 hours per treatment standard "most clearly qualifies under the Medicare Act as a guideline of general applicability," which had to be published in the Federal Register. Thus, the appeals court reversed and remanded Alpena's case, although it affirmed the district court’s decision on Northern's and Chippewa's claims, finding no error in the conclusion that these providers failed to establish their atypical patient mix in the first place. Chippewa Dialysis Servs. v. Leavitt, No. 06-5371 (D.C. Cir. Dec. 21, 2007).

U.S. Court In D.C. Holds LTC Pharmacy Groups Lacked Standing To Sue CMS For Allegedly Faulty Part D Data System

Long term care pharmacy associations do not have standing to sue the Centers for Medicare and Medicaid Services (CMS) for their alleged failure to timely and accurately notify Medicare prescription drug plans (PDPs) of beneficiaries’ status as “institutionalized dual eligibles” for purposes of the Part D benefit, the U.S. District Court for the District of Columbia held January 11, 2008. CMS’ failure to identify certain nursing home residents as “institutionalized dual eligibles,” according to the lawsuit brought by plaintiffs Long Term Care Pharmacy Alliance and the American Society of Consultant Pharmacists, has deprived long term care (LTC) pharmacies of reimbursements owed to them and forced them “to carry tens of millions of dollars of cost-sharing debt.”

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), beneficiaries who qualify as “institutionalized dual eligibles” are not required to make copayments for covered medications obtained through their PDPs. In these instances, LTC pharmacies seek full reimbursement from PDPs and do not collect copayments from the nursing home resident. Plaintiffs contended that CMS' system for notifying PDPs of a beneficiary’s status as an “institutionalized dual eligible” entails a significant “lag time” often extending several months after the LTC pharmacies have dispensed medications and submitted their reimbursement claims. According to plaintiffs’ estimates, 15% of institutionalized dual eligibles are not correctly identified in the current data CMS provides to the PDPs.

In an earlier action, plaintiffs sued the nation’s largest PDP—United Health Group. The U.S. District Court for the District of Columbia dismissed that action finding plaintiffs lacked standing. Plaintiffs in the instant action alleged CMS violated the Administrative Procedure Act (APA) and their member pharmacies’ due process rights under the Fifth Amendment.
The court dismissed plaintiffs’ action, finding they lacked constitutional standing and that their claim was not cognizable under the APA. First, the court noted that plaintiffs could not establish causation because the LTC pharmacies’ rights to reimbursement for the prescriptions dispensed to institutionalized dual eligibles were governed by their contracts with the PDPs. Those pharmacies, the court continued, had no independent contractual relationship with CMS. The court also pointed to evidence that at least some PDPs, despite receiving the same data from CMS, did reimburse the LTC pharmacies for erroneous copayments, which “strongly suggests that the terms of the PDP-LTC pharmacy contracts or the independent actions of some PDPs are the real impediments to reimbursement, not the actions of the government.”

More importantly, the court said, plaintiffs lacked standing because any relief the court could grant would not redress their members’ injuries. The MMA gave CMS the discretion to design and implement a process for providing eligibility data to PDPs. The statute did not, however, establish any benchmarks for data accuracy or mandate any specific time tables. CMS opted to reimburse the PDPs with estimated interim payments and later make retroactive adjustments as necessary. “Given that no process that CMS could design would produce completely accurate eligibility data instantaneously, the notification process that it has instituted is a reasonable exercise of its discretion,” the court commented. Likewise, the due process claim lacked merit because plaintiffs failed to identify “the additional procedural safeguards that they believe are constitutionally mandated.” *Long Term Care Pharmacy Alliance v. Leavitt*, No. 07-115 (ESH) (D.D.C. Jan. 11, 2008).

**U.S. Court In Florida Overturns DHHS Secretary’s Denial Of DSH Adjustment For Hospital**

The Department of Health and Human Services (DHHS) Secretary erred in denying a hospital’s request for a disproportionate share hospital (DSH) adjustment to its 1998 Medicare cost report, a federal district court in Florida ruled January 11, 2008. North Okaloosa Medical Center (NOMC) sought review of the DHHS Secretary's final decision to deny the hospital approximately $1.36 million in Medicare DSH reimbursements for the cost reporting year ended March 31, 1998.

Under relevant legislation, a hospital eligible for a DSH adjustment is one that has a disproportionate patient percentage that equals or exceeds 15%, is located in an urban area, and has 100 or more beds. From its review of the legislative history, the district court noted Congress’ intention that “beds...counted should be staffed and available beds.” (H.R. Rep. 99-241 (1985)). “Congress thus linked the bed-count criterion to available beds and not to the actual use of the beds by acute care patients,” the court said.

In implementing the DSH adjustment, the Secretary also adopted a regulation (42 C.F.R. § 412.106) that linked DSH eligibility to three factors (i.e., number of beds, number of patient days, and the hospital’s location). The Secretary’s Medicare Provider Reimbursement Manual (PRM) further explained that "the term 'available beds'...for purpose of counting beds is not intended to capture the day to day fluctuations in patient
rooms and wards being used" but rather "is intended to capture changes in the size of a facility as beds are added to or taken out of services." The parties disagreed over what constituted an “available bed” in determining eligibility for the adjustment.

The Secretary concluded the hospital had fewer than 100 acute care beds for inpatient use because it sometimes placed outpatients requiring observation in acute care beds when those beds were not needed for inpatients. The Secretary concluded the "observation bed days" must be excluded from the count of available beds because observation bed days are not recognized as part of NOMC's inpatient prospective payment system operating costs.

According to the district court, the Secretary was essentially arguing that “a hospital’s bed count for purposes of DSH eligibility is a function of the use to which those hospital beds are put.” Finding “no support for such proposition in the relevant statute, regulation, or [PRM],” the district court emphasized that Congress said only that “beds” for DSH bed-counting purposes must be “staffed and available,” and said nothing about the use to which the beds were put. The district court also concluded the Secretary’s decision to disallow beds that were staffed and available for acute-care inpatient use at all times during the cost reporting period at issue could not be reconciled with the clear language of the Secretary’s own regulations and the PRM. North Okaloosa Med. Ctr. v. Leavitt, No. 3:07cv26-WS (N.D. Fla. Jan. 11, 2008).

U.S. Court In D.C. Rules In Favor Of Massachusetts Hospitals Challenging Medicare Wage Index Calculation
A federal district court in the District of Columbia granted February 26, 2008 summary judgment in favor of 62 Massachusetts hospitals claiming that a change in the government's method for calculating their area wage index cost them $200 million in Medicare reimbursements. The action against Department of Health and Human Services Secretary Michael Leavitt in his official capacity asserted he exceeded his statutory authority by deciding to exclude wage data from hospitals that had become critical access hospitals (CAHs) beginning in fiscal year (FY) 2004.

Unlike hospitals reimbursed under the prospective payment system (PPS) (referred to as “subsection (d) hospitals”), CAHs are reimbursed at 101% of their reasonable costs. From 1997 to 2003, the Secretary included in periodic wage surveys wage data from hospitals that later were redesignated as CAHs, but changed this approach in FY 2004. According to a final rule issued in August 2003 (68 Fed. Reg. 45346), this change in policy was justified because CAHs “are significantly different from other short-term hospitals” and the change would have “a minimal redistributive effect on Medicare payments to hospitals.” Massachusetts, where plaintiff hospitals are located, was one state that did show a substantial decrease in its wage index as a result of the Secretary’s change in calculating the wage index. Plaintiffs argued the Secretary’s actions were unlawful.

The U.S. District Court for the District of Columbia granted summary judgment to plaintiffs, finding the Secretary violated clear statutory language in excluding the CAH
wage data for hospitals that had been paid under the PPS at the time of the relevant survey. Examining the statutory provision, 42 U.S.C. § 1395ww(d)(3)(E)(i), the court found Congress required a survey of wage-related costs of subsection (d) hospitals that “faithfully reflect the actual wage costs of those hospitals in different geographic regions at the time of the survey.” According to the court, the Secretary had no discretion under this statute “to exclude from the survey an entire category of institutions that were subsection (d) hospitals at the time of the survey, nor to choose to exclude those same hospitals when updating the area wage index on the basis of the survey because the Secretary felt those hospitals have ‘substantially different labor costs in many labor market areas where they exist.’”

The court also held, alternatively, that the Secretary’s actions were arbitrary and capricious because he considered factors Congress did not intend him to consider—i.e. that wage data from hospitals that had converted to CAH status after the survey year were “significantly different” and that “removing CAHs from the wage index would have a minimal redistributive effect on Medicare payments to hospitals.” *Anna Jacques Hosp. v. Leavitt*, No. 05-625 (D.D.C. Feb. 26, 2008).

**Federal Government To Pay Hospitals $666 Million To Settle Medicare DSH Dispute**
The federal government will pay $666 million to more than 660 hospitals under a settlement agreement that resolves a long-standing dispute over Medicare disproportionate share hospital (DSH) payments. In April 2006, the U.S. Supreme Court denied review of a D.C. Circuit decision in *Baystate Health Sys. v. Leavitt*, No. 04-5203 (D.C. Cir. July 1, 2005), which required the reopening of certain hospitals' Medicare cost reports to recalculate their DSH payments. The dispute stemmed from a change in Medicare policy regarding the DSH calculation.

In 1986, the Department of Health and Human Services (HHS) Secretary adopted regulations implementing the DSH adjustment statute, which is designed to compensate hospitals serving a disproportionate share of low-income patients. As a result of subsequent litigation invalidating the regulations, the Secretary issued Health Care Financing Administration Ruling 97-2 on February 27, 1997, detailing a new calculation to be applied prospectively only. But hospitals argued that the Secretary should be required to reopen their cost reports to recalculate their DSH payments retroactively. Under the settlement announced March 12, 2008, participating hospitals agreed to dismiss their claims with prejudice.

An attorney with Akin Gump Strauss Hauer & Feld LLP, which represented 70 of the hospitals, said he thought the agreement was the single largest Medicare reimbursement settlement in the program’s history.

**U.S. Court In D.C. Says PRRB Has Jurisdiction To Hear Provider’s Claims Not Previously Brought Before Fiscal Intermediary**
Under Medicare statutes, the Provider Reimbursement Review Board (PRRB) has jurisdiction over a Medicare provider’s appeal claiming dissatisfaction with the total
reimbursement amount determined in a Notice of Program Reimbursement (NPR) for a particular cost year, including reimbursement claims for allowable costs not previously included in the cost report submitted to the fiscal intermediary, the U.S. District Court for the District of Columbia ruled March 7, 2008.

Plaintiff UMDNJ-University Hospital (UMDNJ) submitted to its fiscal intermediary cost reports for fiscal years 2000-2003 that did not claim costs related to its clinical medical education programs (CMEP). For each of the cost reports issued by the fiscal intermediary for these years, UMDNJ filed an appeal of the NPR with the PRRB in accordance with Medicare statutes (42 U.S.C. § 1395oo). In each appeal, UMDNJ contended several issues contained in the NPRs, including whether costs associated with the CMEPs should have been reimbursed in each cost year at issue.

Under 42 U.S.C. § 1395oo(a), a provider must meet certain criteria to obtain a hearing before the PRRB with respect to a cost report, including “dissatisfaction” with a final determination of its fiscal intermediary as to the amount of total program reimbursement due the provider for the period covered by the cost report at issue. Another relevant provision of the statute, 42 U.S.C. § 1395oo(d), confers upon the PRRB the power to affirm, modify, or reverse a fiscal intermediary’s final determination with respect to a cost report and to make any other revisions on matters covered by such report, “even though such matters were not considered by the intermediary in making such determination.”

The fiscal intermediary challenged the PRRB’s jurisdiction to hear the CMEP issue, arguing that because the costs associated with the UMDNJ’s CMEPs had not been claimed as allowable costs when the relevant cost reports were filed, the PRRB lacked jurisdiction on appeal to determine whether reimbursement was required. The PRRB agreed, finding it lacked jurisdiction over UMDNJ’s reimbursement claims pertaining to its CMEPs.

On appeal, UMDNJ argued that it had satisfied all statutory requirements for bringing an appeal before the PRRB set forth in 42 U.S.C. § 1395oo(a), and that the PRRB had jurisdiction under 42 U.S.C. § 1395oo(d) to consider the CMEP issue even though it was not first considered by the fiscal intermediary. UMDNJ also cited Bethesda Hosp. Ass’n v. Bowen, 485 U.S. 399 (1988), in which the Supreme Court held that once the PRRB properly assumes jurisdiction under § 1395oo, it has the power to “make any other revisions on matters covered by such costs report . . . even though such matters were not considered by the intermediary in making such final determination.”

The Secretary of the Department of Health and Human Services (Secretary) argued, however, that UMDNJ did not meet the “dissatisfaction” requirement in 42 U.S.C. § 1395oo(a), and that its reading, as the agency in charge of administering Medicare, was entitled to deference, according to the district court. In addition, relying on dicta in the Bethesda decision, the Secretary argued the case supported its view that a provider’s failure to claim all reimbursement it is entitled to in its cost report constitutes a failure to exhaust administrative remedies before the fiscal intermediary, which establishes that the
The district court acknowledged a split among the circuit courts addressing this issue since the Bethesda decision, with the First and Ninth Circuits adopting an interpretation of 42 U.S.C. § 1395oo similar to that of UMDNJ in the present case, and the Seventh Circuit adopting a statutory interpretation similar to that of the Secretary. The district court ultimately rejected the Secretary’s argument as contrary to the plain language of 42 U.S.C. § 1395oo(a) and (d).

“As §1395oo(a) explicitly requires only dissatisfaction with the total amount of program reimbursement [i.e., not specific reimbursement claims] in order to obtain a hearing, and §1395oo(d) allows the [PRRB] to consider evidence not put before the intermediary and make modifications based upon that evidence, [we] cannot accept the Secretary’s contention that Congress actually intended to impose an issue-specific exhaustion requirement to access administrative appellate review,” the district court said. Under 42 U.S.C. § 1395oo, “[t]here is no such limitation on the [PRRB’s] jurisdiction or upon its power of review once jurisdiction is obtained.” UMDNJ-University Hosp. v. Leavitt, Civ. No. 06-1200 (EGS) (D.D.C. Mar. 7, 2008).

U.S. Court In D.C. Says New Owner Of Nursing Homes Liable For Overpayments During CHOW Period

A nursing care provider that accepted assignment of a former operator’s Medicare provider agreement was liable for $2 million in overpayments resulting from duplicate payments made during the change of ownership (CHOW) period, a federal court in the District of Columbia ruled April 21, 2008. The dispute arose after Triad, which consists of five separate but affiliated nursing care facilities in Georgia, and Brian Center Nursing Care/Austell, Inc., a wholly-owned subsidiary of Mariner Health Care, Inc. (Mariner), both received Medicare reimbursements for the same services provided at the nursing facilities from December 2006 through April 2007.

Triad had been trying to take over Mariner’s facilities for a number of years and eventually filed five 855A applications with the Centers for Medicare and Medicaid Services (CMS) to have Mariner’s Medicare provider agreements assigned to Triad. CMS acknowledged the CHOW for each of the five facilities in April 2007 and indicated the Medicare provider agreements had been “automatically assigned” to Triad effective December 1, 2006. Triad’s fiscal intermediary paid it for services provided at the five homes during the five-month CHOW period. At the same time, Mariner’s fiscal intermediary continued to pay Mariner for services rendered at the facilities, which it had not provided, until it received the change in ownership, or “tie-in,” notices from CMS in April 2007.

CMS then attempted to recoup a roughly $2 million overpayment (i.e. its double payment for the same services) from Triad, which had accepted assignment of Mariner’s provider agreement and thereby agreed to assume liability for any overpayments. Triad sued the CMS Administrator and the Department of Health and Human Services Secretary in their
official capacities (collectively, defendants), arguing they should have to recoup the
overpayments from Mariner.

The U.S. District Court for the District of Columbia dismissed Triad’s claims, finding the
court lacked subject matter jurisdiction under 42 U.S.C. § 405(h) and any amendments to
Triad’s complaint would be futile. On the issue of subject matter jurisdiction, the court
agreed with defendants that Triad had to channel its claims through the administrative
process under 42 U.S.C. § 405(g). The court rejected Triad’s argument that it would be
forced to go out of business if CMS recouped the $2 million overpayment and therefore
requiring it to undergo the lengthy administrative process would effectively deprive it of
meaningful judicial review. Citing the Supreme Court’s decision in *Shalala v. Illinois
Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), the district court concluded that an
individual provider’s delay-related harm is insufficient to demonstrate complete
preclusion of judicial review. Moreover, the court continued, Medicare regulations allow
a provider to negotiate an extended repayment plan based on hardship so it can continue
operations while awaiting administrative review.

The court also refused to allow Triad to amend its complaint, saying to do so would be
futile. Aside from the fact that Triad had not exhausted its administrative remedies, the
court said Triad’s claims failed on the merits. Triad argued that, while it agreed to assume
Mariner’s liabilities at the time it submitted its 855A application, the overpayments in
question occurred *after* the effective date of the assignment, i.e. December 1, 2006. The
court agreed with CMS, however, that the assignment was not instantaneous at the time
Triad submitted its 855A applications. Rather, the provider agreements were not treated
as “assigned” until CMS issued its “tie-in” notices in April 2007. The court found CMS’
interpretation of the regulations reasonable—including, that Medicare must continue paying
the former owner during the CHOW period. To hold otherwise, the court said, “would
allow providers who are ineligible to participate in the Medicare program to receive
Medicare funds simply by submitting an application (even a false application) for a
CHOW.”

Finally, the district court rejected Triad’s argument that it was not responsible for the
overpayments because Mariner’s conduct in accepting Medicare payments for services it
did not provide amounted to fraud. “While Mariner may be liable to Triad for the amount
of the overpayment (and the Court expresses no opinion one way or the other on that
issue), the present record cannot support Triad’s claims that Mariner’s purported fraud
excuses Triad from the liability associated with the Provider Agreements that it
knowingly accepted,” the court said. *Triad at Jeffersonville I, LLC v. Leavitt*, No. 08-329
(CKK) (D.D.C. Apr. 21, 2008).

**Sixth Circuit Upholds Dismissal Of M+C Plan Enrollee’s Lawsuit Alleging
Wrongful Termination Of Medical Care**

A federal district court properly dismissed for lack of subject matter jurisdiction a lawsuit
brought by a Medicare+Choice (M+C) plan enrollee seeking damages for an alleged
wrongful termination of medical care by his M+C plan, a majority of the Sixth Circuit
ruled April 23, 2008. Plaintiff Raymond Giesse was a Kaiser M+C plan enrollee when he
suffered a stroke in June 2003. He initially was treated at a Cleveland hospital and was transferred a month later to a skilled nursing facility (SNF) where he continued to undergo daily physical and occupational therapy. At the end of July 2003, the SNF’s director notified Giesse of her determination that he no longer required daily therapy, and that, as of August 1, Medicare would no longer cover Giesse’s daily SNF benefit. Under Medicare Part B, Giesse was eligible for homebound care with intermittent care on an outpatient basis, however. Despite this information about homecare, Giesse decided to move into an assisted living center, financing the move by selling his house far below market value, according to the appeals court. Giesse received physical, occupational, and speech therapy at the assisted living center on an intermittent basis.

In September 2003, Giesse filed a request with the Kaiser M+C organization (Kaiser) to reconsider the termination of his daily SNF benefits. In his request, Giesse asked Kaiser to rescind its decision and pay damages resulting from out-of-pocket disbursement to the assisted living center, the distress sale of his house, and other damages. After denying his request, Kaiser submitted the case to an independent, external reviewer, which concluded the Giesse’s request was a “grievance” rather than a “valid appeal for medical coverage.” In March 2004, an administrative law judge (ALJ) also dismissed the case, finding that under federal regulations it had no jurisdiction to review the matter because Kaiser had not made a reconsideration decision. The Medicare Appeals Council denied Giesse’s request for review.

Giesse filed a lawsuit in the U.S. District Court for the Northern District of Ohio raising procedural and substantive due process claims and other claims, including federal constitutional tort, breach of contract, and fraud. Giesse sought review of the ALJ’s decision, as well as over $42,000 in monetary damages, and $4 million in compensatory and punitive damages. In the alternative, Giesse sought reversal of the administrative decisions and remand for an administrative hearing with an ALJ. The district court dismissed Giesse’s complaint without prejudice for lack of subject matter jurisdiction and denied Giesse’s motion to file a second amended complaint.

Affirming, the Sixth Circuit agreed with the district court’s conclusion that Giesse’s claims did not constitute appeals from an administrative decision, as defined under M+C regulations, and therefore should be categorized as a “grievance.” In reaching this conclusion, the appeals court noted Giesse did not seek the reinstatement of daily therapy that he had been receiving at the SNF, but instead sought reimbursement of payments made to the assisted living center and millions in damages. “Because these remedies are unavailable forms of relief under the M+C framework, Kaiser was unable to render an ‘organizational determination’ concerning Giesse’s claim,” the appeals court said.

The appeals court rejected Giesse’s arguments that he had a vested property interest in the receipt of Medicare benefits and terminating those benefits without adequate due process, amounted to a deprivation of his constitutional rights. These constitutional claims were “wholly collateral” to his administrative claims, Guisse contended, and therefore did not trigger the prohibition of judicial review of claims “arising under” the Medicare Act. The Sixth Circuit found this argument “flawed at the outset” because it
“presupposes that [Giesse] has a vested ‘property interest’ in 100 days of post-hospital SNF nursing care” under applicable M+C statutes. The appeals court pointed out that the applicable statutes only provide that an enrollee may receive “up to” 100 days of post-hospital extended care, and cited previous decisions in which it held that Medicare does not directly provide any entitlement to the medical services themselves.

The Sixth Circuit also rejected Giesse’s argument that treating his claims as grievances deprived him of any judicial review. “[Giesse] had the option to appeal his administrative determination, which would either result in him obtaining relief in the form of reinstated medical care or in judicial review,” the appeals court said. “It was only [Giesse’s] belief that reinstatement of care would be an inadequate remedy that placed him outside the ambit of reviewable claims," the appeals court said.

A dissenting opinion argued Kaiser’s decision related to Giesse’s reconsideration request was "an organizational determination” that was subject to the Medicare appellate process, and that the district court erred in finding otherwise. Giesse v. Secretary of the Dept of Health and Human Serv., No. 06-4497 (6th Cir. Apr. 23, 2008).

**U.S. Court In D.C. Upholds DHHS Secretary’s Decision Disallowing Nursing Homes’ Reimbursement Claims For Medicare Bad Debts**

A federal district court upheld March 28, 2008 a decision by the Secretary of the Department of Health and Human Services (DHHS) disallowing “bad debts” arising from plaintiff-skilled nursing facilities’ (SNFs’) provision of therapy services paid under Medicare Part B, finding the decision reasonable and not arbitrary, capricious, or an abuse of discretion. The U.S. District Court for the District of Columbia granted summary judgment in favor of DHHS Secretary Michael O. Leavitt (Secretary), finding the denial of the SNFs’ request for reimbursement of the bad debts at issue was consistent with controlling Medicare law and regulations.

Plaintiffs in the case are 21 Medicare-certified SNFs owned and operated by Extendicare Health Services, Inc. (Extendicare). These facilities provide physical, occupational, and speech therapy services for their residents as needed. “For residents who have insurance coverage provided by the Medicare program, some of these therapy services are subject to payment under [both] Medicare Parts A and B,” the district court noted.

Under the Balanced Budget Act of 1997 (BBA), Congress eliminated a cost-based payment methodology for reimbursing SNFs for Medicare Part A services, and replace it with a prospective payment system based on a federal per diem rate for Part A services. The BBA provided, however, that Part B services would be paid for according to a specified physician fee schedule. “Since the enactment of the BBA . . . the Secretary has continued to reimburse bad debts arising under the Part A prospective payment system, but has not reimbursed bad debts arising under the Part B fee schedule,” the district court noted.

Turning to the facts of the case, the district court set the beginning of the underlying dispute at the SNFs’ filing of their fiscal year (FY) 1999 Medicare cost reports. Each of
the SNFs claimed reimbursement for bad debts related to certain uncollectible deductibles and coinsurance arising from therapy services payable under the Part B fee schedule. After auditing these cost reports, the fiscal intermediary issued each SNF a notice of program reimbursement (NPR) disallowing the Part B bad debt claims. The SNFs then pursued a group appeal to the Provider Reimbursement Review Board (PRRB). The PRRB determined the intermediary had improperly denied the SNFs’ bad debts. The Secretary then issued a final decision reversing the PRRB, emphasizing that the BBA changed the basis of payments from reasonable cost to a fee schedule for Medicare Part B services and noting Medicare’s long-standing policy of not paying for bad debts for any services paid under a reasonable charge or fee schedule methodology.

The SNFs appealed to the district court, arguing the Secretary’s final decision was arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with controlling law. Both parties moved for summary judgment. The district court concluded that the Secretary’s decision was a reasonable construction of the applicable law and regulations.

The district court acknowledged that the regulations pertaining to reimbursement of bad debts, 42 C.F.R. § 413.80 et seq., did not specifically address the question at issue. Rather, the regulations “simply lay out the Secretary’s general policy that ‘the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs,’” the court said. However, the district court found, contrary to the SNFs’ claims, “the Secretary’s determination that the bad debt provisions are not applicable to services paid under a fee schedule is certainly plausible given the ambiguity of the regulation’s text.” The district court also concluded the Secretary’s final decision in this case was a “reasonable reading” of the applicable law and regulations, and that therefore it must defer to the Secretary’s interpretation.

Finally, the district court rejected the SNFs’ argument that the Secretary was inconsistent in his application of the bad debt reimbursement policy. “[T]he Secretary has explicitly provided [in 42 C.F.R. § 412.115] that bad debts would be reimbursed for services provided under the inpatient prospective payment system . . . [but] no such rule exists for services provided under the physician fee schedule applicable to Part B services,” the court said. Abington Crest Nursing and Rehabilitation Ctr. v. Leavitt, Civ. No. 06-1932 (RJL) (D.D.C. Mar. 28, 2008).

U.S. Court In California Issues Preliminary Injunction Blocking Clinical Lab Competitive Bidding Demo

The U.S. District Court for the Southern District of California enjoined April 8, 2008 the Department of Health and Human Services (DHHS) from moving ahead with a competitive bidding demonstration for clinical laboratory services provided under Medicare Part B. The court granted Sharp Healthcare, Scripps Health, and Internist Laboratory (collectively, plaintiffs) a preliminary injunction preventing DHHS at this time from selecting winners of the Medicare demo project on April 11, 2008 as planned.
In an October 17, 2007 *Federal Register* notice (72 Fed. Reg. 58856), DHHS announced the San Diego-Carlsbad-San Marcos metropolitan area as the first of two locations for the three-year demo, which was mandated by the Medicare Modernization Act of 2003. The demo is aimed at determining whether competitive bidding could be used to provide laboratory tests under Part B at fees below current payment rates without compromising quality and access to care.

Plaintiffs alleged the DHHS Secretary violated notice and comment requirements of the Administrative Procedure Act (APA) in developing certain demonstration project rules; that several of the rules violated the APA because they are arbitrary, capricious, an abuse of discretion or not otherwise in accordance with the law; that the rules cause a taking in violation of the Fifth Amendment; and that the rules violate the applicable statute by expanding the demo beyond laboratory tests to include the collecting and handling of specimens.

In considering whether to grant the preliminary injunction, the court found plaintiffs had demonstrated the possibility of irreparable harm, both in terms of direct economic injury and an adverse effect on patient care. For example, Sharp and Scripps, both integrated healthcare systems, said their potential inability to participate in the Medicare program if they were not selected would lead to a reduction in services and force them to lay off numerous employees. These plaintiffs also asserted that their integrated medical networks would be disrupted and losing the ability to perform laboratory tests for Medicare patients would delay care and increase the probability of medical errors and miscommunications. Internist, a community-based clinical laboratory, said roughly 65% of its patient base consists of Medicare beneficiaries and it would be forced out of business if it was not selected as a winning bidder. The court concluded that these injuries were not too speculative, even though the Secretary argued that the plaintiffs in question could still be selected as winning bidders.

The court also found the balance of harms tipped “sharply” in plaintiffs’ favor. “The Secretary cannot identify hardships that even remotely rival those identified by Plaintiffs . . . . Given that roughly five years have passed since Congress authorized the project, it is doubtful that a short delay will have a significant impact in the ultimate long term goal of reducing Medicare costs,” the court said.

In addition, the court held plaintiffs had a substantial likelihood of prevailing on the merits of most of their claims. Specifically, the court said plaintiffs established a likelihood of success on their claim that the Secretary violated the APA’s notice and comment requirements. According to the court, a number of random presentations at industry and professional meetings held before the October 2007 notice establishing the demo were not sufficient to meet these requirements.

The court also concluded that plaintiffs were likely to succeed in their challenge to the Secretary’s interpretation of the “face-to-face” exception in the statute, 42 U.S.C. § 1365w-3(e)(1). The relevant statutory language states the demo applies only to clinical diagnostic laboratory tests “which are furnished by entities that did not have a face-to-
face encounter with the individual.” The Secretary, however, interpreted the “face-to-face” exception as applying only to laboratories located in a physician’s office or hospital laboratories for their own patients. This interpretation, the court said, altered the unambiguous language of the statute and violated the APA.

Similarly, the court held plaintiffs had established a likelihood of success on their claim that the Secretary had impermissibly expanded the scope of the demo to the collection of patient specimens. According to the court, the statutory language unambiguously established that the demo was for clinical diagnostic laboratory tests only, not specimen collection. Sharp Healthcare v. Leavitt, No. 08-CV-0170 W (S.D. Cal. Apr. 8, 2008).

Ninth Circuit Upholds DHHS Interpretation Of “Available Beds” In Formula Used To Calculate Hospital’s IME Medicare Payment

The Department of Health and Human Services (DHHS) Secretary’s interpretation that the term “available beds” in the Medicare statute and regulations pertaining to indirect medical education expenses (IME) reimbursement means “physical beds,” rather than “budgeted beds,” was not arbitrary and capricious or otherwise an abuse of discretion, the Ninth Circuit ruled March 31, 2008 in a 2-1 decision. The appeals court affirmed a federal district court’s decision upholding a final determination by the Provider Reimbursement Review Board (PRRB) that the fiscal intermediary for a public teaching hospital properly used a physical bed count in calculating the hospital’s IME adjustment.

The hospital, Los Angeles County/University of Southern California Medical Center (County/USA), is subject to Medicare’s inpatient prospective payment system, and entitled to an additional payment to cover the added costs of IME. The relevant statutory provision, 42 U.S.C. § 1395ww(d)(5)(B), provides that the amount of the IME adjustment is based on a hospital’s ratio of full-time equivalent interns and residents to available beds. “The calculation is complicated, but the bottom line is that the higher the number of beds the lower the eventual payment and vice versa,” the appeals court explained.

County/USC used “budgeted beds” as the number of “available beds” estimated in its cost reports sent to its fiscal intermediary from 1986 through 1993, and the intermediary calculated its IME payment based on this number. For fiscal year (FY) 1994, however, the intermediary increased the bed count based upon its finding that the “budgeted beds” number understated by 123 beds the number of beds physically available in County/USA's inpatient areas. County/USA appealed to the PRRB.

After the PRRB issued a decision concluding that the intermediary properly used the number of County/USC’s physical beds as a measure of the available beds for calculating IME payments, County/USC appealed. When the DHHS Secretary declined review of the case, the PRRB’s decision became DHHS’ final decision. County/USC sought review of that decision in federal district court. The U.S. District Court for the Central District of California subsequently granted summary judgment in favor of the Secretary.
On appeal to the Ninth Circuit, County/USC argued that it was arbitrary and capricious for the Secretary to move from using budgeted beds to using physical beds without an explanation. At the outset of the majority opinion, the Ninth Circuit noted that the Secretary’s interpretation of “available beds” as presumptively meaning physical beds was entitled to deference as long as such interpretation was reasonable. The appeals court acknowledged federal case law holding an agency that changes its course must supply a reasoned analysis indicating that “prior policies and standards are being deliberately changed, not casually ignored.” But the appeals court found this rule did not apply here because it was the fiscal intermediary, not the Secretary, that approved County/USC’s claims for IME payments based on budgeted beds. Moreover, “County/USC points to no decision by the PRRB or the Secretary that embraces a budgeted-bed approach, nor does it suggest that the Secretary has taken inconsistent litigation or rule-making positions on this issue,” the appeals court continued.

The fiscal intermediary’s approvals based on a budgeted beds calculation did not make the Secretary’s determination that the intermediary properly used a physical bed count for FY 1994 arbitrary and capricious, the Ninth Circuit concluded. “[While] the Secretary’s judgment is that a facility’s size is what relates to teaching load and that the best measure of this is the number of beds maintained for use,” the appeals court said, County/USC counters that budget resources (i.e., beds) are the appropriate measure for publicly funded hospitals. Concluding the Secretary’s view was “reasonably grounded in the statutory scheme,” the Ninth Circuit emphasized that Congress “chose to gauge the extra cost of the teaching load by reference to available beds rather than available staffing.” Therefore, “we cannot say that the [S]ecretary unreasonably pegged the formula to an actual bed count rather than a budgeted bed count that turns on staffing,” the appeals court said.

A dissenting opinion said the PRRB’s decision was arbitrary and capricious because it disregarded substantial evidence presented by County/USC in support of its argument that the 123 physical beds at issue were not actually available for patient use during the year and therefore should have been excluded from the IME calculation. In addition, County/USA met its burden of showing that the budgeted beds figure more accurately reflected the actual number of available beds at County/USC in FY 1994 than the physical beds figure, the dissenting opinion said. County of Los Angeles v. Leavitt, No. 06-55222 (9th Cir. Mar. 31, 2008).

U.S. Court In D.C. Rejects Challenge To Regulations Affecting Hospital Wages And Wage-Related Costs Adjustment
A federal district court in the District of Columbia rejected March 26, 2008 a lawsuit brought by 113 Alabama hospitals alleging the Department of Health and Human Services Secretary exceeded his statutory authority in promulgating regulations for adjusting the proportion of hospitals’ costs that are attributable to wages and wage-related costs. The U.S. District Court for the District of Columbia found plaintiff hospitals failed to show the regulations were unambiguously forbidden by the statute or otherwise exceeded permissible bounds and therefore granted summary judgment to the Secretary.
The dispute centered on certain regulations implementing a provision of the Medicare Act, 42 U.S.C. § 1395ww(d)(3)(E), that calls for an adjustment to hospital payments under the inpatient prospective payment system (IPPS) to account “for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.” At issue was the amount of reimbursement the hospitals received under the IPPS for fiscal years 2003 and 2004.

The court first rejected the hospitals’ argument that the Secretary impermissibly included the cost of workers compensation, fees paid to outside consultants, and fringe benefits—such as employee health, dental disability, and life insurance—as wages and wage-related costs. A plain text reading of the statute did not support such limitations on what constitutes wages and wage-related costs, the court found. The court likewise rejected the hospitals’ argument that only hospital wage and wage-related costs that vary locally should be included in the applicable calculation. The court again said the hospitals’ contention could not be squared with the statutory language, which did not use the word “local” and instead referred to “area differences,” “geographic area,” and “national average.”

The hospitals also asserted the Secretary’s failure to implement a congressional mandate to collect data on occupational mix for the 1987-2003 period resulted in lower reimbursement in 2002 and 2003 than they actually should have received. The court noted that, before September 30, 2003, there were no deadlines to collect occupational mix data. Moreover, at that point, Congress only directed the collection of occupational mix data “to the extent deemed feasible by the Secretary.” Southeast Ala. Med. Ctr. v. Leavitt, No. 04-1143 (RWR) (D.D.C. Mar. 26, 2008).

U.S. Court In Massachusetts Allows Due Process Claim Alleging DHHS' Failure To Timely Correct Part D Premium Withholding Errors

The U.S. District Court for the District of Massachusetts, in an April 9, 2008 decision, declined to dismiss plaintiff-Medicare Part D beneficiaries’ claim that the Department of Health and Human Services (DHHS) and the Social Security Administration (SSA) violated their due process rights by failing to timely correct errors in calculating and withholding plaintiffs’ prescription drug plan premiums. Recognizing that an unreasonable delay in processing an entitlement constitutes a constitutional violation of due process, the district court said it needed more information about the cause of the delays before judging the legal viability of plaintiffs’ due process claim. The district court did dismiss, however, plaintiffs’ allegations that DHHS and SSA (collectively, defendants) violated the Medicare Prescription Drug, Modernization and Improvement Act (MMA), 42 U.S.C. §§ 1395w-101 et seq., by withholding excessive premiums and then delaying the refund of these improperly withheld amounts.

Plaintiffs are participants in the Medicare Part D prescription drug benefit program, under which they have several options as to how they will pay required monthly premiums to the provider offering the benefit plan they select. Those options include paying directly or requesting that premiums be deducted from Social Security benefits. If the option of
paying premiums through Social Security withholding is elected, MMA provisions require SSA and the Centers for Medicare and Medicaid Services (CMS) to communicate regarding the correct premium amounts to be deducted from the Part D enrollee’s Social Security benefits “by the beginning of each year,” the district court explained. In addition, DHHS is required to properly update that information periodically throughout the year “by means of supplemental communication” with SSA.

In their lawsuit, plaintiffs alleged that defendants violated the MMA’s communication provisions and their due process rights by negligently withholding incorrect and excessive premium amounts from their Social Security checks and refunding those withheld amounts only after unreasonable delay. Plaintiffs sought an injunction directing defendants “to cease improperly retaining withheld Part D premium amounts,” “to refund to beneficiaries on a prompt and efficient basis all premium amounts that have been improperly withheld to date,” and to take other steps as necessary to protect beneficiaries’ rights to elect how to pay their premiums and to choose their prescription drug benefit plans.

The district court first rejected plaintiffs’ claim based on violation of the MMA’s communication provisions, noting that the MMA sets no deadline by which defendants must correct premium withholding errors and no time limit within which CMS must refund any incorrectly withheld benefits. “It is hard to see how these implementing provisions can be construed to constitute a vehicle for redress of inevitable errors and delay,” the district court said.

As for plaintiffs’ due process claim, the district court said “it is well-established that a sufficiently egregious delay in processing or awarding an entitlement may constitute a remediable constitutional violation, even if the relevant statutory framework does not specify a timeline for agency action.” Such delays, most of which were in the range of five to thirteen months, “were undisputably substantial,” the district court said, noting that “the magnitude of the delays [was] especially significant for plaintiffs, most of whom had no other source of income besides their Social Security benefits.”

While acknowledging the complexity of the Medicare Part D program, the district court said “the errors in question . . . appear to have been relatively straightforward, and the justification for delays of several months or [more] . . . is unclear in the context before the court now.” The district court therefore concluded plaintiffs’ due process claim “cannot be resolved on the pleadings alone,” and allowed the claim to proceed for further factual development. *Machado v. Leavitt*, Civ. Action No. 07-30111-MAP (D. Mass. Apr. 9, 2008).

**U.S. Court In D.C. Enjoins Enforcement Of DHHS Anti-Markup Rule**

A federal court in D.C. issued a preliminary injunction March 31, 2008 blocking enforcement of the so-called anti-markup rule as it applies to anatomic pathology diagnostic testing services furnished in a centralized building. The Secretary of the Department of Health and Human Services (DHHS) issued the anti-markup rule in November 2007 (72 Fed. Reg. 38122). Subsequently, on January 2, 2008, DHHS issued a
final rule delaying the application of the anti-markup rule for one year to services other than anatomic pathology diagnostic testing services furnished in a “centralized building” that does not qualify as a “same building.” See 73 Fed. Reg. 404. The anti-markup rule would limit payment for anatomic pathology diagnostic testing services performed at a “site other than the office of the billing physician or other supplier” to the lesser of: (1) the performing supplier’s net charge to the billing physician or other supplier; (2) the billing physician or other supplier’s actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

Plaintiffs, three urology physician group practices that own and operate pathology laboratories, Dr. Sam Michaels, a self-employed pathologist who performs testing services for other physician groups, and Uropath, LLC, a company that manages various pathology laboratories and its director of clinical operations, sued DHHS seeking to enjoin and invalidate the final rule. DHHS moved to dismiss for lack of jurisdiction. The U.S. District Court for the District of Columbia refused to consider the jurisdiction issue, holding that it need not do so prior to entering a preliminary injunction.

Turning to the preliminary injunction, the court first found that plaintiffs had shown a likelihood of success on the merits. Noting that the “Secretary issued the Final Rule without notice and comment,” the court said “this constitutes evidence in support of a finding of arbitrary and capricious rulemaking, evidence sufficient to support a preliminary injunction.” Second, the court found plaintiffs sufficiently demonstrated irreparable harm as they had shown that they would lose their business if the anti-markup rule went into effect. Third, the court noted no other interested parties who would be affected by the issuance of a preliminary injunction. Lastly, the court said that public policy favors fair and open agency rulemaking. Accordingly, the court issued a preliminary injunction enjoining the Secretary from enforcing the anti-markup rule as to anatomic pathology diagnostic testing services furnished in a centralized building. Atlantic Urological Assocs., P.A. v. Leavitt, No. 08-141 (RMC) (D.D.C. Mar. 31, 2008).

In a subsequent development, the U.S. District Court for the District of Columbia vacated the preliminary injunction and concluded it lacked jurisdiction to hear plaintiffs’ claims because the final rule delaying application of the anti-markup rule did not affect them. The district court in the May 5, 2008 ruling noted “[t]he Anti-Markup Rule that issued in November 2007, after multi-year consideration and a full blown administrative process, is what changed the Medicare billing landscape for pod laboratories, including those managed by Uropath,” the district court said. Since the January 2008 final rule “did not change anything for these Plaintiffs, invalidating it would not afford them any relief.”

The district court also said that, to the extent that plaintiffs sought to have a suspension of the anti-markup rule applied to them as well as all other diagnostic testing services, it was unclear whether it had such “modification authority,” without any evidence that the order was arbitrary and capricious, or promulgated in violation of the Administrative Procedure Act.
Further, the district court noted that, even if plaintiffs had standing, it must dismiss the case because it lacked jurisdiction to hear claims “arising under” the Medicare Act prior to plaintiffs’ exhausting their administrative remedies. The district court rejected plaintiffs’ argument that requiring them to proceed through the administrative process would drive them out of the diagnostic testing business, and therefore deprive them any judicial review of their claims. “Plaintiffs overstate their case,” the district court said. They “can submit their claims for reimbursement, noting their disagreement with the application of the Anti-Markup Rule, and then pursue an administrative challenge.” *Atlantic Urological Assocs., P.A. v. Leavitt*, No. 1:08-cv-00141-RMC (D.D.C. May 5, 2008).

**PATIENT SAFETY**

**Joint Commission Announces 2008 Patient Safety Goals**
The Joint Commission announced June 25, 2007 its 2008 National Patient Safety Goals and related requirements for each of its accreditation programs and its disease-specific care certification program. Compliance with the requirements set out in the Goals is a condition for continuing accreditation or certification for Joint Commission-accredited or certified organizations. One significant change in the Goals for 2008 is the addition of a new requirement to take specific actions to reduce the risks of patient harm associated with the use of anticoagulant therapy. Another new Goal is directed at improving the recognition of, and response to, unexpected deterioration in a patient’s condition. The new requirement in this area calls for hospitals “to select a suitable method for enabling caregivers to directly request and obtain assistance from a specially-trained individual(s) if and when a patient’s condition worsens.” Both of these new requirements will be phased in over a one-year period that includes “defined milestones,” with full implementation slated for January 2009. Also, an existing requirement to assure the timely reporting of critical test results has been extended to the long term care program. Finally, another existing requirement to limit and standardize drug concentrations to improve the safety of using medication will be “retired” for 2008, but will continue to be evaluated as part of the Joint Commission’s medication management standards, the release said.

**Physicians Onboard With Discussing Medical Errors, But Skeptical About Current Reporting Systems**
Only 30% of physicians were satisfied with the adequacy of current systems for reporting medical errors, according to a study funded by the Department of Health and Human Services’ Agency for Healthcare Research and Quality (AHRQ). The study, which appeared in the online journal *Health Affairs*, concluded that physicians are willing to report and learn from medical errors, but rely mostly on informal discussions with their colleagues, AHRQ said. “As a result, such information is not aggregated for analysis and systemic improvement.”

The study involved a poll conducted between July 2003 and March 2004 of more than 1,000 geographically diverse physicians and surgeons practicing in rural and urban areas in Missouri and Washington state. Fifty-six percent of the physicians reported a prior
involvement with a serious error, 74% with a minor error, and 66% with a near miss, the study found. According to AHRQ, 83% of those surveyed said they had used at least one formal reporting mechanism, most commonly reporting an error to risk management (68%) or completing an incident report (60%).

But few physicians thought they had access to reporting systems that improved patient safety, and nearly half (45%) did not know if one existed at their organization. Physicians said they would be more willing to formally report medical errors if they were assured that information would be kept confidential and non-discoverable (88%); that information would be used to improve patient safety (85%) and not for punitive action (84%); that the error-reporting process would take less than two minutes (66%); and that review activities would be confined to their department (53%).

**Aetna Incorporates “Never Events” Policy In Hospital Contracts**

Aetna announced January 15, 2008 that it is incorporating language in its template for hospital contracts regarding so-called “never events,”—medical errors that are such a threat to patient safety they should never happen. According to Aetna’s press release, it is the first health plan to endorse the Leapfrog Group’s approach to “never events.” The language, which will be used in negotiations or renegotiations that involve a new contract, calls on hospitals to report the medical error to either the Joint Commission, state reporting programs for medical errors, or patient safety organizations within 10 days of becoming aware of the occurrence. The language also asks hospitals to take action to prevent future events, waive all costs related to the “never event,” and apologize to the affected patient and family, the release said.

The National Quality Forum has compiled a list of “never events” that include surgery performed on the wrong body part or the wrong patient, leaving a foreign object inside a patient after surgery, or discharging an infant to the wrong person. “More than 600 hospitals across the country already have agreed to report these events voluntarily. We want to support their leadership and safer health care for all patients,” said Aetna’s Chief Medical Officer Troyen Brennan, M.D.

**CMS Issues Much-Anticipated Proposal Implementing Patient Safety Act**

The Centers for Medicare and Medicaid Services (CMS) published in the February 12, 2007 Federal Register (73 Fed. Reg 8112) the much-anticipated proposed rule to implement patient safety legislation enacted in 2005 to promote medical error reporting. The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, sets forth privilege and confidentiality protections in civil and criminal proceedings to “patient safety work product” reported by providers to new patient safety organizations (PSOs). The PSOs will then collect, aggregate, and analyze the data to identify ways to prevent medical errors.

In the proposed rule, the Department of Health and Human Services (DHHS) noted that state-based peer review protections are limited in that they only apply in the hospital setting, seldom allow for the pooling or sharing of data, and do not exist in all jurisdictions. According to DHHS, strong federal confidentiality and privilege protections
for information that is patient safety work product “will enable all health care providers, including multi-facility health care systems to share data within a protected legal environment, both within and across states,” without the fear of litigation.

The proposed rule establishes the process for certification and listing of PSOs, which would be implemented by the Agency for Healthcare Research and Quality. Under the proposal, most types of organizations—public, private, for-profit, and not-for-profit—could become PSOs. DHHS noted that the statute prohibits health insurance issuers from becoming PSOs, and the agency also proposed precluding entities that conduct regulatory oversight of healthcare providers, including accreditation or licensure, from seeking listing as a PSO. According to DHHS, allowing organizations with regulatory authority as PSOs could undermine provider confidence “that adequate separation of PSO and regulatory activities would be maintained.”

PSOs would be required to seek contracts with multiple providers, DHHS said in the rule. For the most part, PSOs could aggregate patient safety work product from their multiple clients and with other PSOs, DHHS added. DHHS cautioned that, per the statute, PSOs are deemed business associates of covered entities under the Health Insurance Portability and Accountability Act (HIPAA). Thus, HIPAA covered entities will need to enter into business associate agreements with PSOs.

In addition, the proposed rule sets forth confidentiality protections for “patient safety work product,” permitted disclosures, and the conditions under which the specific protections no longer apply. The proposal also establishes procedures for imposing civil money penalties, up to $10,000 per violation, in the event of a knowing or reckless impermissible disclosure of patient safety work product. Comments on the proposed rule were due April 14, 2008.

PHYSICIANS

Tennessee High Court Holds Information Otherwise Available From Original Sources Is Discoverable But Not From Peer Review Committee

Information provided to a hospital’s credentialing committee that is “otherwise available from original sources” may be discoverable, but not directly from the committee and only to the extent the information is not otherwise privileged, the Tennessee Supreme Court ruled May 14, 2007. Dr. Alexander Stratienko, a physician at Erlanger Hospital in Chattanooga, Tennessee, was involved in a physical altercation at the hospital with another physician, Dr. Stephen Monroe. Following this incident, the Chattanooga-Hamilton County Hospital Authority, which owns and operates the hospital, suspended Stratienko’s privileges and recommended that he be evaluated by the Tennessee Medical Foundation’s Physicians Health Program. Stratienko sought and obtained a temporary restraining order prohibiting the Hospital Authority from suspending his hospital privileges pending an evidentiary hearing. After the Medical Executive Committee upheld the suspension, the Hospital Authority moved for dissolution of the temporary restraining order.
As part of the discovery process, Stratienko requested copies of Monroe’s credentials. The Hospital Authority refused, contending the credentialing documents were confidential and protected from disclosure by Tennessee’s peer review statute, Tenn. Code. Ann. § 63-6-219. Stratienko moved to compel production. The trial court denied the motion to compel, finding the documents were privileged, but granted Stratienko permission to take an interlocutory appeal on the issue. The appeals court reversed, holding that documents and information “otherwise available from original sources” are subject to discovery from a peer review committee as well as directly from the original source.

The Tennessee Supreme Court reversed in part, concluding that while such documents are discoverable, they may not be obtained from the peer review committee. The broad protection of the peer review privilege statute excepts from its scope “records made in the regular course of business” and “information documents or records otherwise available from original sources . . . merely because they were presented during proceedings of such committee.” The high court said the statutory language was ambiguous, but concluded that Stratienko’s interpretation—i.e. permitting discovery of original source documents in the possession of the peer review committee—would undermine the legislative intent behind the law to encourage confidentiality in the peer review process.

According to the high court, the peer review statute makes clear that all information “furnished to” a peer review committee from an original source is shielded from discovery. Under the high court’s reading of the statute, “information that is available from a source other than the committee does not become privileged simply by being acquired by the review committee.” Thus, Stratienko may discover “information, documents or records otherwise available from original sources” to the extent he does not seek them from the peer review committee and they are not otherwise privileged. “If information ‘otherwise available from original sources’ were excluded from the protection of the Peer Review Law, then most documents gathered during the peer review process would be subject to discovery from the peer review committee.” This interpretation “could have a chilling effect on the furnishing of information to peer review committees,” the high court held. Stratienko v. Chattanooga-Hamilton County Hosp. Auth., No. E2005-01043-SC-S09-CV (Tenn. May 14, 2007).

Oklahoma High Court Reinstates Physician’s Suit Against Hospital, Finding Peer Review Statute Does Not Provide Blanket Immunity

The Oklahoma high court found the state’s peer review statute only provides immunity from liability under certain conditions and does not provide blanket immunity from suit. Reversing a lower court’s grant of summary judgment to a hospital, members of its credentialing committee, and others, the high court held the defendants must first show they are immune from liability under the statute.

Jeffery J. Smith, M.D. is a gynecological oncologist and surgeon with privileges at Deaconess Hospital. After 16 of Smith’s patient charts were reviewed by a quality review organization, Deaconess’ Hospital Credentialing Committee recommended denial of Smith’s reappointment based on the anonymous report. The Medical Executive
Committee (MEC) approved the recommendation, as did other levels of appeal. Smith sued Deaconess, its then President, its Vice-President of Medical Affairs, practically every member of the Credentialing Committee, the MEC, the Fair Hearing Panel, and the Appellate Committee. Defendants moved to dismiss on the grounds of qualified immunity. The trial court granted defendants’ motion and Smith appealed.

The Oklahoma Supreme Court noted the state’s peer review statute “does not provide immunity from suit, but rather a defense to liability,” adding “the immunity once enjoyed by private hospitals under the common law, has been superseded by this statute.” The high court found defendants would be entitled to qualified statutory immunity from liability—not from suit—provided they could prove they met all the conditions listed in the statute. Accordingly, the high court reversed the dismissal and remanded to the trial court for further proceedings on this issue. *Smith v. Deaconess Hosp.*, No. 103876 (Okla. May 29, 2007).

**Eleventh Circuit Finds No Peer Review Privilege In Federal Civil Rights Cases**

The Eleventh Circuit held June 12, 2007 that the peer review privilege does not apply in federal civil rights cases. Although it was an issue of first impression in the Eleventh Circuit, the court joined the Fourth and Seventh Circuits in finding no privilege in federal courts. Dr. Russell Adkins was a staff physician with privileges at the Houston Medical Center (HMC). According to Adkins, he was treated differently from the start of his employment because of his African American race. Adkins eventually filed a federal civil rights action against the hospital and several HMC physicians (defendants) pursuant to 42 U.S.C. §§ 1983, 1981, and 1985.

Defendants moved to dismiss claiming qualified immunity. Adkins requested documents relating to peer review of all physicians at the hospital during the seven years that Adkins was a hospital staff member. In response, defendants moved for a protective order, arguing that Adkins was seeking information relating to the peer review process, which was covered by the Georgia medical peer review privilege. The trial court found the peer review privilege applied to federal civil rights claims, but nevertheless, ordered defendants to provide descriptions of all incidents giving rise to peer review, without disclosing the documents themselves. The court also limited production to documents relating to physicians in the Department of Surgery during a five-year time period, rather than documents relating to all physicians with staff privileges during the seven-year time period as requested by Adkins. After reviewing the documents, the trial court granted summary judgment to defendants.

After noting that privileges are disfavored in federal courts, the Eleventh Circuit found the peer review privilege does not apply in federal court. While acknowledging the interests HMC sought to protect, the appeals court concluded the interest of eliminating employment discrimination was paramount. The documents at issue are "critical to Adkins' discrimination claims" because the "only way that Adkins can demonstrate the existence of disparate treatment in his case against the hospital is to compare his peer review with the peer review files of other physicians at HMC," the appeals court said. Moreover, HMC had other protections available to it, including protective orders,
confidentiality agreements, and when appropriate, disclosure only after an in camera review of these documents. The appeals court also distinguished between the interests at issue in a discrimination case and those in a malpractice case. The appeals court also found the trial court erred in limiting Adkins' scope of discovery. According to the appeals court, "Adkins is entitled to compare the general standard that hospital physicians were held to in order to establish that his punishment was excessive." *Adkins v. Christie*, No. 06-13107 (11th Cir. June 12, 2007).

**Minnesota Appeals Court Upholds State Board Of Medicine’s Temporary Suspension Of Physician’s License**

Upholding a decision by the Minnesota State Board of Medical Practice (Board) to temporarily suspend a physician’s medical license, the Minnesota Court of Appeals in a June 26, 2007 opinion rejected the physician’s argument that the Board's disciplinary proceedings violated his due process rights because it applied a “preponderance of evidence” rather than a "clear and convincing" standard of proof. The Board’s Complaint Review Committee filed a petition seeking to have Dr. Fatih M. Uckun’s medical license temporarily suspended. The committee undertook this action based on a two-year investigation into patient-care complaints. Following a hearing during which Uckun was allowed to make an oral presentation, but not to present live testimony or cross-examine witnesses, the Board concluded his continued practice would create a serious risk of harm to others and temporarily suspended his license pending a final decision after a contested case hearing.

The appeals court found Minnesota law supported the conclusion that the Board properly applied the preponderance of evidence standard of proof in its temporary suspension of Uckun’s license. Minnesota administrative rules specify that the preponderance of evidence standard applies “unless the substantive law provides a different burden or standard.” The appeals court also noted that Minnesota case law did not support the use of the clear and convincing evidence standard at a preliminary stage of disciplinary proceedings, i.e., a temporary suspension pending a contested case hearing. The appeals court noted that, even at the contested hearing stage of suspension proceedings, Minnesota courts have applied the preponderance of evidence standard for both dentists and physicians. In summarily rejecting Uckun’s claims based on his due process rights under the Fourteenth Amendment of the U.S. Constitution, the appeals court found that the state’s interest in protecting the public from serious risk of harm resulting from incompetent or irresponsible physicians outweighed Uckun’s claimed property and liberty interests in this case. *Uckun v. Minnesota State Bd. of Med. Practice*, No. A06-1365 (Minn. Ct. App. June 26, 2007).

**Tenth Circuit Finds Hospital Did Not Violate Radiologist’s Due Process Rights By Signing Exclusive Contract With Another Provider**

A hospital did not violate the due process rights of a radiologist who held privileges there when it entered into an exclusive contract with another provider and closed its radiology department to radiologists who were not part of the group, the Tenth Circuit ruled July 6, 2007. Plaintiff Dr. Robert L.G. Stears sued Sheridan County Memorial Hospital claiming it violated his due process rights under 42 U.S.C. § 1983 by denying him access to its
radiology department; the terms of the bylaws by entering into an exclusive contract with a different provider without providing him a hearing; and a state statute that allows physicians to practice in public hospitals pursuant to "reasonable and uniform rules and regulations covering staff admissions and staff privileges.”

As to his procedural due process claim, the Tenth Circuit found Stears was not deprived of a protected property interest, i.e. his hospital privileges, even if he could not exercise them. “The distinction between having medical staff privileges and being able to exercise those privileges is not a ‘fiction,” the appeals court said. As a non-employee of the new radiology group, he was not legitimately entitled to exercise his privileges, the appeals court reasoned.

According to Stears, his privileges were effectively reduced and therefore he should have received notice and a hearing under the bylaws. But the appeals court disagreed, noting that Stears was still a member of the active medical staff, with its attendant rights, and that the hospital’s decision to obtain a new exclusive provider of radiology services did not reflect negatively on his professional competence.

The appeals court also rejected Stears’ claim that the hospital breached its bylaws by entering into an exclusive contract with the radiology department without providing him a hearing. The procedural requirements of the bylaws to provide a hearing are not invoked where, as here, the hospital’s action was the result of a business decision to use an exclusive contract and did not involve a corrective action taken directly against Stears regarding his competence, the appeals court reiterated.

Finally, the appeals court found Stears’ state law claim without merit. Even if the statute created an expectation of enjoyment of staff privileges subject only to reasonable and uniform regulations, his staff privileges “have not been revoked” within the meaning of the bylaws. Stears v. Sheridan County Mem’l Hosp. Bd. of Trustees, No. 05-8092 (10th Cir. June 27, 2007).

**Eighth Circuit Upholds Revocation Of Physician’s License For Repeated Failure To File State Income Tax Returns**

The temporary revocation of a Missouri physician’s medical license for his repeated failure to file state income taxes did not violate the physician’s rights to due process and equal protection, the Eighth Circuit ruled July 27. Affirming a lower court’s grant of summary judgment in favor of the Missouri Director of Revenue (Director) and Missouri’s Board of the Healing Arts (Board), the appeals court concluded that the state statute at issue, Mo. Rev. Stat. § 324.010, which authorized the Director to revoke licenses on the basis of tax deficiencies or failure to file tax returns, did not violate the physician’s rights under federal or Missouri law.

Mo. Rev. Stat. § 324.010 requires many state licensing boards to report the names and social security numbers of licensees to the Director. If the Director discovers that any licensee is delinquent on state taxes or has failed to file a tax return in the last three years, the Director must send the licensee a notice indicating this delinquency or failure. In
practice, unless the Director verifies that the licensee is making arrangements to remedy the problem, the licensee’s license is revoked 90 days after the mailing of the notice.

Dr. Jerry Crum received from the Board in late 2003 a license renewal packet containing a renewal application and other information, including a note that explained requirements set forth in Mo. Rev. Stat. § 324.010. The Department of Revenue (Department) subsequently notified Crum that he had not filed his state income tax returns for 2000, 2001, and 2002 that, if he failed to do so within 90 days, his Missouri medical license would be revoked by operation of law. The Department received no response, and over three years later, mailed Crum notices of deficiency for tax years 2000, 2001, and 2002 totaling over $47,500 in tax liability. When Crum failed to respond, the Director sent a certificate of non-compliance to the Board, stating that Crum’s medical license would be revoked pursuant to § 324.010 in July 2004.

In September 2004, Crum filed his returns for the years at issue, and the Department issued him a certificate of tax compliance. Crum then presented this certificate to the Board, which reinstated his license the same day. Crum subsequently filed a lawsuit in federal court against the Director and the Board, seeking declaration that § 324.010 violated his due process and equal protection rights and that the revocation of his license was void. Crum also sought an injunction directing the Board to expunge all records of the revocation.

The Eighth Circuit rejected Crum’s argument that § 324.010 deprives a licensee of property without due process of law, in violation of federal and state constitutions, noting the Department repeatedly provided him with notice that he had failed to file his tax returns and with information indicating that this failure could lead to the revocation of his license. In addition, the appeals court found that the Department satisfied the requirements of due process by giving Crum an opportunity for a hearing at a meaningful time and in a meaningful manner. “The tax deficiency notices mailed to Crum in April explained how he could request a hearing to challenge the Department’s assessment,” the appeals court said, adding that Crum never received such a hearing “simply because he never requested one.”

The appeals court also rejected Crum’s argument that § 324.010 infringed his right to equal protection of the laws because it did not apply to certain professional licensees, such as security brokers and teachers, or to practitioners of unlicensed professions. The appeals court concluded that this distinction did not amount to an equal protection violation under rational-basis review, noting several plausible reasons for imposing higher penalties on licensed professionals who fail to meet their Missouri tax obligations than on those without licenses. “The General Assembly may have perceived licensed professionals as more financially secure and better educated, thus increasing the amount of tax they likely owe and making their neglect less excusable,” the appeals court said. In addition, the appeals court noted that state boards already monitor licensees, and therefore, the General Assembly may have decided that limiting § 324.010 to licensees would be “a more efficient way to increase tax compliance than a statute that applied more broadly.” Crum v. Vincent, No. 06-3471 (8th Cir. July 27, 2007).
New York Appeals Court Upholds Physician’s License Suspension Following Conviction For Violating Anti-Kickback Statute

A New York appeals court upheld August 2, 2007 the state medical board’s penalty of license revocation imposed on a physician who had pled guilty to receiving illegal kickbacks. Plaintiff Andre B. Celestin was licensed to practice medicine in New York. He was convicted, after pleading guilty, of violating the Anti-Kickback Statute by accepting $6,000 in illegal referral fees from another doctor. The Administrative Review Board for Professional Medical Conduct (ARB) subsequently revoked plaintiff’s license to practice medicine in New York. In so holding, the ARB overturned the recommended penalty of the Hearing Committee, which recommended that plaintiff be censured and reprimanded and that his license be suspended for three months.

On appeal, the New York Supreme Court, Appellate Division, Third Department, affirmed. According to the appeals court, “even taking into consideration petitioner’s self-proclaimed modest lifestyle, dedication to underprivileged populations and contributions to society generally,” the penalty of revocation was not “so incommensurate with the offense as to shock one’s sense of fairness.” The appeals court noted plaintiff’s argument that no patient was harmed by his conduct and that the $6,000 in kickbacks was “not a particularly large amount.” However, the appeals court pointed out that plaintiff refused to accept responsibility for the kickbacks and stated that “the refusal to accept responsibility for prior wrongful conduct is a significant factor in assessing an appropriate penalty.” Celestin v. Novello, No. 2007 N.Y. Slip Op. 06324 (N.Y. Sup. Ct. App. Div. Aug. 2, 2007).

Sixth Circuit Finds OSU Medical Facilities Properly Revoked Physician's Privileges

In an unpublished decision issued August 8, 2007, the Sixth Circuit upheld the dismissal of a physician’s action against the defendant-healthcare facilities affiliated with the Ohio State University (OSU) healthcare system alleging the revocation of his medical privileges amounted to a violation of his due process rights or discrimination on the basis of national origin. Plaintiff-physician, David Benjamin, is an Iraqi-born Israeli and a naturalized citizen of the United States. Benjamin was hired by the OSU College of Medicine as a researcher and faculty member and granted full medical privileges at the OSU Medical Center and the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (James Institute). OSU Medical Center’s Department of Internal Medicine subsequently adopted a requirement that all members of the medical staff be board certified in a medical specialty. Benjamin was initially granted a waiver from this requirement, but his privileges were ultimately revoked after he failed subsequent exams for board certification.

The Sixth Circuit first rejected Benjamin’s argument that he was denied procedural due process in the peer review proceedings. The appeals court found Benjamin received adequate notice of the charges against him even if he was never informed he would be evaluated under an academic medical center or tertiary standard of care. “There is no question that Plaintiff knew that he was practicing at an academic facility,” the appeals court said. The Sixth Circuit also rejected Benjamin’s claims that his procedural due
process rights were violated because of the medical staff committee’s bias against him, finding no evidence of “ill will.” Likewise, the appeals court held Benjamin’s substantive due process arguments lacked merit, noting the revocation of his medical privileges did not bar him from practicing medicine generally, but barred him from practicing at OSU only. Moreover, “while there may be a liberty interest in entering a profession of one’s choosing, there is not a liberty interest in remaining free from regulation while engaged in that profession,” the appeals court said.

Finally, the appeals court found no evidence of discrimination in the peer review process, noting none of the alleged discriminatory comments against Benjamin were made by committee members during the relevant decision-making process. The Sixth Circuit also determined Benjamin had presented insufficient evidence of indirect discrimination because he failed to show he was similarly situated to the other American-born physicians he claimed were treated more favorably in peer review proceedings. Benjamin v. Brachman, No. 05-4659 (6th Cir. Aug. 8, 2007).

U.S. Court In Illinois Holds Quality Control Reports Are Not Privileged Under State Law
Quality control reports routinely prepared for a hospital quality assessment committee were not privileged under Illinois law because they were created before the peer review process began, a federal district court in Illinois ruled August 20, 2007. Plaintiff Gloria Rodas brought a medical negligence/wrongful death action following the death of her child against Swedish American Health System Corp, d/b/a Swedish American Hospital. The action was removed to federal court because the United States was named as a defendant. Plaintiff sought documentation prepared before and after any morbidity and mortality conferences were conducted about her labor and delivery. The hospital claimed the material plaintiff sought was privileged under the Illinois Medical Studies Act.

The U.S. District Court for the Northern District of Illinois concluded that quality control reports (QCRs) routinely collected for the hospital’s standing committee on Quality Assessment and Improvement were not privileged under the Act. Reviewing Illinois case law, the court noted the Act was intended to promote peer evaluation to advance healthcare quality “but was never intended to shield hospitals from potential liability, nor [to] protect all information used for internal quality control purposes.”

The hospital argued the QCRs triggered the peer-review process and therefore the information contained therein was privileged under the Act. The court said the hospital’s policy of “preemptively collecting information that might prove useful in subsequent peer-review proceedings” presented an interesting question—i.e. whether the hospital could claim the QCR was “initiated, created, prepared or generated by a peer review committee” even where no peer-review committee was investigating the events described in the report at the time it was created. Answering this question in the negative, the court noted “Illinois courts have expressly disapproved of the preemptive application of the peer-review privilege.” To hold otherwise, would deprive medical negligence victims of any evidence to support their claims. Here, the QCRs were generated the day plaintiff delivered her child, not after a peer-review committee initiated an investigation. Thus, the
QCRs were not privileged under the Act and the court ordered the hospital to produce them.

The court did find that documents concerning a regional morbidity and mortality conference required by the Illinois Department of Public Health as a part of infant mortality reduction efforts were privileged pursuant to the Act because “they were specifically initiated, created, prepared or generated by a peer-review committee.” *Rodas v. Swedish Am. Health Sys. Corp.*, No. 05 C 50105 (N.D. Ill. Aug. 20, 2007).

**Washington Appeals Court Upholds Revocation Of Physician’s License Based On His Internet Prescribing Practices**

The Washington State Department of Health’s (DOH’s) Medical Quality Assurance Commission (Commission) properly revoked the medical license of a physician based on its conclusion that his practice of prescribing medications over the Internet constituted unprofessional conduct, a state appeals court ruled September 4, 2007. The physician, Dr. Stephen Ancier, was formerly licensed to practice medicine in the state of Washington. Ancier lives in New Jersey and has only resided in Washington for temporary work assignments. Ancier was affiliated with a number of Internet-based companies offering prescription medications to customers without existing prescriptions. Ancier’s role, according to the appeals court, was to review online customers’ applications to obtain prescription medication and decide whether to issue the requested prescription. Between 2001 and 2004, Ancier reviewed approximately 200,000 requests and issued 180,000 prescriptions. He did not physically examine or personally interview any of the persons receiving prescriptions.

In 2003, the Washington DOH received two independent complaints about Ancier, both alleging he had prescribed medication over the Internet based solely upon customers’ online questionnaires, without any physical examination of or direct communication with the customer. After investigating these complaints, DOH charged Ancier with unprofessional conduct in violation of the Uniform Disciplinary Act, Wash. Rev. Code, ch. 18.130, which, in part, defines “unprofessional conduct” as “incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed.”

Following a two-day hearing in which both sides provided expert testimony, the Commission ultimately ruled in favor of DOH and revoked Ancier’s license indefinitely. In addition, the Commission prohibited Ancier from seeking relicensure for 10 years, and ordered him to pay a $10,000 fine. On appeal, Ancier argued that there was insufficient evidence to demonstrate his conduct created an unreasonable risk of harm to patients.

The Washington Court of Appeals disagreed, finding neither of Ancier’s expert witnesses presented a credible methodology supporting his conclusions. “Not only were their statistics contrived, their opinions questionable, and their protocols not accepted in the medical community, both expert witnesses were doctors who have been disciplined in other states for Internet prescribing,” the appeals court said. “In sum, Ancier’s evidence defeated itself.” The appeals court also rejected Ancier’s argument that his due process
rights were violated because the Commission improperly relied on its own guidelines in assessing the standard of care. Although the Commission considered both its own and the American Medical Association guidelines regarding Internet prescribing, these guidelines were not dispositive, according to the appeals court. Rather, “[t]he only issue squarely presented by this appeal is whether his conduct posed an unreasonable risk of harm, which is not addressed by the guidelines,” the appeals court said. *Ancier v. State Dep't of Health*, No. 58232-1-L (Wash. Ct. App. Sept. 4, 2007).

**Colorado Supreme Court Says Physician Must Exhaust Hospital Peer Review Before Challenging Process**

Under Colorado law, a physician must exhaust his peer review administrative remedies before suing a hospital even for common law claims arising out of the process rather than the governing board’s final decision, the state high court ruled October 15, 2007. Dr. Jimmie R. Crow brought an action against the Penrose-St. Francis Healthcare System for injunctive relief and common law claims arising out of the hospital’s peer review of him before the process was completed. The hospital initiated the peer review process to consider Crow’s treatment of an emergency room patient. The hospital summarily suspended his privileges pending the outcome of the peer review process citing patient safety concerns.

Over a three-year period, the hospital completed three of its five-step peer review process. The process stalled at the evidentiary hearing stage because of a dispute over whether the hospital had to provide Crow with certain documentation before proceeding. Crow sued the hospital alleging breach of contract and tort claims, seeking actual and consequential damages and a permanent injunction. The hospital moved to dismiss, arguing Crow, under the Colorado Professional Review Act (CPRA), must exhaust his administrative remedies through the peer review process. The district court denied the hospital’s motion.

The Colorado Supreme Court reversed, holding the case was not ripe for judicial review. The high court rejected Crow’s argument that the CPRA only requires exhaustion if a physician is challenging the board’s final decision and not seeking monetary damages for common law tort and contract claims arising out of the process. Citing case precedent and “persuasive policy reasons,” the high court concluded that “common law claims arising out of the peer review procedure are subject to the exhaustion of administrative remedies requirement” in the CPRA. The high court noted that the peer review process is an administrative action because the legislature authorized private hospital committees to function as an extension of the state Board of Medicine (BME) for peer review purposes. According to the high court, Crow’s reading of the statute’s exhaustion requirement to apply only to challenges concerning a final board decision rather than the peer review process itself “is inconsistent with the general assembly’s treatment of a hospital’s peer review as an extension of the BME.”

In addition, the high court continued, Crow’s interpretation would conflict with the whole statutory scheme, including immunity provisions that protect good faith conduct and require a full administrative record to evaluate. The high court also cited case precedent
as well as various policy reasons for requiring exhaustion, including preserving hospital autonomy during the peer review process and the need to develop an expert factual record. Without showing futility of the administrative process or the existence of a question of law, Crow could not bring his common law process claims until the hospital board made its final decision, the high court ruled. *In re Crow v. Penrose-St. Francis Healthcare Sys.*, No. 06SA323 (Colo. Oct. 15, 2007).

**Second Circuit Finds State Medical Review Boards Have Absolute Immunity**

The Second Circuit held October 29, 2007 that state medical board review committees enjoy absolute judicial immunity with regard to medical license revocation proceedings. The appeals court, in affirming the dismissal of race discrimination and due process allegations, distinguished the instant case from a prior holding finding no judicial immunity attaches to medical license suspension proceedings.

Plaintiff Monica J. Applewhite alleged that defendants, members of the state medical review board, engaged in race discrimination when they deprived her of her medical license without due process in violation of 28 U.S.C. §§ 1981, 1983. The district court granted defendants’ motions to dismiss on the grounds of absolute judicial immunity, statute of limitations, and failure to state a claim.

The Second Circuit affirmed, specifying “that absolute judicial immunity attaches to a state medical review board’s disciplinary proceeding where, as here, the individual charged has the right to be represented by counsel, to present evidence and to cross-examine witnesses, and where the board articulates its findings and conclusions in a binding order—as opposed to a mere recommendation—under a preponderance of the evidence standard.”


**California Appeals Court Upholds $200,000 Damages Award To Physician Claiming Retaliatory Discharge Against Employer**

A physician who sued Southern California Permanente Medical Group (Medical Group) and Kaiser Foundation Health Plan, Inc. (Kaiser) (collectively, defendants) claiming his employment was terminated in retaliation for “advocating medically appropriate care” was properly awarded $200,000, a California appeals court ruled in an opinion posted December 20, 2007. The California Court of Appeal, Second District, found the physician was entitled to sue defendants in tort for their retaliatory conduct in violation of “public policy” as defined in Cal. Bus. & Prof. Code § 2056.

Physician Dr. Mark L. Woods had worked for defendants for 15 years as an emergency room (ER) physician at Kaiser Permanente Bellflower Hospital (Kaiser-Bellflower) in
Bellflower, CA. Woods claimed he complained about working conditions and patient care in the ER, and in retaliation, defendants placed him on administrative leave and reduced pay in November and December of 2003. Woods filed his lawsuit charging that defendants’ actions violated public policy. Although Woods was later reinstated, he was transferred to another Kaiser hospital where he was suspended again in retaliation for his continued complaints, the opinion said.

According to the appeals court, evidence presented at trial supported Woods’ allegations that the hospital failed to provide appropriate medical screening examinations and stabilizing treatment for emergency medical conditions. “Kaiser-Bellflower’s policy was to keep patients waiting in the emergency room until they left without treatment,” the appeals court said. “Between 1999 and 2006, more than 5,000 patient were sent home without receiving medical screening exams.” Moreover, incidents reported as part of the administrative citations process showed that “Kaiser intentionally understaffed and understocked the hospital to increase profits . . . and provided inadequate and unsanitary care for its patients,” the appeals court noted.

In June 2006, the jury in the case returned a special verdict finding Woods’ patient advocacy was a motivating factor for defendant-Medical Group’s placement of Woods on administrative leave and reduction of pay in 2003. In addition, the jury answered a number of questions, responding “no” when asked whether Woods was an employee of the Medical Group, and “yes” when asked whether Kaiser and the Medical Group were a “single employer” of Woods.

Defendants argued that because the jury found Woods was not an “employee” of the Medical Group, his claim for wrongful retaliation in violation of public policy in § 2056 failed as a matter of law. In rejecting this argument, the appeals court explained “the jury’s finding that the Medical Group was not Dr. Woods’s employer was merely a finding that it alone was not . . . Woods’s employer; it was not an exoneration of defendants.” Rather, the jury expressly found Kaiser and the Medical Group were Woods’ “single employer,” the appeals court continued.

In addition, the appeals court noted that the jury verdict reflected its determination that the Medical Group had authority over Woods, e.g., placing him on administrative leave and reducing his pay. These actions were “indicia of an employer/employee relationship” between the Medical Group and Woods consistent with the finding that the Medical Group, together with Kaiser, were Woods’ single employer, the appeals court said. “Because Woods was an employee of the Medical Group and Kaiser,” he was entitled to bring his tort claims based on defendants’ retaliatory conduct in violation of the public policy set forth in § 2056. Woods v. Southern Cal. Permanente Med. Group, No. B193021 (Cal. Ct. App. filed Nov. 20, 2007 and posted Dec. 20, 2007).
Missouri Supreme Court Holds Medical Staff Bylaws Are Not Contracts, Permits Judicial Review Of Staffing Decisions Only For Substantial Compliance With Bylaws

The Missouri Supreme Court has created a very narrow exception to the doctrine of non-review of privilege decisions of private hospitals, holding that aggrieved physicians have a limited right to judicial review for the sole purpose of determining whether procedures set forth in the Medical Staff Bylaws were followed. Review of the merits of such staffing decisions is still precluded.

Robert C. Egan, M.D. sued St. Anthony’s Medical Center, following the Board’s decision to revoke his medical staff membership and all clinical privileges. He asserted several equitable claims based on alleged violations of the Medical Staff Bylaws, and demanded a new hearing and restoration of his clinical privileges. He did not seek money damages. St. Anthony’s moved for and obtained a dismissal of the lawsuit on the grounds that the staffing decisions of private hospitals are not subject to judicial review, based on Cowan v. Gibson, 392 S.W.2d 307 (Mo. 1965). Egan appealed to the Missouri Court of Appeals, which affirmed the decision. The Missouri Supreme Court accepted his request to review the case, and its decision is an important new precedent in Missouri law.

The Missouri Supreme Court accepted all of Egan’s allegations as true, as is legally required in cases challenging the dismissal of a lawsuit. The court reviewed the Cowan holding that the staffing decisions of private hospitals are not subject to judicial review, a decision based on and consistent with precedents in other states in 1965. The court noted that since Cowan, 46 states and the District of Columbia allow some form of judicial review of privilege restrictions.

The court also looked at a Missouri hospital licensing regulation (first promulgated in 1982) requiring procedures for hearings and appellate review in Medical Staff Bylaws. Based on the regulation and, to a lesser extent, the national tide in favor of judicial review, the high court carved out a very limited exception to the Cowan precedent, which allows judicial review for the sole purpose of determining whether the procedures set forth in the Medical Staff Bylaws were substantially followed. However, the court emphasized that there can be no judicial review of the merits of a privileging decision. The high court also specifically held that Medical Staff Bylaws do not form a contract between a hospital and the individual members of the Medical Staff, as other state courts have concluded. The high court emphasized that doctors may not seek damages for privilege decisions. Egan v. St. Anthony's Med. Ctr., No. SC88493 (Mo. Feb. 5, 2008).

This summary was prepared for Health Lawyers by Tracy Mathis, Lewis, Rice & Fingersh, L.C., St. Louis, Missouri.

RICO

U.S. Court In New Jersey Rejects Hospitals' RICO, Unfair Competition Claims Against Saint Barnabas Group

A federal district court in New Jersey dismissed June 26, 2007 two hospitals’ Racketeer Influenced and Corrupt Organizations Act (RICO) and unfair competition claims against
not-for-profit Saint Barnabas Corporation (SBHCS), the parent company of the largest
tax-exempt integrated healthcare system in New Jersey. In an unpublished decision, the
court found, among other things, that plaintiff hospitals failed to show SBHCS’ alleged
practice of inflating charges to increase their outlier payments was the proximate cause of
the hospitals’ alleged injuries (i.e. lower reimbursement from Medicare) for purposes of
their RICO claims.

According to plaintiffs, Longmont United Hospital and Maine Coast Memorial Hospital,
SBHCS’ practice of “turbocharging” caused the national threshold for Medicare
payments to rise, thereby reducing outlier payments available to other providers including
them. The government conducted an investigation of the outlier payments made to
SBHCS and a number of other healthcare providers. SBHCS eventually agreed to pay the
government $265 million to settle two qui tam suits but did not admit liability. Plaintiffs
alleged causes of action for civil RICO violations, unfair competition, and negligence.

The U.S. District Court for the District of New Jersey granted SBHCS’ motion to
dismiss. As a threshold matter, the court found plaintiffs did not have to exhaust the
administrative process before seeking judicial review because the case did not involve
claims for Medicare reimbursement but instead sought damages from a private company.
The court rejected, however, plaintiffs’ RICO action as a matter of law because it failed
to establish two necessary elements—proximate cause and an enterprise.

SBHCS argued plaintiffs’ asserted injury resulted from the intervening discretionary acts
of the Centers for Medicare and Medicaid Services in setting annual loss thresholds. But
according to plaintiffs, CMS had no discretion and had to automatically raise the levels
necessary to qualify for outlier reimbursement to maintain a 5.1% target. The court
agreed with SBHCS, noting “[w]here, as here, the complained of harm flows through an
intermediary that has the discretion to act in a certain way or not, there is no proximate
cause sufficient to establish a RICO violation.” Moreover, the court noted, calculating
damages “would be arduous, complex and would lead to speculation,” weighing against a
finding of a direct causal connection between the alleged conduct and the asserted harm.
The court further observed that plaintiffs’ claim could be vindicated by another, more
directly injured party—namely, the government, which already reached a settlement with
SBHCS.

The court also found plaintiffs failed to establish a RICO enterprise. Plaintiffs asserted an
“association-in-fact” enterprise consisting of SBHCS and its individual constituent
hospitals and their officers, directors, managers, employees, and agents. But the court
held “a RICO plaintiff cannot evade the distinctiveness requirement by pleading a
corporate enterprise composed solely of a combination of the corporation and its
subsidiaries, employees and/or agents.”

Finally, the court rejected plaintiffs’ unfair competition claim under New Jersey common
law. The court declined to find that plaintiffs and SBHCS were competitors in the sense
that they both sought to obtain government funds. In the instant case, plaintiff hospitals
were located in Maine and Colorado and therefore did not compete with SBHCS’ New

**U.S. Court In Florida Rejects RICO Action Against Tenet Based On Alleged Outlier Scheme**

A federal district court in Florida granted August 2, 2007 summary judgment to Tenet Healthcare Corp. in an action brought by plaintiff Boca Raton Community Hospital alleging Tenet violated the Racketeer Influenced and Corrupt Organizations Act (RICO) by engaging in a scheme with its affiliated hospitals to increase outlier payments from Medicare. The U.S. District Court for the Southern District of Florida found plaintiff failed to show Tenet’s alleged practice of inflating charges to increase their outlier payments was the proximate cause of Boca’s alleged injuries (i.e. lower reimbursement from Medicare) for purposes of the RICO claims.

While finding plaintiff’s RICO claims “insufficient as a matter of law,” the court nonetheless issued a strong rebuke to the national healthcare corporation and its affiliated hospitals. “The evidence in this case paints a clear picture of unmitigated corporate greed. Tenet’s shameless appetite for profit at the expense of a taxpayer supported medical system designed to benefit the less fortunate in society is unconscionable,” the court said. The court noted that the government had already sued Tenet to recover for the same overcharging scheme Boca alleged. The case resulted in a $900 million settlement with Tenet in June 2006, nearly $800 million attributable to the excessive outlier payments.

Plaintiff Boca contended Tenet’s practice of “turbocharging” caused the national threshold for Medicare payments to rise, thereby reducing outlier payments available to other providers including Boca. According to plaintiff, Tenet’s outlier reimbursement rose from roughly $231 million in 1999 to almost $831 million in 2003. Plaintiff alleged Tenet engaged in a pattern of racketeering in violation of RICO, predicated on a violation of the National Stolen Property Act by receiving stolen or converted funds from Medicare.

Although the court rejected most of Tenet’s arguments, including that plaintiff did not plead a RICO enterprise, it ultimately dismissed the action as a matter of law because Boca failed to establish proximate cause—i.e. that the alleged theft from Medicare directly caused Boca’s alleged loss of outlier reimbursement. “Given the operation of the outlier program, Tenet’s receipt of funds from Medicare . . . had no immediate impact on Boca,” the court said. Moreover, Boca failed to account for Tenet’s lawful price increases during the period in question, complicating “the relationship between Tenet’s charging and Boca’s subsequent lost outliers.” The court also noted that CMS’ decision about where to set the national outlier threshold in any given year “was largely a matter of administrative discretion.” Other factors weighing against proximate cause, the court continued, included Boca’s failure to determine how much Tenet overcharged for purposes of calculating damages and the fact that the federal government was in the best position to sue and recover for the alleged theft of outlier funds. *Boca Raton Community Hospital, Inc. v. Tenet Healthcare Corp.*, No. 05-80183-CIV-SEITZ/MCALILEY (S.D. Fla. Aug. 2, 2007).
CMS Issues Controversial Guidance To States On Expanding SCHIP To Higher Income Children

The Centers for Medicare and Medicaid Services (CMS) sent guidance to states August 17, 2007 clarifying its policy regarding eligibility under the State Children’s Health Insurance Program (SCHIP) to children in families with income levels above 250% of the federal poverty level (FPL). Existing regulations at 42 C.F.R. § 457.805 provide that states must have “reasonable procedures” to prevent substitution of public SCHIP coverage for private coverage (known as “crowd-out” procedures). According to the guidance, in order to expand eligibility beyond 250% of FPL, states’ reasonable procedures should include five general crowd-out strategies: (1) imposing waiting periods between dropping private coverage and enrollment; (2) imposing cost sharing in approximation to the cost of private coverage; (3) monitoring health insurance status at the time of application; (4) verifying family insurance status through insurance databases; and/or (5) preventing employers from changing dependent coverage policies that would favor a shift to public coverage.

The guidance clarified further that the five strategies must incorporate the following components:

- The cost sharing requirement under the State plan compared to the cost sharing required by competing private plans must not be more favorable to the public plan by more than one percent of the family income, unless the public plan’s cost sharing is set at the five percent family cap;
- The State must establish a minimum of a one year period of uninsurance for individuals prior to receiving coverage; and
- Monitoring and verification must include information regarding coverage provided by a noncustodial parent.

In addition, a state must make the following assurances to CMS:

- Assurance that the State has enrolled at least 95 percent of the children in the State below 200 percent of the FPL who are eligible for either SCHIP or Medicaid (including a description of the steps the State takes to enroll these eligible children);
- Assurance that the number of children in the target population insured through private employers has not decreased by more than two percentage points over the prior five year period; and
- Assurance that the State is current with all reporting requirements in SCHIP and Medicaid and reports on a monthly basis data relating to the crowd-out requirements.

A number of states, including New Jersey, Illinois, Arizona, California, New York, Maryland, New Hampshire, and Washington, have filed lawsuits challenging the CMS guidance, which they say limit historical state flexibility and essentially block efforts to expand their SCHIP programs. According to the lawsuits, the CMS guidance constitutes illegal rulemaking without notice and comment in violation of the Administrative
Citing the recent guidance, CMS in early September rejected New York’s bid to expand SCHIP for children to up to 400% of the FPL, or $82,600 for a family of four.

**Congress Fails To Override Bush Vetoes Of SCHIP Reauthorization Bills, Extends Current Funding Through 2009**

Over the last year, Congress passed two versions of legislation to reauthorize the popular State Children’s Health Insurance Program (SCHIP), which expired October 1, 2007, but was unable to muster enough votes to override President Bush’s vetoes of the measures. Both bills would have provided an additional $35 billion in funding for the program over five years above baseline levels. In rejecting the legislation, Bush and lawmakers wrangled over funding levels and the administration’s concern that the measure would result in government coverage displacing private health insurance for many children. The program continued under stop-gap measures that maintained funding at existing levels. In end-of-the-year legislation, Congress extended the program until March 31, 2009.

On October 3, 2007, Bush vetoed the first SCHIP reauthorization bill (H.R. 976), which supporters of the measure said would preserve coverage for all 6.6 million children currently enrolled in the program, and add about 3.8 million children to SCHIP’s rolls. While the Senate cleared the measure by an overwhelming 67-29 vote, the 265-159 approval margin in the House was short of a veto-proof majority. A subsequent override vote (273-156) failed to garner a two-thirds majority.

The House and Senate passed a revised bill (H.R. 3963) in late October that Democrats hoped would address what they said were unfounded concerns about the earlier measure (H.R. 976). To this end, H.R. 3963 specified that states could only receive federal funding for children covered in SCHIP with family incomes up to 300% of the federal poverty level for a family of three; phased out coverage of childless adults after one year; and clarified that the program is for U.S. citizens only. The bill’s backers, however, refused to budge on the extent of additional funding, leaving intact the $35 billion over five years included in the original legislation. Like the earlier version, the bill also included a 61-cent hike in the federal tobacco tax. Bush vetoed H.R. 3963 on December 12, 2007, and the House again failed in its override attempt. According to Bush, the revised bill would still shift SCHIP away from its original purpose by covering adults and individuals with higher incomes, as well as move roughly 2 million children who already have private health care coverage onto SCHIP's rolls.

**GAO, CRS Say CMS Failed To Follow Applicable Rulemaking Requirements In Issuing SCHIP Directive**

The Centers for Medicare and Medicaid Services (CMS) did not meet applicable legal requirements in issuing an August 17, 2007 directive on the State Children’s Health Insurance Program (SCHIP), which set forth stricter requirements for expanding eligibility to children in families with higher incomes, according to the Government Accountability Office (GAO) and the Congressional Research Service (CRS). Senate Finance Committee Subcommittee on Health Care Chairman John D. Rockefeller, IV (D-
WV) and Senator Olympia Snowe (R-ME) requested the opinions. After their release, both lawmakers renewed their call for the administration to rescind the SCHIP directive.

According to GAO, the directive constitutes a “rule” for purposes of the Congressional Review Act (CRA), 5 U.S.C. §§ 801-808, and therefore CMS was required to submit it to Congress and the Comptroller General before it could take effect. Applying the definition of a rule under the Administrative Procedure Act (APA), GAO found the directive “is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to SCHIP.” GAO said the directive had little resemblance to a policy statement, as CMS contended, because it included a deadline for “affected states” to implement its measures or face corrective action by the agency. Moreover, the agency relied on the letter to disapprove New York’s state plan amendment, “treating the letter as if it were a binding rule.” After reviewing the statute, its legislative history, and relevant legal opinions, CRS found the CMS directive arguably constituted a change in the previous "binding norm" and therefore required compliance with the CRA.

CMS Issues Letter To State Health Officials Clarifying SCHIP Crowd-Out Policy
The Centers for Medicare and Medicaid Services (CMS) sent a letter May 7, 2008 to state health officials to clarify the policy contained in an August 17, 2007 directive that set forth stricter requirements for expanding State Children’s Health Insurance Program (SCHIP) eligibility to children in families with higher incomes. Under the August 17 SCHIP directive, before expanding eligibility beyond 250% of the federal poverty level (FPL), states must establish a minimum one-year period of uninsurance and have 95% enrollment of eligible children under 200% of the FPL, among other things. CMS has said the directive was intended to ensure that states have reasonable procedures in place to prevent substitution of public SCHIP coverage for private coverage (known as "crowd-out").

In its current letter, CMS reiterates "that any changes made to a State’s crowd-out procedures in response to the August 17 letter need not be applied to prior enrollees." Thus, the policy should have no effect on current enrollees as long as they are continuously enrolled, CMS said. The letter also clarifies that the crowd-out procedures described in the August 17 directive need not be applied to enrollees with effective family incomes at or below 250% of the FPL. However, CMS notes that states "do have the option to apply these crowd-out procedures to enrollees with family incomes at or below 250 percent of FPL as part of efforts to ensure that SCHIP coverage does not substitute for private coverage." In addition, the letter says that the crowd-out procedures do not apply to unborn children.

Regarding the requirement that states must show a one-year period of uninsurance, CMS said it "will review alternative proposals from States, and the justifications for them." In addition, the agency will "consider exceptions for categories of individual enrollees (based on particular circumstances) if the State furnishes justifications and data demonstrating a low substitution risk."
TAX

Eleventh Circuit Holds Medical Residents May Qualify For FICA Exemption
The Eleventh Circuit found May 18, 2007 that medical residents may be eligible for the student exemption from Federal Insurance Contributions Act (FICA) taxation. In so holding, the appeals court refused to apply a bright-line rule that medical residents can never qualify for the exemption, as urged by the government. The U.S. filed suit against Mount Sinai Medical Center of Florida, Inc. alleging that the Internal Revenue Service (IRS) issued an erroneous refund of $2,450,177.32 for FICA taxes paid and withheld by Mount Sinai for payments made to medical residents participating in Mount Sinai’s Graduate Medical Education Program (GMEP) for the tax years 1996 through 1999. Mount Sinai argued that the taxes were properly refunded pursuant to the student exemption under FICA regarding “service[s] performed in the employ of . . . a school, college, or university . . . if such service is performed by a student who is enrolled and regularly attending classes at such school, college, or university.” 26 U.S.C. § 3121(b)(10). The trial court found, as a matter of law, that medical residents are never eligible for the student exemption.

The Eleventh Circuit reversed, holding the trial court erred by relying on legislative history without first determining whether the language of the statute was ambiguous. Turning to the statute as currently written, the appeals court found it was not ambiguous. “By its plain terms, the student exemption does not limit the types of services that qualify for the exemption,” the appeals court held. Whether a medical resident is a “student” and whether he is employed by a “school, college, or university” are separate factual inquiries that depend on the nature of the residency program in which the medical residents participate and the status of the employer, the appeals court said. Thus, Mount Sinai is not precluded as a matter of law from attempting to prove that its students qualify for the exemption, the appeals court held. United States v. Mount Sinai Med. Ctr. of Fla., Inc., No. 06-11693 (11th Cir. May 18, 2007).

Ohio High Court Finds Provider Of Hospice And In-Home Nurse Services Entitled To Property Tax Exemption
Evidence was sufficient to support the findings of the Ohio Board of Tax Appeals (BTA) that a state corporation and its two subsidiaries, which provide hospice and in-home nursing services, qualified for a real estate tax exemption because a parcel of the corporation’s property was used in furtherance of a charitable purpose, the highest court in that state ruled May 30, 2007. Community Health Professional Inc. (CHP) provides skilled, in-home nursing care and hospice services. One of its subsidiaries—VNA Comprehensive Services, Inc (VNA)—provides similar in-home services but focuses on Medicaid patients. The other subsidiary—Private Duty Services, Inc. (Private Duty)—offers non-skilled health services, including an adult daycare center. CHP owns six acres of real estate in Defiance County, Ohio, including the two-acre parcel at issue in this case. On the two-acre parcel is an administration building shared by all three entities (i.e., CHP, VNA, and Private Duty). VNA and Private Duty both lease their space in the building from CHP and the amount of the rent equals their respective costs for utilities and depreciation. In addition to administrative offices, a portion of the building on the
two-acre parcel is used for Private Duty’s adult daycare center that it operates for private pay and qualifying Medicaid clients.

CHP applied for a property tax exemption on the two-acre parcel for the 2002 tax year. Finding that CHP had submitted insufficient information concerning whether the three nonprofit entities provided services free of charge or on a sliding scale, the Tax Commissioner denied CHP’s application. The Commissioner concluded that CHP had failed to show that it uses the property either exclusively for a charitable purpose or in furtherance of its charitable purpose and without the view to profit. The BTA reversed.

Affirming, the Ohio Supreme Court concluded first that CHP qualified as a charitable institution, and second that the BTA reasonably found the property at issue was used in furtherance of CHP’s charitable purpose and not with a view to return a profit. The Tax Commissioner argued that “each of the three nonprofit corporations accepts reimbursement from private and government sources and writes off unpaid balances” and that none of the three entities offer their services free of charge or in accordance with a sliding scale. But the high court rejected these arguments as a basis for reversing the BTA’s decision, noting “these circumstances concern the question of whether CHP is a charitable institution, which, as we have emphasized, is not before this court.” Instead, the court emphasized that the three entities—CHP, VNA and Private Duty—share a common origin; have overlapping resources, services, and purposes; and provide services without regard to a patient’s ability to pay. Community Health Professionals Inc. v. Levin, No. 2006-1086 (Ohio May 30, 2007).

**Indiana Tax Court Finds Taxpayer Failed To Show Medical Facility Was Used Predominantly For Charity, Denies Property Tax Exemption**

An Indiana tax court found the owner of a parcel of land that housed a medical facility was not entitled to a property tax exemption merely because the facility was used to provide some charity care and education. In order to qualify for an exemption, the taxpayer must show that charity is the property’s predominate use, the tax court said. HCPI Inc. owns a 7.77 acre parcel of land in Indiana. Located on the land is Methodist Medical Plaza of Carmel (the MMP). During the year at issue, HCPI leased 59% of the MMP to Clarian Health Partners, Inc. (Clarian), a domestic nonprofit corporation, which used the buildings to perform surgeries and provide other forms of medical care in addition to providing free or reduced fee care to eligible patients and to provide an educational setting for medical students.

On May 17, 2004, HCPI filed an application for a tax exemption with the Hamilton County Property Tax Assessment Board of Appeals (PTABOA), seeking a charitable purposes exemption, an educational purposes exemption, or a hospital purposes exemption for the portion of the MMP leased to Clarian. After the PTABOA denied HCPI’s requests, HCPI appealed to the Indiana Board of Tax Review (Board). The Board issued a final determination denying each of HCPI’s requests for exemption. HCPI appealed.
Affirming, the Tax Court of Indiana, finding while HCPI did present evidence that the MMP was used for charitable activities, “HCPI did not present any evidence showing that the MMP was used more than 50% of the time (i.e., predominately) to educate medical students or to provide charitable health care.” According to the tax court, “given that HCPI’s evidence merely demonstrates that Clarian used the MMP to provide an unspecified amount of educational and charitable activity, the Indiana Board did not err in denying it the exemption,” the tax court held. *HCPI Indiana LLC v. Hamilton County Property Tax Assessment Bd. of Appeals*, No.49T10-0604-TA-36 (Ind. Tax Ct. May 31, 2007).

**IRS Releases Draft Form 990 For Comment**

The Internal Revenue Service (IRS) released for comment June 14, 2007 a redesigned draft Form 990. Tax-exempt organizations must file the Form 990 to report information about their operations to the IRS. The IRS said it "hopes to have the form ready for use for the 2008 filing year (returns filed in 2009)." According to the IRS, the redesigned Form 990 was guided by the goals of enhancing transparency, promoting compliance, and minimizing the burden on filing organizations. Comments on the draft were accepted until September 14, 2007. The draft redesigned Form 990 has a core portion to be completed by all filers and 15 Schedules that focus reporting on certain areas of interest to the public and the IRS, including a Schedule for the hospital sector.

**IRS Finds Wide Variation In Hospitals’ Reporting Of Community Benefit**

The Internal Revenue Service (IRS) released July 19, 2007 an interim report summarizing the responses given by 487 nonprofit hospitals to a community benefit questionnaire sent by the IRS in May 2006. Although the IRS “is still in the process of analyzing the reported data,” it noted “nearly all hospitals reported that they provided various types of community benefit that were the subject of the questionnaire.” According to the report, 97% of responding hospitals said they have a written uncompensated care policy, but no uniform definition of what constitutes “uncompensated care” seemed to apply. In addition, the report found “considerable variation in how hospitals report uncompensated care.”

“The lack of consistency or uniformity in classifying and reporting uncompensated care and various types of community benefit often makes it difficult to assess whether a hospital is in compliance with current law,” Lois G. Lerner, director of the IRS Exempt Organizations division said. “That’s one reason more analysis is needed.” According to the IRS, the new redesigned Form 990 schedule for hospitals is one way to address the lack of uniformity in definitions and reporting.

The report further found that, in the aggregate, uncompensated care accounted for 56% of the total community benefit expenditures reported by the respondents. After uncompensated care, the next largest categories of expenditures ranked as a percentage of total reported community benefit expenditures were medical education and training (23%), research (15%), and community programs (6%), the report said. Treatment of bad debt expense was mixed, the IRS reported, with 56% of responding hospitals saying they
did not include bad debt expense as uncompensated care, and the remaining 44% reporting that they did include at least some bad debt expense as uncompensated care. Senate Finance Committee Ranking Member Charles Grassley (R-IA) commented on the report, noting his “longstanding interest in making sure tax-exempt groups justify their extensive tax breaks with public service.” Grassley pointed out that according to the report, 22% of the responding nonprofit hospitals spend less than 1% of total revenue on uncompensated care and that 21.6% reported spending less than 2% on community benefit as a percentage of total revenue.

“The report makes clear that we need to change business as usual at many of our nation’s nonprofit hospitals,” Grassley said. “These are self-reported numbers and often include inflated costs or bad debt. It’s troubling that even the overly broad figures paint a bad picture of a significant number of nonprofit hospitals doing very little charity care.” However, the report also found that 20% of the responding hospitals provided over 10% of total revenues for uncompensated care. “The question we have to answer is how to get the poor performers to do as good of a job helping provide medical care to vulnerable populations as the best performers,” Grassley said.

Grassley Issues Discussion Draft On Nonprofit Hospital Reforms

Senate Finance Committee Ranking Member Charles Grassley (R-IA) issued July 18, 2007 a minority staff discussion draft on potential reforms for nonprofit hospitals. Grassley emphasized in a statement that the draft is not intended as potential legislation but rather a starting point for discussing ways to ensure the nation’s nonprofit hospitals are providing an adequate level of charity care.

The discussion draft was released the same day that the Internal Revenue Service (IRS) issued an interim report summarizing the responses given by 487 nonprofit hospitals to a community benefit questionnaire sent by the IRS in May 2006. In the introduction, the discussion draft highlights the particular areas of focus addressed in the document that have resulted thus far in the staff’s ongoing investigation of the nonprofit healthcare sector including establishing charity care polices and publicizing those policies at nonprofit hospitals; the amount of charity care and other community benefits provided by nonprofit hospitals; converting nonprofit hospital assets for use by for-profit entities; ensuring that an exempt purpose is furthered in joint ventures between a nonprofit hospital and a for-profit entity; transparency and accountability of nonprofit hospital governance and activities; and use of unfair billing and aggressive collection practices. “[T]he staff believes that the present community benefit standard is extraordinarily vague and does not correlate with the federal tax benefits received by the hospital,” the document says.

The discussion draft recommends implementing an exempt structure that would require hospitals to meet different requirements depending on whether they seek § 501(c)(3) or § 501(c)(4) status. "Staff are unaware of any hospitals that are currently a 501(c)(4),” the discussion draft notes. According to the draft, there should be a higher threshold for § 501(c)(3) organizations given the additional benefits of being able to issue tax-exempt bonds and receive deductible contributions. For example, the discussion draft
recommends that to maintain 501(c)(3) status a hospital must dedicate a minimum of 5% of its annual patient operating expenses or revenues, whichever is greater, to charity care, while a 501(c)(4) hospital would have to dedicate a minimum of 5% of its annual patient operating expenses or revenues to community benefit. Community benefit is defined in the discussion draft as charity care; an emergency room open to all, regardless of ability to pay; burn units; trauma centers; health profession education and training programs; health research; and activities conducted in response to a community needs assessment.

In addition, the draft recommends that nonprofit hospitals be required to conduct a community needs assessment every three years. "Policymakers should consider whether there should also be a minimum amount of other community benefits, such as education and outreach, training or research, health protection and health promotion for vulnerable populations," the draft says. The staff discussion draft seeks comments on a host of specific issues such as the definition of hospitals, the circumstances under which revocation of exemption would be appropriate, and "the propriety of any transition rules from present law to a new exemption regime particularly in regards to the 5% quantitative test." Comments on the discussion draft are due August 24, 2007.

**Provena Covenant Ruled To Meet Qualifications For Religious And Charitable Exemption**

On July 20, 2007, a circuit court judge in Springfield, Illinois overturned an earlier decision by the Director of the Illinois Department of Revenue denying charitable and religious property tax exemption to Provena Covenant Medical Center, a community hospital located in Urbana, Illinois and affiliated with the Provena Health system. The Provena Covenant case is believed to represent the first instance where state taxing authorities had revoked the charitable property tax exemption of a non-profit and full service hospital facility. Given the unprecedented nature of the state action, and the underlying controversy concerning the nature and extent of the Provena hospital's charity care and other community contributions, the case has been watched closely by hospitals and industry observers around the country and is considered to reflect a leading example of the evolving nature of exemption challenges being directed toward healthcare organizations.

Following oral arguments by counsel for the hospital and state tax authorities, Circuit Court Judge Patrick Londrigan ruled from the bench that Provena Covenant qualified as both a charitable and religious exempt organization. Provena Covenant argued that the Illinois authorities acted in disregard of clear and binding precedent which requires that qualification for charitable exemption be evaluated on the basis of factors that go beyond the quantum of free or discounted care that is given away in any given year. The hospital also argued that the Director of the Illinois Department of Revenue had committed error by disregarding voluminous uncontested (and even stipulated) evidence that demonstrated that the hospital offered unlimited free care to all who sought it. The Illinois tax authorities argued that Provena Covenant had failed its burden of proving that its "primary purpose was the delivery of free care," and the amount of care given away by the hospital was inadequate to carry that burden.
Provena Covenant's property tax exemption first came under attack in 2004 when the facility was summarily denied exemption benefits that it had enjoyed for over 70 years. That case went to a lengthy hearing before an administrative law judge (ALJ) for the Department of Revenue in late 2004. In October 2005, the ALJ issued a lengthy ruling, supported by findings of fact and conclusions of law, finding that the Provena facility should continue to be recognized as a charitable exempt hospital. That recommended ruling, however, was rejected by the Director of the Illinois Department of Revenue in a separate ruling issued in September 2006. Last week, Judge Londrigan overturned the September 2006 ruling. The summary reversal of the Illinois tax authorities' position on hospital qualification for charitable tax exemption is subject to appeal. The ruling last week is not expected to end the continuing controversy over the duties and obligations of tax-exempt hospitals in Illinois. (This summary was written by Patrick S. Coffey (Lord Bissell & Brook LLP, Chicago, IL), counsel to Provena Covenant.)

Subsequently, the Illinois Attorney General’s Office filed a notice of appeal to seek reversal of the decision that Provena Covenant qualified as both a charitable and religious exempt organization. In a statement, Provena said it was disappointed by the decision to appeal and was confident that the circuit court’s ruling would be upheld. “We are disappointed that state authorities choose to continue to ignore the plain facts and governing law which more than amply supports our position,” Provena said.

IRS To Propose Rules Regarding Type III Supporting Organizations
The Internal Revenue Service (IRS) issued an advance notice of proposed rulemaking in the August 2, 2007 Federal Register (72 Fed. Reg. 42335) regarding the payout requirements for Type III supporting organizations that are not functionally integrated. The new rules also will address the criteria for determining whether a Type III supporting organization is functionally integrated, the modified requirements for such organizations that are organized as trusts, and the requirements regarding the type of information Type III supporting organizations must provide to its supported organization(s) to demonstrate responsiveness. According to the advance notice, modifications in the Pension Protection Act of 2006 prompted the need to revise the Treasury Regulations regarding the four matters. Comments on the proposed payout requirement and the proposed criteria for qualifying as functionally integrated were due October 31, 2007.

IRS Announces Compliance Check Questionnaire On Tax-Exempt Bond Financings
The Internal Revenue Services (IRS) has announced a new compliance check questionnaire to help evaluate whether certain tax-exempt organizations are ensuring their qualified 501(c)(3) bond financings comply with federal tax requirements post-issuance. The five-page compliance check questionnaire will be sent to more than 200 exempt organizations that indicated outstanding balances of tax-exempt liabilities on their 2005 Form 990, according to a cover letter accompanying the questionnaire.

In general, the questionnaire contains a host of questions relating to 501(c)(3) organizations’ post-issuance bond compliance and record retention practices. The cover letter explains that a qualified 501(c)(3) bond generally is one where at least 95% of the net proceeds are to be used by no person other than a 501(c)(3) organization or a
governmental unit. However, if more than 5% of the net proceeds are used by the exempt organization in an unrelated trade or business, then the bond is not a qualified 501(c)(3) bond. The questionnaire seeks information in five general areas: post-issuance compliance; general recordkeeping; investments and arbitrage compliance; expenditures and assets; and private business use.

**U.S. Court In Minnesota Finds Invalid IRS Rules Imposing FICA Taxes On Certain Medical Residents’ Stipends**

Internal Revenue Service (IRS) regulations providing that medical residents who work 40 hours or more per week do not qualify for the student exclusion from payment of employment taxes required by the Federal Insurance Contributions Act (FICA) are invalid, a federal district court in Minnesota ruled August 3, 2007. The U.S. District Court for the District of Minnesota granted summary judgment in favor of plaintiffs challenging the regulations—Mayo Clinic (Mayo) and the Mayo Foundation for Medical Education and Research (MFMER), which serves as Mayo’s agent for withholding FICA taxes and filing related tax returns. The district court also held that Mayo was entitled to a refund from IRS of over $1.6 million for FICA taxes withheld and paid on Mayo’s medical residents’ stipends for services performed on or after April 1, 2005.

Of particular relevance to the present case, the federal district court in a prior decision, *United States v. Mayo Found. For Med. Educ. & Research*, 282 F. Supp. 2d 997 (D. Minn. 2003), held that stipends paid to medical residents in 1994-1996 qualify for the “student” exclusion from FICA taxation and that Mayo is a “school, college, or university” for purposes of the exclusion. At that time, IRS regulations provided simply that “the term ‘school, college, or university’ within the meaning of [the FICA] exception . . . is to be taken in its commonly or generally accepted sense.”

The IRS amended its regulations in 2004, which became effective April 1, 2005, and are codified at 26 C.F.R. § 31.3121(b)(10)-2(c), to provide that an organization is a “school, college, or university . . . if its *primary function* is the presentation of formal instruction, it normally maintains a regular faculty and curriculum, and it normally has a regularly enrolled body of students in attendance at the place where its educational activities are regularly carried on.” With regard to student status, the amended regulations provide that “an employee whose normal work schedule is 40 hours per week is considered a full-time employee” and therefore services performed by that individual are “not incident to and for the purpose of pursuing a course of study.” Consequently, under the amended regulations, a medical resident who works 40 hours or more per week does not qualify for the student exclusion from FICA taxation.

The present case arose following the April 1, 2005 effective date of the amended regulations. MFMER withheld and paid FICA taxes on the stipends of Mayo's medical residents’ for services performed on or after April 1. MFMER and Mayo then filed a refund claim with the IRS of $1,676,119.06 plus interest. After the IRS refused to act upon the claim, MFMER and Mayo commenced an action against the federal government seeking to recover on its refund claim. Moving for summary judgment, they argued that various provisions in the amended IRS regulations were invalid.
The district court agreed, concluding that the ordinary definition of the terms “school, college, or university” under the student exclusion (i.e., 26 U.S.C. §3121(b)(10)) is not ambiguous, and therefore the amended regulations’ use of the “primary function” standard to define these terms is contrary to the plain meaning of the statute. “The language of the Student Exclusion is clear; if Congress desires to use the ‘primary function’ test as the standard for defining ‘school, college, or university’ then Congress will have to make that change,” the district court said.

The district court also found that the term “student” unambiguous, and rejected the addition of a “full-time employee” exception to the definition of “student” in the amended regulations. The court ultimately concluded that this exception is inconsistent with the plain meaning of the statute, as well as “the expressed intent of Congress.” Mayo Found. for Med. Educ. and Research v. United States, No. 06-5059 (RHK/JSM) (D. Minn. Aug. 3, 2007).

**IRS Releases Final 2008 Form 990 For Tax-Exempt Organizations**

The Internal Revenue Service (IRS) issued December 20, 2007 an updated version of Form 990, the return that charities and other tax-exempt organizations are required to file annually. The final form retains the redesigned draft's format of a core form and a series of schedules. The new form will be used for the 2008 tax year (returns filed in 2009). The IRS plans to release the related instructions in early 2008. "We are continuing to work with the nonprofit sector to complete the new form's instructions," said Lois G. Lerner, Director of Exempt Organizations.

In response to public comments, the new core form allows an organization to describe its exempt accomplishments and mission up-front and provides more opportunities throughout the form for the organization to explain its activities. Other major changes were made to the form's summary page, governance section, and various schedules, including those relating to executive compensation, related organizations, foreign activities, hospitals, non-cash contributions, and tax exempt bonds. A checklist of schedules was also added.

Of particular interest to healthcare organizations, the IRS also announced a phase-in of the form's new hospital and tax exempt bond schedules. Certain identifying information will be required for the 2008 tax year, with completion of the entire schedule required for the 2009 tax year. "We believe the transition relief we are providing is appropriate and meaningful, and will ease the concerns raised by commenters," said Lerner. *This summary was prepared by James R. King, Esq., of Jones Day, Columbus, Ohio.*

**IRS Issues Final Regulations On Excess Benefit Transactions**

The Internal Revenue Service (IRS) published in the March 28 Federal Register (73 Fed. Reg. 16519) long-awaited final regulations clarifying the relationship between tax exemption under § 501(c)(3) and the imposition of intermediate sanctions under § 4958 of the Internal Revenue Code on excess benefit transactions. An excess benefit transaction arises when a tax-exempt organization provides a benefit to a "disqualified
person” such as an officer, director, or executive that exceeds fair market value or is otherwise commercially unreasonable. When an excess benefit transaction occurs, the IRS can impose a penalty in the form of excise taxes on the disqualified person.

The final regulations describe and respond to comments the IRS received on proposed regulations issued September 9, 2005 (70 Fed. Reg. 53599), which provided guidance on the factors the IRS will consider in determining whether a tax-exempt organization that engages in an excess benefit transaction should lose its tax exemption. The IRS said it was finalizing the factors described in the proposed regulations without major revisions, although it added new examples on the application of intermediate sanctions.

In the final regulations, the IRS emphasized “that implementation by an organization of safeguards that are reasonably calculated to prevent excess benefit transactions will be treated as a factor weighing in favor of continuing to recognize exemption regardless of whether such safeguards are implemented in direct response to the excess benefit transaction(s) at issue or as a general matter of corporate governance or fiscal management.” To this end, the IRS added an example “to illustrate how implementation of safeguards, including preexisting safeguards, will be taken into account in determining whether to continue to recognize an organization’s tax-exempt status.”

U.S. Court In Minnesota Finds Medical Residents Are “Students” Not Subject To FICA Taxes
The University of Minnesota (U Minn) is entitled to a refund of Federal Insurance Contributions Act (FICA) taxes withheld and paid on stipends of medical residents who were enrolled in its residency program and performed clinical rotations at affiliated hospitals, the U.S. District Court for the District of Minnesota ruled April 1, 2008. In granting summary judgment in favor of U Minn, the district court found that the University and its residents were exempt from payment of FICA taxes under 26 U.S.C. § 3121(b)(10), otherwise known as the “student exclusion.” That provision excludes from FICA taxation “service performed in the employ of . . . a school, college, or university . . . if such service is performed by a student who is enrolled and regularly attending classes at such school, college, or university.” The district court ordered that judgment be entered in favor of U Minn, and that the judgment declare that U Minn was entitled to a refund of FICA taxes amounting to $1,094,804 plus interest.

Plaintiff Regents of the U Minn initiated the lawsuit against the federal government in December 2006. Before the underlying dispute arose in the case, the Internal Revenue Service amended relevant regulations to add a “full-time employee” exclusion to the “student exemption” from FICA taxes. More specifically, the amended regulations, which became effective April 1, 2005, provided that “an employee whose normal work schedule is 40 hours or more per week is considered a full-time employee” (26 C.F.R. § 31.3121(b)(10)-2(d)(3)(iii). Therefore, under this new provision, medical residents working such hours no longer qualified for the student exemption.

Subsequent to plaintiff U Minn’s filing of its lawsuit to recover withheld FICA taxes, the U.S. District Court for the District of Minnesota rendered a decision in August 2007—
Mayo Foundation for Medical Education & Research v. United States, 503 F. Supp. 2d 1164 (D. Minn. 2007)—which held that the amended regulations were invalid. In response, U Minn moved for summary judgment in the present case, filing its motion in the same district court that rendered the Mayo decision. The district court noted that the Mayo decision has been appealed by the government to the Eighth Circuit (Mayo Found. for Med. Educ. & Research v. United States, No. 07-3242 (8th Cir., appeal pending)).

The district court explained at the outset of its decision that, because it had previously held the amended regulations to be invalid, it would apply the pre-amended regulations to determine whether the medical residents in the present case qualified for the “student exemption” from FICA taxes. The district court rejected the government’s position that the affiliated hospitals were the actual employers of the medical residents at issue because they controlled the residents’ activities. Concluding instead that the residents were employed by U Minn, the district court noted that U Minn and the directors of its residency programs interviewed candidates and selected the residents for the programs. In addition, U Minn assigned the residents to their specific clinical rotations, and U Minn faculty physicians at the affiliated hospitals supervised the residents and evaluated their performance. The district court also pointed out that U Minn paid the residents’ stipends and benefits, which included malpractice insurance, and had the power to suspend or terminate a resident from the residency program.

The district court then turned to the questions of whether the medical residents at issue qualified as students, i.e., individuals “enrolled and regularly attending classes,” and whether they performed services “incident to . . . a course of study.” On the first question, the district court found the residents were enrolled and regularly attending classes, highlighting evidence of the residents’ enrollment at U Minn, including deduction of $1200 from their paychecks in payment for tuition over the relevant time period. In concluding that the residents were regularly attending classes, the district court said that the record established that “the clinical setting [was] the classroom for residents.”

Finally, the district court held that the patient-care services provided by residents in U Minn’s residency programs were “incident to” a course of study, finding that the express purpose of the programs were to provide educational experiences to the residents in a clinical setting. Regents of the Univ. of Minn. v. United States, No. 06-5084 (D. Minn. Apr. 1, 2008).

IRS Issues Revised Draft Instructions For Final Form 990

The Internal Revenue Service (IRS) released the final 2008 Form 990 on December 20, 2007. This new Form 990 requires detailed disclosure of all significant aspects of an exempt health care organization’s purposes and operations. On April 7, 2008, the IRS released the draft Instructions accompanying this new Form 990. These draft Instructions spell out how the IRS anticipates that organizations will make highly detailed disclosures regarding virtually every aspect of their operations.

In this regard, the draft Instructions contemplate highly detailed disclosures regarding compensation for top management and other financial transactions with “insiders” as well
as descriptions of the kinds of policies and procedures the organization follows in reviewing and approving financial transactions with insiders. In addition, in the draft Instructions for Schedule H, the IRS sets forth what is very likely the IRS’ view of the factors it will look at to judge whether an organization continues to qualify as a tax-exempt organization under the community benefit standard, including highly detailed disclosures regarding how an organization identifies and computes the “community benefit” that is at the core of tax-exempt status, how the organization determines whether a patient is eligible for charity care, how the organization distinguishes between bad debt and charity care, how the organization educates patients about charity care and collection matters and how the organization assesses the needs of the communities it serves.

These detailed disclosures will provide an in-depth look at the tax-exempt healthcare sector, and the information provided in the Form 990 will enable the IRS to engage in more focused and more effective audit and enforcement activities. In addition, because the Form 990 is a publicly available document, the disclosures required by the Form and its Instructions will be the principal way an organization presents itself not only to the IRS but also to federal, state, and local legislative bodies, to state regulators, including state attorneys general and state taxing authorities, to the various media and to the general public, including various special interest groups that may not have the organization’s best interest at heart. The IRS accepted comments on the draft through June 1, 2008. This summary is an excerpt of an article by James R. King, Gerald M. Griffith and Travis F. Jackson, Jones Day, in Health Lawyers Weekly.