AMERICAN HEALTH LAWYERS ASSOCIATION

Year in Review 2004-2005
Healthcare Liability and Litigation

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The areas of health law and policy continued to develop at a rapid pace over the past year. The U.S. Supreme Court issued several important decisions impacting the healthcare industry. CMS issued regulations implementing the changes mandated by the Medicare Modernization and Improvement Act of 2003 (MMA). The judiciary engaged in an altercation with the legislative and executive branches regarding end-of-life issues, with ramifications that will be felt for years to come. Providers continued to battle amongst themselves, with the courts refereeing and issuing major decisions covering a broad range of topics. Patient safety and joint ventures were again hot issues and the pharmaceutical industry continued to be the focus of several government agencies.

The Year in Review summarizes the leading developments in case law, legislation, and administrative actions affecting healthcare. These developments demonstrate society’s efforts to balance accountability, efficiency, individual rights, and affordability in the delivery of healthcare. As more federal dollars are spent on healthcare due to technological advances, increased prices, and the aging baby boomers, and less money is available to state and local governments due to the current economic climate, this balancing becomes more precarious.

Health law and policy have also become important political concerns, as the major political parties use issues like prescription drug coverage for the elderly, medical malpractice reform, and right-to-life choices (both abortion and euthanasia) to garner votes. This increased focus has led to rapid developments, making it even more critical for practitioners to keep up with an already dynamic field.

The Year in Review will assist the practitioner in this endeavor. Each practice group section is summarized below. While we hope that practitioners are able to read the Year in Review in detail, this synopsis will serve as an important tool in understanding the past year’s major developments.

I. PRACTICE GROUP ANALYSES

Antitrust

The FTC continued its enforcement focus on the pharmaceutical industry, utilizing for the first time its July 2003 disgorgement policy to charge generic drug marketers with entering into an illegal market allocation agreement. Fed. Trade Comm’n v. Perrigo Co., File No. 0210197 (Fed. Trade. Comm’n Aug. 12, 2004). However, in a reversal of a full FTC decision from last year, the Eleventh Circuit vacated the FTC’s decision in Schering-Plough Corp., Dkt. No. 9297 (Fed. Trade.
Comm’n Dec. 18, 2003), holding that even though the patent settlements between Schering-Plough, Upsher and ESI involved “reverse payments,” the settlement agreements were not anti-competitive. Schering-Plough Corp. v. Fed. Trade Comm’n, 402 F.3d 1056 (11th Cir. 2005).

Continuing a theme from last year, the FTC entered into a number of consent decrees over the past year that disciplined “messengers” for using illegal means to negotiate fees with payors. The FTC requires substantial integration for separate practices to form an entity that can negotiate on behalf of the group. See In the Matter of Southeastern New Mexico Physicians IPA, Inc, and Barbara Gomez and Lonnie Ray, File No. 0310134 (Fed. Trade Comm’n Consent Order June 7, 2004); In the Matter of White Sands Health Care System, LLC, Alamogordo Physicians Cooperative, Inc., Dacite, Inc., and James R. Laurenza, File No. 0310135 (Fed. Trade Comm’n Consent Order Jan. 14, 2005).

After Congress granted a special exemption to the antitrust laws in April 2004 stating that the National Resident Matching Program (NRMP) does not violate antitrust laws, a federal court granted the Association of American Medical Colleges’ motion to dismiss the resident physicians’ antitrust class action regarding the NRMP. Subsequently, the court did not allow the plaintiffs to amend their complaint, finding that the April 2004 legislation rendered amendment futile. See Jung v. Ass’n of Am. Med. Colleges, 339 F.Supp.2d 26 (D.D.C. 2004); 226 F.R.D. 7 (D.D.C. 2005).

Various providers used the antitrust laws as a tool in the battle for patients and revenues. In Rome Ambulatory Surgical Center, LLC v. Rome Memorial Hosp., a federal court in New York allowed an ambulatory surgical center to continue with its antitrust claims against a hospital charged with entering into exclusive contracts with managed care plans and thereby potentially monopolizing the market. 349 F.Supp.2d 389 (N.D.N.Y. 2004). In another development in the specialty hospital controversy, Heartland Surgical Specialty Hospital, LLC, filed an antitrust action in federal court alleging that several major insurers conspired with traditional acute care hospitals to direct patients to the traditional hospitals to the exclusion of Heartland. Heartland Surgical Specialty Hosp., LLC v. Midwest Division, Inc., No. 05-CV-2164 (complaint) (D. Kan. April 26, 2005). Both of these cases will be interesting to follow, as they represent the next wave in the ongoing battle between specialty and traditional hospitals for patients and revenue.

**Fraud and Abuse, Self-Referrals and False Claims**

The Practice Group leadership discussed important cases regarding the federal sentencing guidelines, false claims, fee splitting, and formulary issues, as well as the OIG’s Advisory Opinions.

The U.S. Supreme Court issued a landmark decision in United States v. Booker, 125 S.Ct 738 (2005), holding that the U.S. Sentencing Guidelines violate the
Sixth Amendment. For healthcare providers, this decision will significantly affect the strategies surrounding settlement and plea negotiations. An unresolved issue, and one that bears watching in the future, is how Booker will impact the new sentencing guidelines for organizations.

The Appellate Court of Illinois held that, regardless of how an administrative fee was calculated (i.e., percentage vs. fixed), payment of such fees by physicians to a provider network developer violated the state’s fee-splitting statute due to the referral relationship between the parties. Vine Street Clinic v. Healthlink, Inc., 819 N.E.2d 363 (Ill. App. 2004).

A federal court in California applied the collateral estoppel provision of the False Claims Act (FCA) to grant the government summary judgment in a civil action after a jury found the defendants guilty in a criminal trial. The court held that the jury made an affirmative finding on each of the essential elements of an FCA violation; therefore, the FCA’s collateral estoppel provision had been met. United States v. St. Luke’s Subacute Hosp. And Nursing Ctr., 2004 WL 2905237 (N.D. Cal. 2004).

Several relators saw their qui tam actions dismissed under the FCA’s public disclosure bar. The Fifth Circuit adopted the Third Circuit’s view and determined that the disclosure of information in response to a Freedom of Information Act request constitutes a public disclosure under the FCA. United States ex rel. Reagon v. East Texas Med. Ctr. Reg’l Healthcare Sys., 384 F.3d 168 (5th Cir. 2004), citing Unites States ex rel. Mistick v. Housing Auth. of the City of Pittsburgh, 186 F.3d 376 (3d. Cir. 1999).

The use of formularies by states to reduce prescription drug costs withstood a challenge by the pharmaceutical industry, as the D.C. Circuit held that states may require rebates from pharmaceutical manufacturers as a condition of inclusion on states’ formularies under both their Medicaid and non-Medicaid pharmaceutical programs. Pharmaceutical Research and Mfrs. of America v. Thompson, 362 F.3d 817 (D.C. Cir. 2004).

The OIG, as usual, issued many significant Advisory Opinions. Interestingly, the OIG issued several Advisory Opinions on the same or similar topics: gainsharing, reduced cost sharing obligations for ambulance services, and malpractice subsidies. In addition, the OIG declined to approve several arrangements, finding one arrangement suspect under its previous guidance regarding suspect contractual joint ventures. See Advisory Opinion 04-17 (Dep't Health & Human Servs. Office of Inspector Gen. December 10, 2004).

**Health Information and Technology**

The HIT Practice Group focused on the federal government’s initiatives regarding electronic health records and various developments regarding HIPAA.
The development of electronic health records (EHRs) was a top priority for the federal government. DHHS held its first summit on HIT and released a report entitled, “The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care,” that outlined the federal strategy to foster the promotion of widespread EHRs. Shortly after this summit and in response to a Senate committee request, the GAO released an assessment of DHHS’ efforts to promote EHRs, as well as the legal barriers associated with such initiatives. See HHS’s Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption, GAO-04-991R. In addition, the Office of the National Coordinator for Health Information Technology issued a Request for Information regarding EHRs. National Coordinator for Health Information Technology; Development and Adoption of a National Health Information Network, 69 Fed. Reg. 65599 (Dep’t Health and Human Servs. Request for Information Nov. 15, 2004).

HIPAA was further refined through the release by the Office of Civil Rights (OCR) of several Frequently Asked Questions (FAQs) regarding privacy issues. OCR addressed the role of lawyers under HIPAA and the use of protected health information (PHI) in litigation, offering clarifications that are somewhat contrary to widely held views regarding the use and disclosure of PHI in litigation, such as how to meet the duty of satisfactory assurances. OCR also released FAQs addressing subcontractor business associate agreements, which suggest that “agents” include all persons who performed for an attorney “in furtherance of” providing legal services.

CMS took steps to nudge the industry towards compliance with the HIPAA Security Rule, releasing Security FAQs, issuing an educational paper entitled “Security 101 for Covered Entities,” and convening a HIPAA Roundtable to describe the Security Rule and answer questions. The technical assistance offered generally lacks the bright line guidance many were anticipating; in addition, it demonstrates the challenge the industry faces to achieve comparable levels of security across widely varying enterprises.

The DOJ obtained its first criminal conviction under HIPAA, entering into a plea agreement with an individual who admitted obtaining PHI for fraudulent purposes. Significantly, the DOJ chose the HIPAA felony law to prosecute the defendant, not a covered entity himself, even though various other laws were available. Many see this use of HIPAA by the DOJ as a signal that the DOJ believes the HIPAA felony provisions reach well beyond covered entities. See Department of Justice United States Attorney’s Office Western District of Washington Statement on Seattle Man Pleads Guilty in First Ever Conviction for HIPAA Rules Violation (U.S. Dept. of Justice United States Attorney’s Office Western District of Washington Press Release Aug. 19, 2004).
Healthcare Liability and Litigation

The Healthcare Liability and Litigation Practice Group examined cases regarding statute of limitations issues, the extension of physicians’ liability for medical malpractice, and arbitration agreements.

In a case of first impression for any jurisdiction, the Louisiana Supreme Court ruled that the statute of limitations for birth defects runs from the date of birth for both mother and child even when the defect was identified by prenatal testing. *Bailey v. Khoury*, 891 So.2d 1268 (Louis. 2005).

In other developments, various state courts extended a physician’s liability regarding medical malpractice. The Minnesota Supreme Court held that physicians owed a duty of care regarding genetic testing and diagnosis, not just to the affected child but also to her parents, as it was reasonably foreseeable that the parents, being of childbearing age, would have been injured for the failure to diagnose the genetic disorder. *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004). A New Jersey appellate court permitted an adult to litigate an injury that occurred during his birth twenty years earlier, thereby extending the statute of limitation for birth injury through the age of the child’s majority. *Draper v. Jasionowski*, 858 A.2d 1141 (N.J. Super.A.D. 2004).

The California Appeals Court was active in the interpretation of arbitration agreements, distinguishing between the authority to act on behalf of a patient in medical matters and the authority to bind a patient to an arbitration provision. See *Goliger v. AMS Properties, Inc.*, 19 Cal.Rptr.3d 819 (Cal. App. 2004). In addition, the court held that an arbitration clause in an employment agreement applied to all of the plaintiff physician’s claims, including those claims that arose after his termination, as such claims were rooted in the parties’ contractual relationship. *Buckhorn v. St. Jude Heritage Med. Group*, 18 Cal.Rptr.3d 215 (Cal. App. 2004).

HMOs and Health Plans

The Practice Group leadership focused its review on ERISA preemption issues and the continuing tension between providers and plans.

In a significant decision regarding ERISA preemption, the Supreme Court held that where an individual is entitled to coverage only by his or her relationship to an ERISA-governed plan, claims based on denial of coverage must be pursued under ERISA, as ERISA preempts state law. *Aetna Health, Inc. v. Davila*, 542 U.S. 200 (2004). This decision will assist the lower courts as they distinguish between permissible state penalties for negligence and permissible federal remedies for coverage decisions. Several courts have already rendered decisions under the *Davila* standard. See *Land v. CIGNA Healthcare of Florida*,
The economic tensions between providers and plans, a hot topic from last year, continued to be an important development over the past year. The Eleventh Circuit rendered two decisions in the ongoing war between physicians and the managed care industry regarding claims of RICO violations, conspiracy and fraud by health plans in an effort to systematically underpay physicians for their services. In the first decision, the Eleventh Circuit affirmed the certification of plaintiffs’ federal law claims, but reversed certification of the state law claims. *Klay v. Humana*, 382 F.3d 1241 (11th Cir. 2004). In a victory for the physician plaintiffs, the Eleventh Circuit affirmed the lower court’s ruling precluding arbitration of the plaintiffs’ indirect-RICO and non-participating provider claims. *Klay v. All Defendants*, 389 F.3d 1191 (11th Cir. 2004).

In addition to the Eleventh Circuit decisions, two more managed care plans, Health Net, Inc., and Prudential Financial, Inc., announced that they had settled with the physician class. Under the settlements, Health Net will make a cash payment of $60 million and invest $80 million over four years in various administrative changes. Prudential agreed to a $22.2 million settlement. Health Net and Prudential join Aetna, Inc., and CIGNA Healthcare Plan in settling with the physicians, while litigation remains pending with WellPoint, UnitedHealthcare, Humana, and Pacificare.

*Hospitals and Health Systems*

The Hospital and Health Systems Practice Group examined significant cases regarding exclusive provider agreements, vicarious liability, and reimbursement issues.

The West Virginia Supreme Court set a new precedent when it ruled that a hospital could not exclude physicians with staff privileges through an exclusive arrangement with another provider. The court felt the hospital could have achieved its goal through the use of less restrictive means, *i.e.*, a preferential rather than an exclusive contract. See *Kessel v. Monongalia County Gen. Hosp. Co.*, 600 S.E.2d 321 (W.Va. 2004).

As in previous years, state courts, when dealing with medical malpractice cases, struggled with the vicarious liability doctrine and cases where independent contractor physicians act with the apparent authority of a hospital. The West Virginia Supreme Court ruled that even though plaintiffs had signed consent forms expressly stating that the physicians were not employees of the hospital, thereby negating any claim of actual agency, the plaintiffs should have been allowed to present evidence to support their claims of apparent agency. *Burless v. West Virginia Univ. Hospitals, Inc.*, 601 S.E.2d 85 (W.Va. 2004). A Michigan appellate court ruled that plaintiffs must establish that the patient reasonably

In a case meaningful to *qui tam* actions, a New York federal district court held that each financial report submitted by a hospital in relation to its federally funded clinical vaccine trials could support a claim under the FCA; however, the relator must first establish that the provider was required to disclose such information. The court declined to find that the individual receipt of an alleged program payment constituted a separate false claim. See *Cantrell v. New York Univ.*, 326 F.Supp.2d 468 (S.D.N.Y. 2004).

In a proposed settlement likely to be followed by similar agreements, Tenet Healthcare Corp. announced that it had agreed to settle certain class action lawsuits regarding prices that uninsured and some underinsured patients were charged for prescription drugs and other products and services at hospitals owned and operated by Tenet subsidiaries. Tenet has agreed to provide a reimbursement mechanism for uninsured patients who received medically necessary services between June 15, 1999, and December 31, 2004, and who paid more than a certain percentage of the hospital’s gross charges.

**In-House Counsel**

The Practice Group leadership analyzed cases involving a myriad of issues that affect the operations of healthcare providers, including disputes over arbitration agreements, privacy issues, medical records, and medical malpractice.

The courts interpreting arbitration agreements generally upheld the use of the arbitration provision as long as there was adequate disclosure of the binding arbitration clause. In *Viola v. Dept of Managed Health Care*, a California appeals court held that an employer has the implied authority as the agent of its employees to agree to binding arbitration of disputes arising under a health plan the employer negotiated as part of its employee benefits package. 23 Cal.Rptr.3d 821 (Cal. App. 2005). However, the same court ruled that if a health plan does not adequately disclose arbitration provisions on enrollment forms, the arbitration provision will not be enforced. See *Malek v. Blue Cross of California*, 16 Cal.Rptr.3d 687 (Cal. App. 2004).

In a case demonstrating the great weight courts give to arbitration provisions, the Texas Supreme Court ordered arbitration between pharmacies and a pharmacy benefits manager based upon an arbitration clause in an unsigned provider agreement. *In re AdvancedPCS Health, L.P.*, 2005 WL 856961 (Tx. 2005).

Courts also examined privacy issues. A New York court held that HIPAA does not allow plaintiffs to withhold medical authorizations that would assist defense counsel by allowing them to meet with plaintiff’s subsequent treating physicians,

A Florida appeals court found that a patient’s right to privacy in his or her medical records was not violated by the retrieval of the records via a valid search warrant; furthermore, the court determined that the patient was not entitled to notice of the record retrieval. Limbaugh v. State, 887 So.2d 387 (Fla. App. 2004).

The Texas Supreme Court issued a medical malpractice decision of interest to in-house counsel, finding that certain causes of action that are extended to an individual or person do not, by definition, include an unborn fetus. Therefore, the parents of a fetus that did not survive birth could not bring an action against the healthcare provider. Fort Worth Osteopathic Hosp. v. Reese, 148 S.W.2d 94 (Tx. 2004).

**Labor and Employment**

The Labor and Employment Practice Group analyzed significant cases under various federal statutes, including the National Labor Relations Act (NLRA), the Civil Rights Act of 1964, as amended in 1991, the Age Discrimination in Employment Act (ADEA), and the Family and Medical Leave Act (FMLA).

The National Labor Relations Board (NLRB) held that seven hospitals in the Minneapolis area violated the NLRA by refusing to hire nurses on strike at other area hospitals. Allina Health System, 343 NLRB 67 (2004). The NLRB’s decision that an employer violated the NLRA by interfering with picketers’ right to protest by contacting the police, however, was overturned by the Fourth Circuit, which held the employer was justified in contacting the police due to concerns for public safety. CSX Hotels, Inc. v. Nat’l Labor Relations Bd., 377 F.3d 394 (4th Cir. 2004).

In a significant victory for plaintiffs in employment discrimination cases, the U.S. Supreme Court held that because a constructive discharge is the equivalent of a formal discharge for remedial purposes, an employer may not raise the *Ellerth* affirmative defense when a supervisor’s conduct is the reason for the constructive discharge. Pennsylvania State Police v. Suders, 542 U.S. 129 (2004). The *Ellerth* defense, enunciated by the Court in Burlington Industries, Inc. v. *Ellerth*, 524 U.S. 742 (1998), provides that an employer, who is strictly liable for supervisor harassment that ends in a tangible employment action, may raise an affirmative defense if no tangible employment action was taken and the employer can show that it used reasonable care in implementing a policy to prevent and correct sexual harassment, and that the employee failed to take advantage of such a policy.

However, the Eighth Circuit ruled that employers may rely on the *Ellerth* affirmative defense in single incident cases even when both prongs of the
defense are not proven. *McCurdy v. Arkansas State Police*, 375 F.3d 762 (8th Cir. 2004).

In a decision long anticipated and dreaded by employers, the Supreme Court approved the use of the disparate impact theory to cases arising under the ADEA. *Smith v. City of Jackson, Mississippi*, 125 S.Ct. 1536 (2005). However, the Court drew a distinction between cases arising under the ADEA and those arising under other anti-discrimination statutes by allowing employers to avoid liability for age discrimination by demonstrating that the challenged plan or practice is based on reasonable factors other than age.

Courts also examined issues arising under FMLA. The Sixth Circuit found that suspicious timing of termination could be sufficient to support FMLA claims when an employer was aware of many of the alleged performance deficiencies prior to the plaintiff’s FMLA leave but took no action to terminate until after plaintiff took leave under the FMLA. *Moorer v. Baptist Mem’l Health Care Sys.*, 398 F.3d 469 (6th Cir. 2005). However, a federal district court in Illinois found that an employee’s acceptance of a light duty assignment rather than FMLA leave did not establish an FMLA claim, as FMLA is satisfied as long as acceptance of the light duty assignment is voluntary and the employee receives twelve weeks of job protection. *Artis v. Palos Community Hosp.*, 2004 WL 2125414 (N.D.Ill. 2004).

**Long Term Care**

The Long Term Care Practice Group focused on end-of-life issues, disability rights, a challenge to nursing home regulations, and Medicare overpayment actions.

One of the most significant events of the year involved state and federal legislative efforts to circumvent various court rulings ending life-prolonging procedures for Theresa Schiavo. Both the Florida legislature and Congress enacted legislation to prevent the withholding of nutrition and hydration to Theresa, who was in a persistent vegetative state, even though various court rulings had authorized the removal of her tubes. However, the Florida Supreme Court found the Florida legislation unconstitutional and various federal courts refused to grant relief under the Congressional act. The U.S. Supreme Court declined to review the case despite several petitions. In the end, Theresa died thirteen days after her nutrition and hydration tubes were removed. *Bush v. Schiavo*, 885 So.2d 321 (Fla. 2004); *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1223 (11th Cir.), *cert. denied*, 125 S.Ct. 1722 (2005). This case highlighted the controversial nature of end-of-life decisions and the willingness of the legislative branch to attempt to circumvent the judiciary.

In a case heralded by disability rights advocates, a federal district court in Arizona ordered the Arizona Medicaid program to offer a rate of pay to home health workers that was sufficient to attract enough workers to deliver all of the

Patient advocacy groups filed a class action on behalf of the State of Washington’s nursing home residents against DHHS, requesting the court to declare illegal the federal regulations allowing nursing homes to employ trained feeding assistants, 42 C.F.R. §§ 483.35(h) and 483.73(e)(1). According to the plaintiffs, the regulations violate the federal Nursing Home Reform Act by allowing feeding assistants to provide direct care because their training is less than that required of certified nurse aides. Resident Councils of Washington v. Thompson (complaint) (W.D. Wash. July 30, 2004).

The First Circuit, rejecting the Third Circuit’s analysis, joined the Ninth and D.C. Circuits in holding that a deduction for Medicare overpayments during a nursing home’s bankruptcy proceedings is a permissible recoupment and does not violate the bankruptcy automatic stay provision. Holyoke Nursing Home, Inc. v. Health Care Financing Admin., 372 F.3d 1 (1st Cir. 2004). It will be interesting to see if the Supreme Court decides to grant certiorari to resolve this split among the federal appeals courts.

**Medical Staff, Credentialing, and Peer Review**

The Practice Group leadership focused on many of the flashpoints between physicians and hospitals, including discoverability of peer review documents and suspension of hospital privileges. In addition, the leadership examined the issue of negligent credentialing.

The Ohio appellate court was busy with questions regarding the discoverability of peer review documents. The court held that plaintiffs may not obtain physician peer review documents from hospitals but must obtain such documents from the original source, and that the peer review privilege extends to information that can identify documents in a hospital’s peer review and credentialing files. See Hammonds v. Ruf, 2004 WL 2674609 (Ohio App. 2004); Huntsman v. Aultman Hosp., 826 N.E.2d 384 (Ohio App. 2005).

An appeals court in California held that a hospital may summarily suspend a physician when the hospital has an adequate basis to believe that the physician was an imminent threat to patients. Medical Staff of Sharp Mem’l Hosp. v. Superior Court, 16 Cal.Rptr.3d 769 (Cal. App. 2004). An Ohio appellate court held that a hospital’s peer review committee was not liable for damages in a suit brought by a physician who had been suspended because the hospital had immunity under the Health Care Quality Improvement Act, as the action taken was in furtherance of quality healthcare. Fox v. Parma Community Gen. Hosp., 2005 WL 793235 (Ohio App. 2005).
The Texas Supreme Court, adopting a contrary view to other state courts, held that a claim for negligent credentialing of a physician by a hospital was a claim for medical liability, as the court found that a negligent credentialing claim could not exist without negligent treatment. *Garland Community Hosp. v. Rose*, 156 S.W.2d 541 (Tx. 2004); but see *Browning v. Burt*, 613 N.E.2d 993 (Ohio 1993).

**Physician Organizations**

The Physician Organizations Practice Group analyzed a variety of issues that impact the practice of medicine, including antitrust, employment, and fraud and abuse.

Several cases dealt with FTC allegations that physicians engaged in anticompetitive conduct through the methods they used to negotiate rates with health plans. See *In the Matter of Piedmont Health Alliance, Inc.*, Dkt. No. 9314 (Fed. Trade Comm’n Consent Order Aug. 11, 2004); *In the Matter of North Texas Specialty Physicians*, Dkt. No. 9312 (Fed. Trade Comm’n ALJ Decision Nov. 16, 2004).

A federal district court in Idaho stayed several claims involving the possible termination of competing physicians. The physicians alleged that Eastern Idaho Regional Medical Center acted illegally by using provisions of a medical staff development plan created several years earlier to punish physicians who invested in competing facilities. *Biddulph v. HCA, Inc.*, No. CV-04-1219 (stay issued) (D. Idaho Aug. 6, 2004). This case demonstrates the tension between physicians and hospitals, and the measures hospitals are willing to take against physicians to protect their own interests.


As stated above, two more managed care companies, Health Net and Prudential, settled national class action claims brought by physicians alleging violations of federal racketeering and state prompt pay laws. Litigation remains pending
against four more MCOs. *In re Managed Care Litigation*, MDL Case No. 1334 (S.D. Fla. settlement announced May 3, 2005).

**Regulation, Accreditation, and Payment**

The Practice Group leadership focused on accreditation developments from JCAHO regarding patient safety initiatives, regulatory refinements to MMA programs and caselaw regarding reimbursement.

CMS issued a final rule implementing the Medicare prescription drug program mandated by the MMA, which is scheduled to become available to beneficiaries on January 1, 2006. Generally, coverage for this benefit will be provided under private plans that will offer prescription drug coverage only, or through Medicare Advantage plans that will offer prescription drug coverage integrated with healthcare coverage offered under Medicare Part C. Subsequently, CMS issued an interpretation in response to comments received in response to the final rule in order to clarify certain issues. *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4193 (Dep’t Health and Human Servs. Final Rule Jan. 28, 2005); *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 13397 (Dep’t Health and Human Servs. Interpretation March 21, 2005).

CMS also issued a final rule implementing the Medicare Advantage (MA) program, mandated by the MMA, that replaces the Medicare+Choice (M+C) program. According to CMS, the MA program is designed to provide for regional plans that may make private plan options available to more beneficiaries, particularly those in rural areas, and expand the number and type of plans provided for so that beneficiaries have several plan options from which to choose. As with the Medicare prescription drug program, CMS subsequently issued an interpretation in response to comments received in response to the final rule in order to clarify certain issues. *Medicare Program; Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 4587 (Dep’t Health and Human Servs. Final Rule Jan. 28, 2005); *Medicare Program; Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 13401 (Dep’t Health and Human Servs. Interpretation March 21, 2005).

In the area of accreditation, the Practice Group leaders discussed the various JCAHO initiatives to enhance its efforts to promote patient safety. JCAHO and CMS announced the signing of an agreement to work together to align current and future common hospital performance measures that address certain conditions in order to make it easier and less expensive for hospitals to comply with both CMS and JCAHO requirements for data collection and reporting. Moreover, JCAHO, along with Joint Commission Resources, announced the establishment of a new patient safety website, www.jcipatientssafety.org, to function as a repository for information and resources relating to patient safety.
In a setback for JCAHO, the GAO issued a report finding fault with JCAHO’s hospital accreditation process. The GAO determined that JCAHO did not identify most of the hospitals that were found to have deficiencies when surveyed by state survey agencies and recommended that Congress give CMS authority over JCAHO’s hospital accreditation program. See Medicare Patient Safety in Hospitals, GAO-04-850 (2004).

The Practice Group leadership also reviewed a number of significant reimbursement cases, including Maximum Comfort, Inc. v. Thompson, in which a federal district court determined that DHHS could not require durable medical equipment suppliers to obtain medical records and make independent judgments regarding medical necessity, as 42 U.S.C. § 1395m(j)(2)(A)(i) supported the supplier’s position that certificates of medical necessity adequately document medical necessity. 323 F.Supp.2d 1060 (E.D. Calif. 2004).

**Tax and Finance**

Once again, joint ventures represented a significant area for the Tax and Finance Practice Group. In addition, plaintiffs’ lawyers turned their sights on nonprofit hospitals, claiming the hospitals benefited from the tax exemption for charitable entities without providing any charitable care.

The litigation that has embroiled the St. David’s Health Care System for the last several years finally came to an end, as St. David’s announced that the federal government withdrew its appeal of the jury’s March 2004 verdict that rejected the IRS’ position that the nonprofit system’s whole hospital joint venture with for-profit HCA, Inc., compromised its charitable mission and required it to forfeit its 501(c)(3) tax exemption. In exchange, St. David’s agreed not to seek attorneys’ fees in the case.

The IRS approved a proposed hospital controlled physician-hospital joint imaging center, affirming its position set forth in Rev. Rule 98-15 that governance control is the most important factor in healthcare nonprofit, for profit joint venture transactions. IRS Priv. Ltr. Rul. 200436002 (June 6, 2004).

A consortium of plaintiff’s firms headed by Richard Scruggs, former big tobacco plaintiff’s counsel, filed class actions against nonprofit hospitals alleging that the nonprofit hospitals retained hundreds of millions of dollars annually as a result of their tax exempt status yet improperly charged uninsured patients inflated prices for services and engaged in aggressive collection efforts, when the hospitals should have been providing charity care. In August 2004, Scruggs announced a settlement with North Mississippi Health Services (NMHS) in which NMHS agreed to forgive debt or refund payments to the uninsured it treated over the last three years. To date, NMHS is the only hospital to have settled the charges. Many of the cases in the federal courts have been voluntarily dismissed or dismissed on the merits, as courts have uniformly rejected the legal theory that a
patient can be a third-party beneficiary of the tax-exempt status granted by the
government to the hospital or that a charitable trust was created for the benefit of
patients. However, Scruggs has announced that the cases will be re-filed in state
courts.

Finally, Practice Group leaders focused on actions regarding exempt
organizations. The IRS announced a major enforcement initiative to identify and
halt abuses by tax-exempt organizations that pay excessive compensation and
benefits to their officers and other insiders, with more than 2000 exempt
organizations planned for contact and possible examination. See IRS Press

Teaching Hospitals and Academic Medical Centers

The Teaching Hospital and Academic Medical Centers Practice Group analyzed
a number of cases in several important areas of law, including Medicare and
Medicaid payment issues, professional rights, and indigent care issues.

Two federal appeals courts deferred to the interpretations put forth by DHHS
regarding disproportionate share hospitals (DSH) and upheld the agency’s denial
Thompson, 364 F.3d 513 (4th Cir. 2004); University Medical Center of Southern
Nevada v. Thompson, 380 F.3d 1197 (9th Cir. 2004).

The Massachusetts high court held that the state could recoup from Medicaid
beneficiaries and their estates payments for tobacco-related illnesses, even
though the state received funds for such care through the national tobacco
litigation settlement, as any right to setoff under state law was trumped by the
federal law prohibiting any claim to a portion of the tobacco settlement by

Several courts took issue with the cutbacks on services provided to the needy
made in response to the current economic crisis faced by state and local
governments. The Ninth Circuit upheld a preliminary injunction enjoining Los
Angeles county from closing one hospital and reducing services at another,
holding that a state budget crisis was not a valid defense to plaintiffs’ state law
claims because the county was statutorily required to provide appropriate health
services to the state’s needy population. Harris v. Bd. of Supervisors, L.A.
County, 366 F.3d 754 (9th Cir. 2004). The Third Circuit allowed plaintiffs to
continue with their 42 U.S.C. § 1983 action against the state of Pennsylvania for
failing to provide services required under the Medicaid Act. Sabree ex rel. Sabree

State courts upheld the application of state reciprocal discipline statutes, even in
a case where the professional at issue did not admit to any wrongdoing. See,
In a decision that could tax already straining state budgets, a North Carolina appeals court upheld a lower court’s ruling that may allow undocumented aliens to qualify for full Medicaid coverage for medical care necessary to treat an emergency medical condition. However, the case remains pending and warrants further attention, as this case could have a major impact on state Medicaid programs. See Diaz v. Division of Soc. Servs., 600 S.E.2d 877 (2004); petition for discretionary review granted, 611 S.E.2d 409 (N.C. App. 2005).

II. CONCLUSION

Over the past twelve months, the federal government refined its prescription drug and Medicare managed care programs by releasing a series of final rules and interpretations in an effort to implement these far-reaching programs.

Providers continued to squabble with each other. Physicians and hospitals fought battles regarding specialty hospitals, exclusive contracting, and the revocation of privileges. Specialty hospitals sued traditional hospitals and health plans alleging antitrust violations. Several health plans settled class action suits with physicians, while others decided to continue the litigation.

Nonprofit hospitals joined the ranks of those sued by class action plaintiffs’ attorneys, as lawsuits were filed challenging their tax exempt status due to the lack of charity care provided to uninsured patients. While one hospital has settled, it appears the remaining hospitals plan to continue the litigation.

The healthcare industry found itself at the center of a separation of powers debate when a state legislature and Congress attempted to circumvent the judiciary’s rulings regarding end-of-life issues. In the end, the judiciary’s decisions were upheld, but the underlying tensions revealed still exist and the ramifications from the sad death of Theresa Schiavo will be felt for years to come.

The variety and complexity of the issues summarized in this publication offer an outstanding demonstration of the challenges faced by the healthcare industry in navigating the treacherous landscape in which they now operate. As the government continues to expend significant resources towards healthcare issues, providers can expect increased scrutiny and regulation in an already overburdened industry. While the various providers battle among each other, they are intertwined and interdependent. Even the state and federal governments are both enemy and friend. This complex web of relationships often results in extraordinary developments and partnerships.

We have much to look forward to over the next year. The prescription drug and Medicare Advantage programs will be rolled out to beneficiaries and will be
intensely scrutinized for flaws. The judiciary will continue to be active in healthcare, rendering many important decisions that will affect providers at all levels. The healthcare industry itself will evolve in response to market and governmental pressures, leading to innovations and initiatives to be analyzed and challenged.

This effort to consolidate one year’s worth of healthcare law developments into a digestible format may serve as a resource for you until Health Lawyers meets again in 2006. Practice Group members should be commended for their efforts in making this resource available.
AMERICAN HEALTH LAWYERS ASSOCIATION

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I. EXCLUSIVE ARRANGEMENTS

First Circuit Says Closed Pharmacy Network Agreements Did Not Violate Antitrust Laws
The First Circuit affirmed a district court ruling that the exclusion of Stop & Shop and Walgreens from a pharmacy network established by Blue Cross of Rhode Island (Blue Cross) and PharmaCare, a pharmacy benefits manager (PBM) operated by CVS, was not per se illegal. In addition, the court found that the arrangement PharmaCare negotiated with Provider Health Services, Inc. (PHS), PBM to United Healthcare of New England, Inc. (United), to allow Pharmacare to join United's closed network while PHS participated in the Blue Cross network was not a per se violation of the antitrust laws.

Rather, the First Circuit affirmed the trial court's judgment that the closed pharmacy networks were merely an exclusive dealing arrangement requiring assessment on a rule of reason basis that weighed the pro- and anti-competitive aspects of the agreement. The court held that plaintiffs failed to establish the relevant market and, therefore, failed to demonstrate that the agreements were an unreasonable restraint of trade. The court also rejected the plaintiffs' claim that the two closed networks joined in an illegal agreement to set prices, stating that they were at least partially integrated and that plaintiffs failed to provide sufficient facts to support their claim. The court found that, on balance, the networks benefited plan members, enabling them to obtain lower prices for prescription drugs.

Stop & Shop Supermarket Co. v. Blue Cross and Blue Shield of Rhode Island, 373 F.3d 57 (1st Cir. 2004).

On a rule of reason basis, this exclusive arrangement was deemed to have sufficient benefits to outweigh any reduction in competition that it fostered.

Third Circuit Says Dealer Exclusivity Policy Violates Antitrust Laws
The Third Circuit reversed a district court ruling that the government had failed to prove that Dentsply's dealer exclusivity policy violated § 2 of the Sherman Act and remanded for entry of injunctive relief. The government alleged that Dentsply's policy of refusing to allow its dealers to carry competing lines of artificial teeth (with limited exceptions) served to prevent the successful entry of two foreign manufacturers in the market for artificial teeth.

The Third Circuit disagreed with the district court's finding that Dentsply had not created a market with supra competitive pricing, noting that Dentsply "sets prices with little concern for its competitors," a hallmark of a firm with monopoly power.
The court took issue with the district court’s emphasis on sales to final consumers (dental labs), ruling that Dentsply’s “customers” included both final consumers and dealers who sold to final consumers. It also found that direct sales by manufacturers to dental labs were not a substitute for sales through dealers.


The mere existence of alternative means of distribution does not preclude a finding that a dealer exclusivity policy serves to maintain a company’s monopoly and violates § 2 of the Sherman Act.

Antitrust Claims by ASC Against Hospital Survive Summary Judgment. Rome Ambulatory Surgical Center (RASC) brought suit against Rome Memorial Hospital (Hospital), claiming that the Hospital had forced it out of business by sponsoring a physician boycott of RASC and intimidating those physicians who chose to use RASC. In addition, RASC claimed that the Hospital had entered into exclusive contracts with managed care companies, thus reducing the number of patients for whom RASC was an option. RASC filed suit under both § 1 and § 2 of the Sherman Act, and the Hospital moved for summary judgment, claiming that RASC did not have standing to sue because it had not demonstrated an antitrust injury.

While the court dismissed nine of the twelve causes of action asserted by RASC, it ruled that RASC had set forth facts sufficient to support a reasonable inference that the Hospital’s behavior had injured RASC and that the injury was the consequence of behavior proscribed under the Sherman Act. The court found that RASC’s claim under § 1 regarding the exclusive contracts with managed care organizations raised questions of fact and that RASC had met its burden in showing foreclosure of a significant amount of trade. The court considered the Hospital’s claims that the contracts were actually pro-competitive but ruled that there were questions of fact regarding the benefits. The court also ruled that, while RASC was unable to show monopolization of the relevant market, it had raised triable issues with two of its § 2 claims, attempted monopolization and conspiracy to monopolize.


Exclusive contracts between managed care organizations and hospitals may face antitrust scrutiny; therefore, business justifications for such contracts must be articulated convincingly.

Optometrists Have No Standing Under Antitrust Laws Against MCO That Uses Ophthalmologists Exclusively

Plaintiffs were a group of optometrists who were excluded from the network for Intermountain Health Care’s (IHC) limited healthcare plans because of IHC’s policy of using ophthalmologists for all its covered eye care, both surgical and
nonsurgical. Plaintiffs alleged that IHC was using its market power in the health plan market to gain market power in a market consisting of hospital and surgical facilities. The court ruled that plaintiffs did not have standing to sue, as they did not compete with ophthalmologists in the surgical facilities market. The court also rejected claims that IHC was illegally “tying those [managed care] sales to the agreement not to use non-panel optometrists for nonsurgical eye care needs,” ruling that there is only one product – the plan’s agreed upon services. The court also found that limited provider panels do not constitute either a group boycott or a refusal to deal, because optometrists do not compete with health plans, stating that “[t]he Sherman Act does not guarantee the Plaintiffs a share of the economic benefit of IHC’s market power in the ‘managed care’ health plan market, or the right to join in IHC’s exercise of its market power for their own financial gain.”


Managed care plans may use limited networks of physicians without violating antitrust laws.

Specialty Hospital Files Antitrust Action Against Acute Care Hospitals and Insurers
Heartland Surgical Specialty Hospital, LLC (Heartland), a specialty surgical hospital, filed an antitrust action in the United States District Court of Kansas against traditional acute care hospitals and several major insurance carriers for the carriers’ refusal to enter into managed care contracts with Heartland. The lawsuit alleges that the named insurance carriers, Blue Cross and Blue Shield of Kansas City, Coventry Health Care of Kansas, United Healthcare, Inc., Humana Health Plan, Inc., Aetna Inc., and Cigna Healthcare of Ohio, Inc., conspired with major hospitals (also named as defendants) to direct patients to the traditional hospitals to the exclusion of Heartland for acute care hospital services and spine and upper extremity services. In denying the allegations, defendants maintain that their network contracting decisions were appropriate and had been made independently.


This case is significant because it demonstrates the ongoing battle between specialty hospitals and “traditional” hospitals for patients and revenue.

II. MERGERS AND ACQUISITIONS

FTC Clears Two Pharmaceutical Acquisitions: Cephalon Acquisition of Cima and Sanofi-Synthelabo Acquisition of Aventis
The Federal Trade Commission (FTC) allowed the acquisition of Cima Labs, Inc., by Cephalon, Inc., subject to conditions specified in a consent agreement. The
FTC found that the acquisition would cause significant anti-competitive harm in the U.S. market for breakthrough cancer pain (BTCP) products, in which Cephalon is currently the only seller and Cima is the best-positioned entrant. The FTC found that other entry would not be timely, likely, or sufficient to counteract the anticompetitive effects of the acquisition, which therefore violated § 5 of the FTC Act and § 7 of the Clayton Act. Thus, the consent order requires Cephalon to grant Barr Laboratories, Inc., an irrevocable license to manufacture and sell a generic formulation of Cephalon’s breakthrough BTCP drug Actiq in the United States.

The FTC also allowed Sanofi-Synthelabo to acquire Aventis, provided the companies divest certain assets and royalty rights in the relevant overlapping markets. According to the FTC’s complaint, the acquisition would be anticompetitive and violate § 5 of the FTC Act and § 7 of the Clayton Act in the markets for Factor Xa inhibitors (anticoagulants), cytotoxic colorectal cancer drugs and prescription insomnia treatments. The FTC maintained that each of these markets is highly concentrated, with entry being difficult. The consent order requires Sanofi to divest all Arixtra assets to GlaxoSmithKline, PLC, all key clinical studies for the Campto® cytotoxic colorectal cancer treatments conducted by Aventis to Pfizer, Inc., and Aventis’ contractual rights to the Estorra insomnia drug to Sepracor, Inc.


FTC Closes Investigation of Waukegan, Illinois Hospital Consolidation
Victory Memorial Hospital (Victory) and Provena St. Therese Medical Center (St. Therese), two hospitals in Waukegan, Illinois, merged in 2000, creating a joint operating venture known as Vista Health (Vista). One and one half years later, the FTC began its investigation regarding the merger, but announced its decision to close its investigation in July 2004. The FTC did not find sufficient evidence of market power or harm to consumers resulting from the merger. Based on an econometric evaluation, testimony, and review of the parties’ documents, the FTC concluded that the post-merger price increases at Vista were no higher than those at similar hospitals in the area. Despite evidence implying substantial pre-merger competition between the two parties, the FTC concluded that St. Therese had been pursuing a non-sustainable strategy and that both hospitals had been losing market share prior to the merger.

Statement of the FTC in the Matter of Victory Memorial Hospital/Provena St. Therese Medical Center (Fed. Trade Comm’n July 1, 2004).

The FTC allowed a merged hospital system to remain intact, even though prices increased post-merger, because both hospitals had been losing market share pre-merger.
DOJ Closes Investigation of Unitedhealth Group’s Acquisition of Oxford Health Plans

UnitedHealth Group Inc. (United) announced an agreement to acquire Oxford Health Plans Inc. (Oxford) in April 2004. United is one of the largest nationwide health insurance companies. Oxford is a regional health insurer, primarily active in the tri-state area of Connecticut, New Jersey, and New York. The Department of Justice (DOJ) investigation focused on whether the merger would give the combined company market or monopsony power. It concluded that the relevant market on the selling side was no broader than the market for fully-insured products in the tri-state area, but acknowledged that lines between particular products (e.g., PPO, POS) have blurred. Oxford is not a significant competitor for self-insured plans, where United makes the majority of its sales. The DOJ determined that the merger should not substantially lessen competition because the two companies are generally not particularly close competitors, and a number of viable competitors will remain post-merger. The DOJ also concluded the merger would not give the combined company buying-side (monopsony) power over physicians or hospitals, indicating that the combined company would not account for a significant share of provider reimbursement. The DOJ noted that Medicare and Medicaid reimbursements must be considered in determining whether the combined company would be able to decrease reimbursement to providers. State regulators in California, Connecticut, New Jersey, and New York also approved the merger. An action filed by the Medical Society of New Jersey against the New Jersey Department of Banking and Insurance, arguing that the merger will have an anticompetitive impact on physicians, remains pending.

Department of Justice Antitrust Division Statement in the Closing of its Investigation of UnitedHealth Group’s Acquisition of Oxford Health Plans (U.S. Dept. of Justice Antitrust Division Press Release July 20, 2004).

III. PRICE-FIXING

FTC Charges Generic Drug Marketers in Its First Implementation of July 2003 Disgorgement Policy Statement

In August 2004, the FTC filed a complaint under the FTC Act, §§ 5 and 13(b), against the generic drug manufacturers Alpharma, Inc., and Perrigo Co., alleging that the defendants, the only two approved manufacturers of a generic over-the-counter liquid ibuprofen for children, agreed to allocate the market, thereby limiting competition and driving up prices. According to the complaint, both companies filed with the FDA in 1996 for approval to sell generic versions of children’s liquid Motrin. Both companies expected to receive FDA approval in June 1998 and aggressively competed to secure customers, thereby driving prices down. Subsequent to a 1998 FDA determination that Alpharma had 180 days of exclusivity, Perrigo approached Alpharma to seek an agreement to eliminate competition and divide the market. In June 1998, the companies signed an agreement that designated Perrigo as the exclusive provider of the drug for seven years, in exchange for an up-front payment plus royalty to Alpharma.
The FTC pursued the investigation as an implementation of its July 2003 disgorgement policy statement. On August 12, 2004, the FTC announced that the charges were settled, with the companies agreeing to pay $6.25 million in disgorgement of profits in addition to signing a consent decree enjoining them from signing non-compete agreements where one party is a first ANDA-filer. In addition, the companies agreed to pay $1.5 million to a group of fifty states and territories that have also filed suit to challenge the non-compete agreement between Alpharma and Perrigo.


This case is significant as it represents the FTC’s first implementation of its July 2003 disgorgement policy statement.

Eleventh Circuit Vacates FTC Decision in K-Dur Case
Upsher filed an ANDA for Klor Con M20 in 1995 and was sued by Schering-Plough Corporation shortly thereafter. In June 1997, the parties negotiated a settlement agreement, under which Klor Con would enter the market no earlier than September 1, 2001, and Schering took a license from Upsher for five of Upsher’s drugs, including Niacor, a sustained-release niacin product in clinical trials for cholesterol reduction, that Schering valued at between $245 and $265 million. Upsher and Schering stopped development efforts with respect to Niacor in 1998. In December 1997, Schering reached a court-mediated settlement with ESI (another generic company) under which Schering was to pay ESI $5 million, and ESI would enter the market no earlier than January 1, 2004 (three years before the patent was to expire).

The FTC filed an administrative complaint against Schering, Upsher, and AHP (ESI’s parent) in March 2001, which was tried before an administrative law judge (ALJ) in early 2002. The ALJ ruled that “both agreements were lawful settlements of legitimate patent lawsuits,” and dismissed the case. This dismissal was appealed to the FTC as a whole, which, on December 8, 2003, issued an opinion reversing the ALJ and finding both agreements to be anticompetitive. Schering and Upsher petitioned for review of the FTC’s decision. On March 8, 2005, the Eleventh Circuit vacated the FTC’s decision with respect to both agreements. With respect to Upsher, they stated “[t]here is nothing to refute that these payments are a fair price for Niacor and the other Upsher products.” With respect to the settlement with ESI, the court stated, “[i]t seems the sole indiscretion committed in the context of the ESI settlement is the inclusion of monetary payments. The Commission ignored the lengthy mediation process and insisted that the parties could have reached an alternative settlement with an earlier entry date.”

Patent settlements that involve “reverse payments” may not be anticompetitive, as courts will consider the benefits of the settlement of patent infringement suits.

Resident Physicians’ Antitrust Class Action
On May 7, 2002, three former resident physicians, Paul Jung, M.D., Luis Llerena, M.D., and Denise Greene, M.D., filed an antitrust class action lawsuit against the National Resident Matching Program (NRMP), and its five sponsors, the Accreditation Council for Graduate Medical Education, and twenty-nine hospitals that sponsor residency programs. Under § 1 of the Sherman Act, plaintiffs alleged that defendants used the NRMP match system to limit competition by sharing salary and other confidential information, fixing wages and restricting opportunities for residents. Plaintiffs alleged that these actions led to lower wages and longer working hours for residents than would have occurred in a competitive situation.

In response to the threat of litigation, the defendants obtained from Congress a special exemption to the antitrust laws stating that the NRMP match system does not violate antitrust law, and that the match system cannot be used as evidence in an antitrust case. The U.S. District Court for the District of Columbia granted the Association of American Medical Colleges’ motion to dismiss the case, citing the April 2004 legislation as a deciding factor.

In addition, the court denied a motion brought by the named plaintiffs for alteration or amendment of judgment to allow for an amended complaint, finding that the passage of the April 2004 legislation did not support amendment. The court further found that futility precluded any amendment to the complaint. Jung v. Ass’n of Am. Med. Colleges, 339 F.Supp.2d 26 (D.D.C 2004); 226 F.R.D. 7 (D.D.C. 2005).

Plaintiffs cannot claim that the April 2004 legislation is a “change in controlling law” as the decision was issued after the legislation was passed and, therefore, may not amend their complaint.

IV. PHYSICIAN IPA/PHO CASES

PHO and IPA Settle Price-Fixing Charges With the FTC
The FTC issued an administrative complaint in December 2003 against Piedmont Health Alliance, Inc. (Piedmont), a physician-hospital organization (PHO) based in North Carolina, and ten of its physician members, for fixing physician prices. The FTC charged the PHO and the physicians with anticompetitive conduct that harmed consumers in four North Carolina counties, thereby violating § 5 of the FTC Act. Respondents agreed to settle the FTC charges. The consent order prohibits Piedmont and the ten physicians from entering into any kind of negotiations with payors on behalf of any physician. It also prevents the physicians from dealing with any payors. Frye Regional Medical Center, Inc., an
acute care hospital that also belonged to the PHO, and its parent company, Tenet Healthcare Corporation, had earlier settled FTC charges against them concerning their role in facilitating the PHO’s price-fixing. Charges were not brought against the other member hospitals, which are non-profit.


The complaint and consent order issued by the FTC indicates the agency’s continued vigilance against anti-competitive activity such as price-fixing. In addition, this action demonstrates that the agency will actively pursue individual physicians.

New Mexico IPA and Employees Settle FTC Price Fixing Charges
A new Mexico-based physicians’ association, Southeastern New Mexico Physicians IPA, Inc., and two of its employees settled FTC charges that the competing physicians agreed to fix prices to third-party payors and health-care plans and refused to deal with payors except on collectively agreed-upon terms, thereby raising the costs of healthcare to consumers in Roswell, New Mexico. The IPA members represented seventy-three percent of all physicians practicing independently in and around Roswell. The consent order prohibits the IPA and its members from entering into any agreement to deal with payors and also requires the two employees to notify the FTC for three years before entering any arrangement to act as a messenger on behalf of any physician.


ALJ Finds Texas IPA Group Guilty of Fixing Prices and Restraining Trade
A September 2003 FTC complaint alleged that physicians participating in North Texas Specialty Physicians (NTSP), an IPA comprising a substantial share of Fort Worth physicians, engaged in horizontal price fixing by collectively bargaining with health insurance plans to obtain higher prices in physician service contracts, thereby violating FTC Act § 5. The ALJ agreed, finding that the evidence established that NTSP physicians communicated the minimum prices acceptable for their services to NTSP, and the NTSP thereby was able to negotiate higher rates and more favorable terms for non-risk contracts than those initially offered by various health insurance plans. FTC staff also provided instances in which NTSP discouraged payors and participating physicians from negotiating directly with payors, resulting in higher prices for physician services. The ALJ concluded that this anticompetitive conduct by NTSP had no plausible or valid efficiency justification and issued an order requiring NTSP to cease and desist from joint negotiation of non-risk contracts or sharing of pricing information with its members. In addition, NTSP must allow termination of all such existing contracts. Finally, for three years, NTSP must notify the FTC before entering into any arrangement with any physician under which it would act as a “messenger,”
on behalf of a physician, with a payor regarding contracting issues. Both sides have appealed the ALJ's decision.


*FTC ALJ finds that non-integrated association of physicians engaged in price fixing when it polled its members on acceptable prices, used the data to screen payor agreements on behalf of the members, and prevented its members from individually considering the proposed payor contracts.*

**New Mexico PHO Settles With FTC on Charges of Collusion**
An FTC consent order resolves allegations of price fixing by physicians and nurse anesthetists who belong to a New Mexico PHO and comprise eighty-four percent of area physicians. White Sands Health Care System (White Sands) is barred from negotiating, refusing to deal, or setting terms for dealing with payors on behalf of its physician members and other providers. The complaint alleged that White Sands’ physician and nurse anesthetist members refused to deal individually with health plans, did not follow a lawful messenger model, and instead entered into contracts negotiated by its consultant, Dacite Inc., on their behalf. The FTC charged that White Sands, Alamogordo Physicians and Dacite orchestrated collective refusals to deal with payors, resulting in higher fees, with no beneficial impact on efficiency and consumer welfare. The consent order prohibits respondents from entering into any collective agreement to negotiate with payors on any provider’s behalf, from not dealing with payors, and from agreeing to terms by which any provider deals with a payor. The respondents are also required to notify the FTC prior to entering any “messenger” arrangement with payors.


**FTC Announces Consent Order with IPA New Millennium Orthopaedics**
The FTC alleged that New Millennium Orthopaedics (NMO), an IPA consisting of two physician groups (Wellington Orthopaedics & Sports Medicine and Beacon Orthopaedics & Sports Medicine), violated § 5 of the FTC Act by “orchestrating and implementing agreements between competing orthopaedic physician groups to fix prices charged to health plans and by refusing to deal with one of the health plans that would not agree to the collectively determined terms.” Under the consent agreement, NMO is to be disbanded, contracts with payors entered into by NMO can be terminated without penalty, and the two physician groups are not to negotiate on behalf of any physician with any payor, although they will be allowed to enter into “qualified risk-sharing joint agreements” or “qualified clinically integrated joint arrangements.”

**In the Matter of New Millennium Orthopaedics, LLC.,** File No. 031-0087 (Fed. Trade Comm’n Consent Order May 2, 2005).
FTC Announces Consent Order with IPA Evanston Northwestern Healthcare Corporation

Evanston Northwestern Healthcare Corporation (ENH), ENH Medical Group, Inc., and ENH Faculty Practice Associates agreed to stop bargaining collectively on behalf of their members. Faculty Practice Associates, a non-profit corporation that employs about 460 salaried physicians, is the sole owner of ENH Medical Group, a for-profit company that negotiates with health plans on behalf of Faculty Practice Associates’ salaried physicians. ENH Medical Group also negotiated with health plans on behalf of about 450 doctors who were independent practitioners in the same geographic area (approximately 300 of the 450 doctors formerly contracted through the Highland Park IPA, which was folded into ENH as a result of the January 2000 merger between ENH and Highland Park).

According to the FTC Complaint, ENH Medical Group converted a number of capitated contracts into fee-for-service contracts and negotiated higher reimbursement levels for existing fee-for-service contracts. Under the consent agreement, respondents are barred from entering into or facilitating any agreement among physicians that would negotiate with payors on behalf of physicians, threaten not to deal with payors, designate the terms of negotiation with payors, or refuse to deal individually with payors. However, respondents are not barred from negotiating and other activities on behalf of their salaried employees.


V. OTHER PHYSICIAN CASES

Partial Summary Judgment Granted to Plaintiffs in Case Alleging Attempted Monopolization by Anesthesiology Group

Plaintiffs, Defiance Hospital (Hospital) and ProMedia West Physicians, LLC, alleged that Fauster-Cameron Inc., d/b/a Defiance Clinic (Fauster), a provider of anesthesia services, attempted to monopolize a market defined by plaintiffs to include anesthesia services within twenty minutes of the Hospital. The court found that Fauster engaged in predatory conduct, as it forced the Hospital to compete at a loss after the plaintiffs rejected an exclusive arrangement with Fauster. In addition, Fauster placed non-compete restrictions on its CRNAs and secured agreements with area physicians to use its CRNAs as their primary source of anesthesia services. It then refused to provide anesthesia coverage to other physicians. As a result, the Hospital had to develop an entire anesthesia service, which it could not operate profitably. The court awarded summary judgment to the plaintiffs on four claims: wrongful acts and unfair competition, interference with recruiting efforts and unreasonable non-compete agreements, deceptive trade practices by disparaging services provided by the plaintiffs and defamation.

Physician specialty practices can be found to possess (and abuse) market power in relatively local markets when they exclude or disadvantage competitors.

Vision Care Companies’ Suit Alleging Group Boycott by Optometrists in Puerto Rico Survives Motion to Dismiss

The plaintiffs, Ivision Puerto Rico and Ivision Florida, are sister corporations that contract with insurers and HMOs to provide vision care services through optometrists. Plaintiffs allege that the named optometrist defendants, working with each other and through a professional association in Puerto Rico, acted to restrain competition by “inciting” optometrists to terminate contracts with Ivision and to boycott Ivision and otherwise interfere with Ivision’s contracts with current and potential providers in order to force Ivision to raise reimbursement rates. Defendants filed a motion to dismiss for failure to show an impact on interstate commerce and failure to allege antitrust injury. The court ruled that Ivision had claimed an impact on interstate competition, as the Puerto Rican boycott led a company to cancel a contract with Ivision Florida, and that “[A]s alleged, Plaintiffs are the direct target of the boycott instigated to financially destroy them. Thus, there is a strong causal connection between the supposed antitrust violation and Plaintiff’s harm.”


Plaintiffs demonstrated impact on interstate commerce by showing that defendants’ actions led to a canceled contract and therefore established subject matter jurisdiction under the Sherman Act.

Health Net and Prudential Settle National Physician Class Action

Health Net, Inc. (Health Net) and Prudential Financial, Inc. (Prudential) announced that they have settled a national class action brought by nearly 700,000 physicians who alleged that Health Net and Prudential, along with other managed care companies, had violated federal racketeering and state prompt-pay laws in processing claims. Under the settlements, which must be approved by the United States District Court for the Southern District of Florida, Health Net will make a guaranteed cash payment of $60 million, and will invest $80 million (over a four-year term) in various administrative changes. Prudential (which owned Prudential Health Care until it was acquired by Aetna in 1999) agreed to a $22.2 million settlement with the physicians.

The agreements with Health Net and Prudential follow settlements between the same physician plaintiffs and two other named defendants, Aetna, Inc. and Cigna HealthCare Plan, in 2003. Litigation remains pending between the physician plaintiffs and WellPoint, United Healthcare, Humana, and PacifiCare.
Physician plaintiffs achieve yet another victory in their fight to change practices of the managed care industry.

VI. PHARMACEUTICAL CASES

Second Circuit Finds no Antitrust Violation by Barr Labs and Its Supplier in Generic Warfarin Sodium Market
The Second Circuit held that a district court should not have granted summary judgment to Barr Laboratories, Inc., and its supplier ACIC/Brantford on charges that they violated Sherman Act § 1 and § 2 by conspiring to restrain trade and monopolize the supply of generic warfarin sodium. The court ruled that the summary judgment was improper as it included DuPont’s branded Coumadin in the relevant market. The court further ruled that genuine issues of disputed fact remain regarding whether the defendants monopolized the generic warfarin market by misusing the monopoly on clathrate (the primary chemical ingredient used to make warfarin sodium) held by ACIC/Brantford. Furthermore, the appeals court also found evidence that defendants conspired to control the only source of clathrate and to deceive the plaintiffs, Apothecon and Geneva. With respect to the unreasonable restraint of trade element, the appeals court ruled that the district court erred in resolving crucial factual issues instead of sending them to the jury.

Genzyme’s Acquisition of Ilex Oncology Receives Conditional Clearance From the FTC
The approval agreement with the FTC requires Genzyme to divest all rights to U.S. revenues associated with the use of Ilex’s drug Campath for treatment of solid organ transplant acute rejection to Schering AG. Schering already distributes and markets Campath in the U.S. The FTC found that, while there are other solid organ transplant drugs in the marketplace, Campath and Genzyme’s Thymoglobulin are similar in terms of mechanism of action and, therefore, particularly close competitors in a small market. The FTC also found that entry into the market would be unlikely. Campath’s main use (and the only indication currently approved by the FDA) is in oncology. As a result, the agreement also specifies that the companies must devise a formula to determine the portion of Campath revenues attributable to solid organ transplant therapy.
FTC Report on Patent Settlements Involving Pharmaceuticals Released

Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, agreements between brand name drug companies and generic companies that involve the manufacture, marketing, or sale of either the generic drug for which the ANDA was filed or the brand name version thereof have to be filed with the FTC. In addition, any agreements (brand name and generic or generic and generic) that affect the 180-day exclusivity period must be filed. Of the twenty-two agreements filed with the FTC in FY 2004, nineteen were between generic and brand name manufacturers and three were between two generic manufacturers. Fourteen of the agreements between generic and brand name companies involved patent infringement litigation; nine of these did not affect the timing of generic entry. Of the remaining five, three restricted generic entry until after the patent expired and two allowed entry prior to the expiration of the patent. All three of the generic-generic agreements involved the 180-day exclusivity period and resulted from the first filer’s inability to market the product.


Defendants Win Summary Judgment in the Cipro Case

Barr Laboratories filed an ANDA for ciprofloxacin in October 1991 with a Paragraph IV certification that Bayer’s patent on ciprofloxacin was invalid and unenforceable. Bayer sued Barr shortly thereafter, and the court denied both companies’ motions for partial summary judgment in June 1996. In January 1997, Bayer and Barr settled the litigation. Under the settlement agreement, Barr was to amend its Paragraph IV certification to a Paragraph III certification, acknowledging the validity of Bayer’s patent and agreeing not to enter the market until the patent expired, and received a payment of $24.5 million. In addition, the parties signed a supply agreement under which Bayer was to supply Barr with ciprofloxacin for resale no later than six months prior to the patent expiration; Bayer also had the option of supplying ciprofloxacin or making quarterly payments in the interim. Between 1997 and 2002, four generic companies filed Paragraph IV ANDAs for ciprofloxacin; none was victorious in litigation.

In May 2003, Judge Trager ruled that the agreements between Bayer and the generic companies were not per se unlawful, leaving open the possibility that he would find them to be unlawful under a rule-of-reason analysis. In March 2005, Judge Trager ruled that the agreements between Bayer and the generic companies were not unlawful, stating, “[H]ere, plaintiffs have failed to demonstrate anticompetitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the ‘444 Patent.” In fact, the agreements allowed Barr to sell generic ciprofloxacin one year prior to the time it would otherwise have been able to do so (Barr entered six months prior to patent
expiration date, and Bayer received a six-month extension of exclusivity for performing pediatric research).


*Patent settlements that involve “reverse payments” may not be anticompetitive, particularly when the settlement is no more restrictive than the underlying patent.*

**Lawsuit Challenging Maine’s PBM Disclosure Law Dismissed**
On April 13, a federal district court in Maine dismissed a lawsuit brought by the Pharmaceutical Care Management Association (PCMA) challenging provisions of Maine’s Unfair Prescription Drug Practices Act (UPDPA). UPDPA, which was signed into law in June 2003 but not yet implemented, requires PBMs to disclose “all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees” to covered entities (health insurers). The court noted that “[w]hether and how a PBM actually saves an individual benefits provider money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider.” In fact, the court stated, “[t]his lack of transparency also has a tendency to undermine a benefits provider’s ability to determine which is the best proposal among competing proposals from PBMs. … although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs. Therefore, the court upheld all of the provisions of the UPDMA. PCMA has announced its intention to appeal the decision.

**Pharmaceutical Care Mgmt. Ass’n v. Rowe**, Civil No. 03-153-B-H (D. Me. 2005).

*This case is significant because it confirms the authority of states to regulate PBM practices, such as drug switching, and allows states to demand greater transparency in transactions between PBMs and their clients.*

**VII. HOSPITAL CASES**

**Altoona-Bon Secours/Holy Family Consent Decree with PA AG Requires Open Medical Staffs**
The Pennsylvania Attorney General entered into a consent decree allowing two acute-care hospitals, Altoona Hospital and Bon Secours Holy Family Regional Health System, to merge. The agreement seeks to maintain consumers’ freedom of choice by requiring the merged hospital system to accept applications for privileges from physicians in most specialties and to maintain privileges for the existing medical staffs of both hospitals. The agreement also prohibits
discrimination against those consumers who purchase non-inpatient healthcare services from providers other than the merged hospital system. 


_This case demonstrates that State AGs remain active in protecting consumer’s freedom of choice regarding their healthcare._

**District Court Denies Defendant Hospital System PeaceHealth New Trial; Subsequent Settlement Allows Plaintiff McKenzie-Willamette to Become Participating Provider in Regence BlueCross**

McKenzie-Willamette, a 114-bed hospital in Lane County, Oregon, filed suit in January 2002 alleging that PeaceHealth, a multi-hospital system that operates facilities in Lane county, excluded it from providing care to more than one-third of the county’s insured residents through its exclusive contract with Regence BlueCross Blue Shield. PeaceHealth was accused of predatory pricing, illegal tying, restraint of trade and conspiracy to monopolize in violation of the Sherman Act. In October 2003, a Eugene, Oregon, jury agreed with some of the allegations and awarded the hospital $16.6 million in damages. The district court refused PeaceHealth’s requests for a new trial and directed verdict. Subsequently, the parties agreed to dismiss the injunctive relief claims stemming from the federal antitrust lawsuit. Effective Jan. 1, 2005, McKenzie-Willamette will join PeaceHealth as a participating preferred provider in the Regence Blue Cross and Blue Shield Preferred Provider Plan. 


**DOJ and Two Hospitals Sign Consent Decree Regarding Procedure Allocation Agreement Stemming From CON Negotiation**

Princeton Community Hospital Associations (PCH) and Bluefield Regional Medical Center (BRMC), both located in southern West Virginia, entered into agreements in January 2003 under which “BRMC agreed not to offer most cancer services, and PCH agreed not to offer cardiac-surgery services in six West Virginia counties and three Virginia counties.” The hospitals, which had been competitors in provision of cancer services and were potential competitors in provision of cardiac-surgery, filed joint certificate of need (CON) requests for BRMC to provide cardiac surgery and for PCH to provide cancer services (transferring BRMC’s existing CON to PCH). BRMC’s CON for cardiac surgery was approved in August 2003; however, PCH’s cancer services application is still pending. The DOJ instituted an investigation. In its “Competitive Impact Statement,” the DOJ explained that while the West Virginia Health Care Authority (WVCHA) suggested that BRMC and PCH should “reach an understanding” that would enable the parties to submit an approvable request for CON, the hospitals’ agreements were not immune from federal antitrust liability under the state-action
While hospitals may need to negotiate with one another in order to obtain Certificates of Need, an agreement to allocate services does not fall under the state-action exemption.
American Health Lawyers Association

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I. FRAUD AND ABUSE

U.S. Court in Louisiana Says State May Intervene in Qui Tam Action
Physician filed a qui tam case under the federal False Claims Act (FCA) against a pharmaceutical company alleging that it failed to offer federal healthcare programs the discounts it offered to hospitals. The state of Louisiana sought to intervene in the action for its share of the alleged excess Medicaid payments. The court granted the state's motion to intervene, concluding that the state had satisfied the requirements of Rule 24 (a). The court also found the state asserted interests directly related to the transactions forming the basis of the qui tam suit: in the regulation and administration of its Medicaid program, in the enforcement of state laws, and in protection of the economic health of its citizens. The court concluded that the state's interest diverged from that of the relator because the state sought damages under state, not federal, law. Specifically, the state sought to recover overpayments of state money under the state unfair trade practices and consumer protection law, state antitrust law, the state's medical assistance programs integrity law, state fraud law, and unjust enrichment. Concerns about parasitic lawsuits that prompted the FCA bar on subsequent intervenors were not present, according to the court.


*This case recognizes a state’s right to intervene in a qui tam case to assert state law- based claims and suggests that defendants in these cases may be subject to such claims in addition to federal penalties and damages under the FCA.*

Seventh Circuit Says Relator in Qui Tam Case Could Not Bring Action Pro Se
Friedrich Lu brought a qui tam action under the FCA against his former faculty advisor at the University of Illinois and his colleagues claiming they fabricated medical research to defraud the Veterans Administration. The district court dismissed the complaint without prejudice for failure to state a claim under the FCA. After Lu failed to amend the complaint to properly state a claim, the district court converted the dismissal to one with prejudice. The Seventh Circuit affirmed the district court's judgment. The appeals court first addressed the issue of whether Lu's appeal, which was filed forty-five days after the entry of final judgment, was timely under the sixty-day period for appeals by the government, or untimely under the thirty-day period for appeals by private parties. The appeals court held that the government is a party; therefore, the sixty-day appeal period applied. As such, Lu's appeal was timely. The court then determined that Lu was not representing his own interests but the interests of the government,
and the government did not allow Lu to represent it. Thus, the appeals court held that Lu could not bring the action pro se.  

**United States ex rel. Lu v. Ou, 368 F.3d 773 (7th Cir. 2004).**

*This case follows the only prior precedent on point, the Eighth Circuit’s ruling in United States v. Onan, 190 F.2d 1 (8th Cir. 1951), which held that a pro se relator cannot pursue a qui tam action because he is improperly acting as the government’s attorney.*

**Federal Court Holds Each Financial Report Submitted to Government Could Subject Hospital Conducting Federally Funded Vaccine Trials to False Claims Liability**

Relator brought a qui tam action under the FCA against New York University (NYU) alleging that its School of Medicine and Hospitals Center defrauded Medicare by “upcoding” certain services provided in connection with its federally funded clinical trials to test the efficacy of vaccines for malignant melanoma.  

Relator also alleged that NYU received “program income” from outside sources including the patients’ private insurers that it failed to report to the government, amounting to a “reverse false claim” under the FCA.

The U.S. District Court for the Southern District of New York addressed the issue of whether each receipt of an item of alleged “program income” from the vaccine trial constituted a separate false claim, finding that each grant application or amendment, progress report, and periodic financial report could support an FCA claim. The court declined to find, however, that the individual receipt of an alleged program payment constituted a separate false claim under the statute.  

The court also held that a false claim potentially arose each time NYU submitted a separate financial report to the government that failed to include “income from fees for services performed.” However, the relator must also show “that the specific filing required disclosure of actual or anticipated program income and that defendant failed to report that income.”


*This case is significant because the court held that each financial report submitted by a hospital could be considered a potential claim for purposes of the False Claims Act if it failed to include income from certain fees or services performed by the provider; however, the relator must establish that the provider was required to disclose such information in order to constitute an FCA violation.*

**Fifth Circuit Says State Fiscal Intermediary Was Not Entitled to Sovereign Immunity in False Claims Act Case**

Plaintiffs brought a quit tam action under the FCA against multiple defendants including NHIC as a Medicaid fiscal intermediary (FI) for Texas, alleging that the FI had acquiesced to certain fraudulent billing practices. The district court held that Eleventh Amendment sovereign immunity applied to any actions in connection with NHIC’s role as Texas’ FI. Plaintiffs appealed.
In *Clark v. Tarrant County*, 798 F.2d 736 (5th Cir. 1986), the Fifth Circuit employed a six-factor test to determine whether sovereign immunity should be granted. Applying the Clark test, the appeals court reversed the district court's judgment on the ground that NHIC failed to show that Texas would be liable for any damages that would be assessed against NHIC. The court found that there was nothing in the state statutes indicating that an FI is anything other than a private corporation. The second Clark factor, the source of the entity's funding, proved to be the controlling factor for the appeals court. The purpose of state sovereign immunity under the Eleventh Amendment is to protect state treasuries, and a court must look to whether a state would be liable for a judgment against the entity. The FI's contract provides that NHIC indemnifies the state from any liability. In addition, the state did not have control over NHIC's board of directors or its internal management, and thus NHIC was autonomous. The remaining Clark factors "also weigh against granting immunity."


*This case applies the Fifth Circuit’s Clark six-factor test to determine when a government contractor is entitled to sovereign immunity under the Eleventh Amendment.*

**Second Circuit Holds Defendant Had Leadership Role in Conspiracy; Therefore, Enhancement Should Have Been Added to Sentence**

A trial court should have added an enhancement to the sentence of a medical testing company president for his leadership role in a scheme to defraud Medicare.

The defendant organized the scheme by paying individuals for blood samples that were submitted for testing. The owner of a medical billing service provided names and identification numbers of Medicare beneficiaries and physicians, which were attached to the blood samples. Defendant submitted the information with test results based on the blood samples for Medicare reimbursement and received over $1.7 million based on the false Medicare claims.

The district court sentenced defendant to five months imprisonment, five months of home detention, and three years supervised release. The district court declined the government's request that a leadership role enhancement be applied to the sentence and granted defendant's request for a downward departure for extraordinary family circumstances.

The Second Circuit found the district court's analysis flawed, as more than one member of a conspiracy may have a leadership role. Moreover, the appeals court held that defendant's active role in the conspiracy supported a finding that his position as president was relevant to the role-enhancement analysis. For a court to grant a downward departure, a central consideration is whether the
defendant's dependants will be cared and provided for during the defendant's incarceration. The appeals court held that the trial court failed to make adequate findings of fact on the issue to support its downward departure. **United States v. Huerta**, 371 F.3d 88 (2d Cir. 2004).

This case illustrates the application of departures from the federal sentencing guidelines, which were held by the Supreme Court to be advisory only and not mandatory in **U.S. v. Booker**, 125 S.Ct. 738 (2005).

**Pharmacy Not Liable Under FCA For Failure to Fully Credit Medicaid For Returned Medications**

Relator brought a qui tam action under the FCA against Pompton Nursing Home Suppliers (Pompton), a subsidiary of Omnicare, Inc. Pompton provides medications to nursing home residents, some of whom are covered by the New Jersey Medicaid program. On occasion, medications for which Medicaid had previously reimbursed Pompton are returned. New Jersey Medicaid rules allow a pharmacy to recycle returned medications if they have been stored properly and are still sealed. Pompton’s practice is to refund Medicaid only fifty percent of the cost of the returned drug, attributing the remainder to restocking and redispensing expenses. Affirming a lower court ruling rejecting the qui tam action of a former pharmacy employee, the Third Circuit found no FCA liability in the absence of any state regulation requiring pharmacies to fully credit Medicaid for returned medications. The appeals court also rejected the relator’s contention that Pompton violated the FCA by failing to void or adjust previous claims for medications after they were returned and redistributed. The appeals court found New Jersey Medicaid regulations do not require a pharmacy to reverse an earlier claim after a medication is returned and recycled. "[I]f there is no requirement to adjust the claim, there is no liability for failure to do so," the appeals court said. **United States ex rel. Quinn v. Omnicare Inc.**, 382 F.3d 432 (3d Cir. 2004).

This case demonstrates the court’s hesitancy to find FCA liability when there is not a reasonable statutory or regulatory basis prohibiting the alleged improper activity.

**Qui Tam Relator’s Claims Were Barred by FCA’s Jurisdictional Bar**

In 1983, the Texas Health Facilities Commission issued to Mother Frances Hospital and East Texas Regional Health Care Facilities a Certificate of Need (CON) to construct and operate University Park Hospital (UPH). UPH is a subsidiary of and leases its facilities from East Texas Hospital Foundation (Foundation). Sally Reagan filed suit in Texas state court against UPH and others claiming she had been terminated from her job for refusing to go along with false Medicare reporting. Reagan also filed another action in federal court as a qui tam relator under the FCA against East Texas Medical Center Regional Healthcare System. Reagan alleged that: (1) UPH misrepresented its compliance with the CON to its intermediary when filing its Medicare cost reports; (2) UPH falsely certified it was in compliance with Medicare regulations; and (3) UPH
received improper Medicare reimbursements because it misrepresented its status as a "related party" to the Foundation.

The district court granted the defendants' motion for summary judgment on the grounds that Reagan's claims failed on the merits and the suit was precluded by the FCA's "public disclosure" bar. Reagan appealed and the Fifth Circuit affirmed the district court's judgment, finding that Reagan's allegations had been publicly disclosed by Reagan's state suit, intermediary audits, and by documents obtained by Reagan through the Freedom of Information Act (FOIA). On the issue of whether Reagan's FOIA request was a public disclosure, the Fifth Circuit agreed with the Third Circuit's holding in United States ex rel. Mistick v. Housing Auth. of the City of Pittsburgh, 186 F.3d 376 (3d. Cir. 1999), that "the disclosure of information in response to a FOIA request is a 'public disclosure' under" the FCA. The appeals court found persuasive the Mistick court's reasoning "that the specific purpose of FOIA was to make certain information available for public scrutiny." Therefore, the appeals court held the allegations had been publicly disclosed under the FCA and, accordingly, the FCA barred Reagan's claims because the information on which she based her claims was publicly available and she was not the original source of the information.


This case clarifies the FCA's “public disclosure” bar in the Fifth Circuit, which adopts the view of the Third Circuit that the disclosure of information in response to a FOIA request is a public disclosure under the FCA.

Qui Tam Complaint Sufficiently Stated Claims to Survive Motion to Dismiss
An orthopedic surgeon (the Relator) filed a qui tam action under the FCA claiming Zimmer, Inc. (Zimmer), a manufacturer and distributor of orthopedic implants, and Mercy Health Systems (Mercy) violated the FCA by entering into an agreement that provided for illegal kickbacks in violation of the Anti-kickback Statute. The Relator alleged Zimmer entered into a contract with Premier Purchasing Partners (Premier), which was a purchasing agent for a group, including Mercy, to provide Zimmer's orthopedic implants to Premier members. The contract provided for a reward system for participants that purchased a certain number of devices each year during a five-year period. The rewards were in the form of "cash or cash equivalents," which the Relators alleged were illegal kickbacks because cost reports that did not disclose the rewards were submitted to the Medicare program. Mercy allegedly induced some of its physicians to assist in meeting Zimmer's purchasing requirements. The Relator also claimed defendants violated the federal Stark law by making Medicare claims pursuant to prohibited referrals.

Zimmer and Mercy filed motions to dismiss; however, Mercy settled with the Relator prior to the court's ruling. The district court granted Zimmer's motion to dismiss, holding that Zimmer itself had not submitted any false cost reports and
that the Relator failed to show that Zimmer caused Mercy to submit any false cost reports; therefore, the Relator failed to state a cause of action for which relief could be granted. The Relator appealed and the Third Circuit reversed the district court’s judgment on the ground that it was "not clear that the alleged conduct of Zimmer passes muster under the Anti-Kickback and Stark Acts" and, therefore, the "issues cannot be resolved in a motion to dismiss." The appeals court also determined that the marketing program might violate the Stark law because physicians allegedly made prohibited referrals and the Relator had sufficiently alleged a violation of the Stark law in the complaint. Regarding the FCA issue, the appeals court determined that the complaint sufficiently alleged Zimmer knowingly assisted Mercy in presenting false claims to the government, and if the Relator could prove the facts alleged in the complaint, a jury could conclude Zimmer knowingly caused Mercy to file false claims. Accordingly, the appeals court reversed the district court’s judgment and remanded the case for further proceedings.


This case demonstrates the potential vulnerability of device manufacturers to claims arising out of the Anti-kickback Statute as well as the Stark law. Moreover, the appeals court leaves open the possibility that a violation of the Anti-kickback Statute and Stark law could result in FCA liability on the part of the device manufacturer.

U.S. Court in Illinois Refuses to Dismiss Hospital's Breach of Fiduciary Duty Counterclaim Against Employee for Secretly Responding to Government Subpoena

Jacqueline Grandeau (the Employee) brought a qui tam action under the FCA against Cancer Treatment Centers of America (CTCA) alleging it engaged in fraudulent billing practices. The Employee worked as a Quality Assurance Coordinator for a CTCA subsidiary, Midwest Regional Medical Center (MRMC), and had a confidentiality agreement that required her not to disclose confidential or proprietary information "for any reason or purpose whatsoever." While working for MRMC, the Employee received a subpoena from the U.S. Department of Justice directed to her as MRMC's Quality Assurance Coordinator. According to MRMC, the Employee responded to the subpoena on behalf of MRMC by producing numerous confidential documents without MRMC's knowledge. After the government declined to intervene and the complaint was unsealed, MRMC filed a counterclaim against the Employee, alleging that she breached her fiduciary duty by failing to disclose her receipt of and response to the subpoena, that she breached the confidentiality agreement, and that she converted the subpoena for her own benefit by secretly responding to it. The court dismissed MRMC's claims against the Employee for breach of a confidentiality agreement and conversion, but refused to dismiss its claim for breach of fiduciary duty. The court noted that the policy arguments asserted by the Employee and the federal government, which filed an amicus brief asserting that MRMC’s breach of fiduciary duty claim could chill future whistleblowers, missed the mark because
MRMC was challenging the Employee’s response to the subpoena, not her ability to file a qui tam action. The FCA provisions providing for secrecy to allow the government time to evaluate a qui tam complaint do not apply to a relator’s response to a subpoena. Moreover, the FCA’s whistleblower protection provision is not a bar to MRMC’s counterclaim because that section is not intended to give employees immunity but to allow them to seek compensation for retaliation.

In a subsequent opinion, however, the court declined to allow MRMC to recoup the Employee’s salary during the period after she breached her fiduciary duty, holding that “allowing defendant to seek the salary at issue here would not only threaten unjust enrichment, it would also cross the fine line that we drew between relator's breach of fiduciary duty and her statutorily protected activity.”


*This case affirms the right of an employer to expect its employees to notify the employer when the employee receives information such as the subpoena at issue in this case. However, courts will not always grant the relief requested even when a breach of fiduciary duty occurs.*

**Illinois Appeals Court Holds That Arrangement Improperly Requires Physicians to Pay Fee for Referral of Patients**

HealthLink, Inc., develops provider networks and makes such networks available to members of health plans that are offered by insurance carriers, self-funded employer groups, governmental entities, and union trusts (payors). Vine Street Clinic (VSC), a partnership consisting of physicians who provide psychiatric services, entered into an agreement with HealthLink, Inc., to be participating physicians in a network created by HeathLink. HealthLink’s participating provider agreement (PPA) imposes an administrative fee on its participating providers in an amount equal to five percent of the amounts allowed in HealthLink's rate schedule for services provided to members. The Illinois Attorney General, who is charged with enforcing the state Medical Practice Act (Act), issued an opinion on March 5, 2002, concluding that the administrative fee provision of the HealthLink agreement violated § 22(A)(14) of the Act and was thus void under Illinois law. Consequently, HealthLink sought to amend the PPA by charging a fixed fee instead of the percentage-based fee. VSC as well as other providers refused to pay HealthLink’s administrative fee and sought a declaration that both the percentage-based fee and the flat fee violated the Act. The providers also sought to recover all fees previously paid to HealthLink.

The trial court found that the percentage-based fee violated the Act, but that the fixed flat fee did not. The Appellate Court of Illinois affirmed the trial court’s decision that the percentage-based fee violated the Act, but reversed the trial court’s decision that the fixed flat fee did not violate the Act. The appeals court found that, because HealthLink refers patients to physicians through its network and the administrative fee charged by HealthLink (both the percentage fee and
the flat fee) is a fee for referral of patients, the section of the PPA requiring the fee violates the Act and public policy and is accordingly void. The appeals court agreed with the trial court that plaintiffs were not entitled to recover fees previously paid, either the percentage fee or the flat fee, because the physicians had violated the Act, not HealthLink, so "the parties will be left where they have placed themselves."


Although limited to the State of Illinois, this case is significant in that the court found that regardless of how the administrative fee was calculated, payment of administrative fees by physicians violated the State’s fee-splitting statute due to the referral relationship that existed between the parties.

**U.S. Court in California Finds Defendants Collaterally Estopped From Denying Liability Under FCA After Criminal Conviction**

St. Luke's Subacute Hospital and Nursing Center (St. Luke's) is a subacute nursing facility located in California. DHHS OIG found that St. Luke’s inflated the cost of nursing services that it provided to Medicare beneficiaries and fabricated nursing schedules to support the false claims. This resulted in a grand jury indictment against St. Luke's and its CEO, charging the defendants with conspiracy to defraud the Medicare program, submitting false Medicare claims, knowingly and willfully making false statements to Medicare auditors, and obstructing a federal audit. A jury found the defendants guilty on all counts. The United States then filed an action under the FCA and, after the conclusion of the criminal trial, moved for partial summary judgment on the issue of defendants' liability under the FCA. The U.S. District Court for the Northern District of California granted the government’s summary judgment motion, holding that the jury made an affirmative finding on each of the essential elements of an FCA violation and, therefore, the FCA's collateral estoppel provision had been met. Accordingly, the defendants were precluded from denying their liability in the civil action.


This case is significant because it demonstrates the application of the FCA’s collateral estoppel provision and the ease with which that provision may be applied based on the facts of the underlying case.

**Sixth Circuit Finds No Jurisdiction for FCA Quit Tam Action Where Claims Were Publicly Disclosed**

Medtronic applied for FDA Premarket Approval (PMA) for two of its pacemakers. Medtronic later altered the design specifications and neither filed a new PMA application nor identified the change in its postapproval report. Thereafter, a large number of leads malfunctioned. Relators brought products liability actions against Medtronic as well as a qui tam action under the FCA, alleging that Medtronic sold leads to physicians and hospitals, which then implanted the leads
and billed Medicare for their services; Medtronic did not have FDA approval for the devices because it altered the coating after approval; and by selling the leads to doctors and hospitals, Medtronic caused the submission of false claims to Medicare.

The Sixth Circuit held that the information necessary to create the specific inference of fraud was contained in two different parts of the complaint, and that the government could reasonably infer fraud from allegations made in the separate parts of the complaint. The court also found that because the claims in the action were previously disclosed and therefore triggered the FCA’s public disclosure bar, the lower court did not have subject matter jurisdiction. United States ex rel. Gilligan v. Medtronic, Inc., 403 F.3d 386 (6th Cir. 2005).

This decision reaffirms the principle that a qui tam action under the FCA may not be based on publicly available information, as the government does not need assistance from private citizens once the information is publicly disclosed but instead can file suit on its own.

II. ADVISORY OPINIONS

DHHS OIG Sees No Bar to Pathology Lab Volunteering in Medical Assistance Program
The OIG concluded that an arrangement in which a pathology lab would provide services to low-income, uninsured patients through a charitable foundation’s medical assistance program on a voluntary basis would not generate prohibited remuneration under the Anti-kickback Statute.

The non-profit tax-exempt foundation runs a coordinated system of volunteer physician care, hospital care, diagnostic services, and medication assistance for low-income, uninsured residents in a certain county. To qualify for assistance, patients must reside in the county, have no medical insurance, be ineligible for government medical assistance, and have incomes that do not exceed 150 percent of the federal poverty level. The pathology lab, a for-profit corporation partially owned by several pathologists, wishes to volunteer its services to the program. The laboratory certified that no remuneration would be provided directly or indirectly to any volunteer physician, the volunteer pathology lab, or the pathologists performing the laboratory services. The lab also certified that its participation in the program was unrelated to any non-program business.

The OIG concluded that the proposed arrangement involving the pathology lab "results in no economic value to any party in a position to refer Federal healthcare program business to the Lab. Rather, the economic benefit of the Lab's participation inures to the public good in the form of increased availability of services for an underserved population."
DHHS OIG Says Municipal Fire District May Reduce Fees Due From Residents Consistent With Cost-Sharing Obligations for Ambulance Services

The OIG will not impose administrative sanctions under the Anti-kickback Statute in relation to a proposed ordinance by a fire district, operated as a municipal corporation, to reduce fees for residents by an amount consistent with their cost-sharing obligations for ambulance services.

The district already funds its ambulance services through real estate taxes but has adopted an ordinance that would establish a fee schedule that includes a base transport rate. The district would bill residents only to the extent of their insurance coverage and treat the local taxes as payment of any otherwise applicable cost-sharing amounts.

While noting its "longstanding" concerns about "insurance only" billing provisions, the OIG said it would not impose administrative sanctions in connection with the ordinance, citing the special rule for providers and suppliers owned and operated by a state or a political subdivision of a state, CMS Medicare Benefit Policy Manual Chapter 16 § 50.3, which provides that "a [state or local government] facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment."

The OIG cautioned that this protection could only be extended so long as the ordinance was implemented for bona fide residents of the fire district. The OIG also emphasized that the manual provision applied only to situations in which the governmental unit is the ambulance supplier.

DHHS OIG Approves Health System’s Provision of Professional Consultative Services to Low-Income Schoolchildren in Predominantly Rural Areas Through a Sponsored Telemedicine Network

An integrated nonprofit healthcare delivery system that includes a tertiary care facility (the Hospital), serving a three-state area covering twenty-two predominantly rural counties, began a school-based health center program for low-income children. The Health System enhanced the school-based health center program by constructing a telemedicine network to link school-based health centers (the spokes) with various departments of the Health System, a family medicine residency training program, a behavioral health center, a community health department, and school-based health centers (the hub sites).
If, as a result of the screening tests and any tele-consultations conducted at the school-based centers, a student requires a referral to a physician, the student is referred to his or her regular primary care provider. If the student has no regular primary care provider, the nurse provides a list of the primary care providers in the student’s community. By developing, operating, administering, and funding the telemedicine network, the Health System confers benefits on three potential referral sources: (i) the school-based health center “spoke” facilities that obtain free telecommunications equipment and subsidized line charges necessary for operation; (ii) the consulting practitioners at the “hub” sites who might receive additional opportunities to earn professional fees; and (iii) the patients.

The OIG held that the arrangement contained safeguards sufficient to reduce the risk that the remuneration would generate appreciable referrals of Federal healthcare program business. Moreover, the arrangement promotes the obvious public benefit in facilitating better access to screening services for low-income children in rural areas.


DHHS OIG Declines to Approve Proposal by Physician Group Practice to Develop and Own a Comprehensive Physical Therapy Center and to Lease the Center's Space, Equipment, and Personnel to Physicians With Patients Requiring Physical Therapy Services

A multi-specialty practice proposed forming a limited liability company (LLC) for the purpose of establishing a comprehensive physical therapy center to lease space, equipment, and the services of a staff therapist to the physicians of the practice and various other licensed physicians with patients requiring physical therapy services. The Center will be located in the same building as the Physician Group and each of the intended lessees. The Center will be open six days a week for eight hours a day on a first-come, first-served basis. The LLC will not bill third-party payors for services. Each Lessee will enter into a one-year lease with the LLC and pay a monthly rental fee for unlimited use of the Center. Lessees utilizing the staff therapist will pay a higher monthly rental fee than those Lessees who provide their own therapist. The rental fee, excluding charges for the staff therapist, will be calculated at the beginning of the lease term by totaling the monthly rental value of all space, equipment, and services and dividing by the total number of Lessees. The monthly rental value of all space, equipment, and personnel services will be verified and audited by an independent appraisal firm to ensure that it is consistent with fair market value (FMV).

The OIG noted that the deal did not meet the lease safe harbor, and that it was difficult to document FMV. Citing the risk that some physicians will pay more or less than FMV and the risk that the guaranteed income stream could be compensation in exchange for referrals, the OIG declined to approve the proposed arrangement.

DHHS OIG Allows Geriatric Group Practice to Employ Certain Primary Care Physicians to Serve As Consultants for Nursing Home Patients
The Requestor, a physician practice specializing in geriatrics, proposed to employ the primary care physicians who treat a patient prior to the patient’s admission to the nursing home as consultants to assist the Requestor in treating the patient. Under the employment agreement, the consulting physician would agree to be on call and available for telephone consultation twenty-four hours per day, seven days a week, to respond to the Requestor’s requests for medical consultation. Such requests for consultation may include, but are not limited to, confirming the accuracy or completeness of the patient’s medical record, and discussing the history of the present illness, past surgical history, family medical history, social history, code status, history of immunizations, previous laboratory or other testing results, previous medications and responses to treatment, the patient’s current medical condition, and the proposed course of treatment.

The consulting physician will receive fifty dollars per hour for a maximum number of hours per month based upon the number of patients for which the consulting physician agrees to consult, capped at $750 for fifteen hours of service provided with respect to twenty or more patients. The IRS previously ruled that the consulting physicians are bona fide employees.

The OIG determined that the proposal met the statutory exception and regulatory safe harbor for employee compensation because the compensation will be pursuant to an employment agreement for the furnishing of covered items and services.


DHHS OIG Approves County’s Proposal to Enter Into Exclusive Contract With Ambulance Company for Second Response Services
The OIG will not impose administrative sanctions in connection with a county’s proposal to enter into an exclusive arrangement for ambulance transport services whereby the ambulance supplier, as the second responder, pays the county for its first responder services.

The county, a political subdivision of the state, currently provides emergency "first responder" services for fire, rescue, and medical emergencies. The county has decided not to provide ambulance transportation, or "second responder" services. Medicare and the state's Medicaid program make one payment for ambulance services to the entity furnishing transportation. Providers of services other than transport must look to the transporting entity for payment.
The OIG said it would not impose sanctions in connection with the arrangement based on a number of factors. First, the proposal was within the county's police powers to regulate the provision of emergency medical services. Second, the OIG found that the proposal did not present the typical anti-kickback concern – overpayment to the source of referrals. Specifically, the OIG noted that the county expected the per-response fees to fall short of its actual costs of delivering the first responder services. Third, the per-response fees did not pose a risk of overutilization or increased costs to federal healthcare programs even though the aggregate payment to the county would vary with the volume of referrals. Fourth, the OIG found it unlikely that the exclusive nature of the arrangement would increase federal healthcare program costs. Finally, the OIG noted that "the prohibited remuneration inures to the public, not private, benefit."


DHHS OIG Approves Proposed Arrangement to Subsidize Malpractice Insurance Expenses for Four Community-Based Obstetricians

The OIG said that it will not impose sanctions relating to obstetrician malpractice subsidies by a hospital. The applicant was a hospital located in a health professional shortage area (HPSA) with respect to its low income, migrant farm worker, and homeless populations. From 2002 to 2003, the malpractice insurance premiums for the independent obstetricians on the hospital's staff increased by more than $36,000 per physician. The hospital asserted that the increased premium expenses derive in part from the special nature of services the obstetricians render to the hospital and the community. The hospital proposed to partially subsidize fifty percent of the increase in premium expenses for the current year from the premiums paid in 2002, with the subsidy capped at $25,000 per obstetrician per year. Approximately ninety percent of the patients treated would reside in the HPSA or medically underserved area (MUA) or be part of a medically underserved population (MUP).

Each obstetrician would be obligated to: (i) abide by the hospital’s rules and regulations, and remain a member in good standing of the hospital’s medical staff; (ii) provide back-up obstetrical services; (iii) notify the hospital of any changes in scope of practice or other changes that would materially affect the obstetrical services provided by the obstetrician; and (iv) notify the hospital of any reductions in malpractice insurance premiums so that the subsidy could be reduced or eliminated as appropriate.

The OIG held that the arrangement met all but one of the safe harbor elements for obstetrician malpractice subsidies (primary care HPSA status), and the arrangement contained appropriate safeguards; therefore, there was minimal risk of abuse.

DHHS OIG Approves Municipal Corporations That Own and Operate Ambulance Services and Propose to Treat Revenue Received From Local Taxes as Payment of Otherwise Applicable Cost-Sharing Amounts Due From Residents

The OIG has approved arrangements whereby a proposed ordinance will allow municipal corporations to reduce fees for residents by an amount consistent with their cost-sharing obligations for ambulance services. In each case, a municipal corporation has the authority to provide emergency medical services (EMS) under state law. The corporations adopted an ordinance under which they will bill residents or their insurers, including Federal healthcare programs, for EMS. However, the corporations will bill residents only to the extent of their insurance coverage (i.e., no out-of-pocket costs) and will treat revenue received from local real estate or income taxes as payment of any otherwise applicable cost-sharing amounts due from the residents (i.e., “insurance only” billing).

As in Advisory Opinion 04-06, the OIG notes that “insurance only” billing may implicate the Anti-kickback Statute to the extent that it constitutes a limited waiver of Medicare or other Federal healthcare program cost-sharing amounts. But, as in Advisory Opinion 04-6, the OIG approved the arrangements.

Advisory Opinion No. 04-12 (September 28, 2004); Advisory Opinion No. 04-13 (October 12, 2004) (Dep't Health & Human Servs. Office of Inspector Gen.)

DHHS OIG Approves Proposal to Treat Revenue Received From Local Taxes as Payment of Otherwise Applicable Cost-Sharing Amounts Owed for Emergency Ambulance Services Furnished by a City

In a logical extension of its earlier Advisory Opinions, the OIG opined that an arrangement that might otherwise constitute an impermissible waiver of cost-sharing amounts would not constitute prohibited remuneration under the Anti-kickback Statute. Specifically, the OIG concluded that a municipal corporation that owns and operates an ambulance service can, pursuant to city ordinance, accept insurance (including federal healthcare program payments) as "payment in full" for emergency medical services provided to that city's taxpayers. The OIG was careful to note that the ambulance service was operated by the city, which did not contract with an outside vendor for the service.

As in the case of OIG Advisory Opinions 04-06, 04-12 and 04-13, the OIG relied upon a section of the Medicare Benefit Policy Manual which provides that "insurance only" billing by a state or local government facility is "not viewed as furnishing free services and may therefore receive program payment."

DHHS OIG Approves Grants Provided by Nonprofit, Charitable Organization to Financially-Needy Patients Suffering From Specific Chronic or Life-Threatening Diseases to Defray the Costs of Prescription Drug Therapies

Under the proposed arrangement, the requestor, a nonprofit charitable organization, would provide grants to assist financially-needy individuals, including Medicare beneficiaries, to defray the costs of prescription drugs to treat certain chronic diseases. The requestor would receive funds from a variety of sources, including drug manufacturers. The question was whether either manufacturer-donors or the requestor would violate the beneficiary inducement law or Anti-kickback Statute by relieving certain Medicare beneficiaries of their cost-sharing obligations.

With respect to the manufacturer-donors, the OIG concluded that the "[r]equestor's interposition as an independent charitable organization between donors and patients and the design and administration of the [p]roposed [p]rogram provide sufficient insulation so that the [r]equestor's subsidy of Medicare Part B cost-sharing obligations should not be attributed to any of its donors."

With respect to the requestor, the OIG concluded that the requestor's subsidy "is not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier" because: (1) drugs will have been prescribed for a participating patient (by his or her existing physician) prior to the patient's application for financial assistance, and (2) the granting of financial assistance will be based solely on the patient's financial need (without consideration of the identity of the patient's provider or any particular donor).

Under these circumstances, the OIG concluded that the proposed arrangement would not violate the beneficiary inducement law and would not be subject to sanctions under the Anti-kickback Statute (or any of the law's related CMP authorities). Advisory Opinion 04-15 contrasts with Advisory Opinion 02-13, in which the OIG rejected a somewhat similar program that did not have the insulation of an independent organization making decisions on grants. Advisory Opinion No. 04-15 (Dep't Health & Human Servs. Office of Inspector Gen. October 29, 2004).

DHHS OIG Concludes That Proposal to Provide Laboratory Employees and Related Equipment and Supplies at No Cost to Dialysis Facilities May Violate the Anti-Kickback Statute

Under the proposed arrangement, a laboratory would contract with dialysis facilities to provide testing services. As part of the arrangement, the laboratory would provide employees and related equipment and supplies to prepare specimens for delivery to the laboratory at no cost to dialysis facilities. Some of the tests provided under the contract are included in the dialysis facilities' composite rate and are not separately billable to Medicare; other tests are not included in the dialysis facilities' composite rate and are separately billable to
Medicare. Under CMS's payment regulations, the test preparation services provided by the laboratory for free are included in the dialysis facilities' composite rate payments.

Advisory Opinion 04-16 is one of the rare instances in which the OIG has actually issued an advisory opinion concluding that a proposed arrangement may violate the Anti-kickback Statute. The OIG began its analysis by reiterating its longstanding skepticism about the provision of free and below-market goods and services to actual and potential referral sources. The OIG then expressed concern that the free test preparation services would constitute a tangible benefit to the dialysis facilities by relieving them of the costs associated with providing such services. The OIG also cautioned that the free test preparation services could be viewed as a functional discount on the tests covered by the composite rate that the laboratory could be "swapping" for referrals of separately billable, noncomposite rate tests. In a somewhat unusual statement, the OIG warned competitors that similar arrangements may also violate the Anti-kickback Statute. 


**DHHS OIG Declines to Approve Proposed Contractual Joint Venture Arrangement for the Provision of Pathology Services**

Citing its longstanding concerns about certain problematic joint venture arrangements between physician groups, or others in a position to refer, and those who provide Medicare or Medicaid services, see *e.g.*, Special Advisory Bulletin "Contractual Joint Venture Arrangements", 68 Fed Reg. 23148 (April 30, 2003) (the Bulletin), the OIG concluded that a proposed arrangement to provide turn key pathology laboratory operations services to several physician groups could potentially generate prohibited remuneration under the Anti-kickback Statute and could result in administrative sanctions against the opinion requestor.

Under the proposed arrangement, a company offering turn key pathology laboratory operations services (e.g., space, equipment, technicians, pathologists, and management, administrative and billing services), would enter into multiple contracts with several physician groups to provide all necessary services for each contracting physician group to operate its own independent and self-contained surgical pathology lab to service its own patients. All of the labs would be located in the same building.

As in the Bulletin, the OIG concluded that the requestor may be offering the contracting physician groups impermissible remuneration by giving them the opportunity to obtain the profits from the pathology services ordered by the group physicians and provided by the physician groups' own pathology labs. Although each of the several contracts involved would satisfy all requirements of applicable safe harbors, such as the space lease, equipment lease, and personal services safe harbors, the OIG nevertheless found the proposal would not be entirely protected. In the OIG's view, those safe harbors would protect only the
remuneration paid by the physician groups for each of those specific items or services and would not protect the physician groups' "profits" obtained from the pathology services as a result of the proposed joint venture arrangement.

The OIG found significant the fact that the proposed arrangement would contain a number of features that the OIG described as problematic in the Bulletin. For example, the arrangement would allow the referring physician groups to capture a new line of business based entirely on referrals from their own physicians, the physician groups would bear little business risk in the joint venture because they could control the amount of business they would refer to the pathology labs, and a monthly "management fee" was to be based on historical utilization data of each physician group.


DHHS OIG Approves a Series of Cash Donations to Nonprofit Hospice From Charitable Foundation Affiliated With Health System

The proposed arrangement involved a series of unrestricted cash donations by a health system's affiliated charitable foundation to a nonprofit hospice. The OIG concluded that the arrangement could potentially generate prohibited remuneration under the Anti-kickback Statute, but that the OIG would not impose sanctions. Under the arrangement, the charitable foundation would make unrestricted donations of up to a specified amount per year to the hospice over five consecutive years. The health system would not influence the hospice's use of the donated funds. The hospice could, but would not be required to, purchase certain items from the health system. The amounts of the donations would not vary, or otherwise take into account, the volume or value of referrals or other business generated by the hospice for the health system.

The OIG concluded that the donations to the hospice would be remuneration, and this remuneration could, at least in theory, improperly induce the hospice to refer Federal healthcare program business to the health system. The OIG also concluded, however, that as a practical matter, there was unlikely to be any nexus between the charitable foundation's donations to the hospice and the generation of Federal healthcare program business by the hospice for the health system because: (1) referrals by the hospice to the health system would likely be quite limited due to the requirements for Medicare reimbursement of hospice services; (2) the donations would be unrestricted, (3) the hospice had many funding sources; and (4) the donations would be capped, occur for a fixed duration, and not be determined in a manner that varies or takes into account the volume or value of referrals to the health system. Moreover, the donations to the hospice would be consistent with the charitable foundation's mission to improve the quality of healthcare services in its area. Accordingly, the OIG found the proposed arrangement unlikely to result in fraud and abuse and declined to impose sanctions.
DHHS OIG Approves Malpractice Insurance Subsidy Arrangement Between Hospital and Two Neurosurgeons

The OIG declined to impose sanctions on a hospital’s proposed malpractice insurance subsidy arrangement involving neurosurgeons under limited circumstances. The neurosurgeons’ malpractice insurance had been abruptly cancelled and a tail premium was required unless they retired from practice. As the hospital needed to maintain neurosurgery for its community, particularly for emergency care, the hospital proposed to pay the tail premium and a portion of the increased cost of claims-made coverage obtained from a new carrier. The arrangement was limited to two years. The surgeons agreed to maintain a full-time practice in neurosurgery in the community; take neurosurgical call for the hospital’s emergency department; participate in assigned hospital committees; continue to provide care to beneficiaries of the Medicare program; provide at least as much Medicaid and/or indigent care as they were providing when they entered into the arrangement; and cooperate with the hospital’s efforts to recruit additional neurosurgeons.

The OIG concluded that the facts and circumstances of the arrangement, in combination, adequately reduced the risk that there could be an improper payment for referrals or the generation of Federal healthcare program business. The OIG noted that the arrangement was temporary and addressed an emergency; the surgeons continued to be responsible for a portion of the increases and did not receive a windfall; the surgeons are required to perform services benefiting the community; and the subsidized insurance was not limited to services at the hospital.

DHHS OIG Issues Six Consecutive Advisory Opinions Approving Gainsharing Arrangements

Beginning in late January 2005, the OIG issued a series of six Advisory Opinions concluding that the gainsharing arrangements at issue would constitute an improper payment to induce reduction or limitation of services under the CMP Law, and would potentially generate prohibited remuneration under the Anti-kickback Statute (if the requisite intent were present), but that it would not impose sanctions on the parties. With a few minor differences, the Advisory Opinions are almost identical to Advisory Opinion 01-01, which also permitted a limited gainsharing arrangement. All six arrangements involved: (1) an acute care hospital, (2) a group or groups of physicians (either cardiologists or cardiac surgeons), and (3) an outside “program administrator” that designed and monitored various aspects of the arrangement at issue. In general, the arrangements included various cost-saving recommendations,
All arrangements provided for the participating physicians to share up to fifty percent of the hospital’s saving resulting from the physicians’ implementation of between twelve and twenty-nine cost reduction recommendations. However, payments to the participating physicians were subject to a number of limitations. First, the payment for each of the cost-saving measures was limited by a "floor" established based on historical utilization at the hospital and other similar facilities. Second, there was no sharing of savings for the additional procedures payable by Federal healthcare programs if the volume of such procedures exceeds the volume in the prior year. Third, a physician was not permitted to share in the savings if there is a significant change in the case severity, ages, and payors of the patients treated by the physician at the hospital. Fourth, the aggregate payment to the physicians was limited to no more than fifty percent of the cost savings projected by the independent program administrator. Finally, the payments were limited to a one-year period.

The OIG considered the proposed arrangements under both the CMP Law and the Anti-kickback Statute and found, with one exception, that the proposed arrangements implicated both prohibitions. Nevertheless, the OIG chose to exercise its discretion and not impose administrative sanctions based on several safeguards included in the proposed program. Significantly, the OIG also identified a number of features of other gainsharing arrangements that may heighten the risk of patient and program abuse, and in each case cautioned that the Advisory Opinion should not be interpreted as throwing open the door to gainsharing arrangements.

Advisory Opinion No. 05-01 (Jan. 28, 2005); Nos. 05-02, 05-03, 05-04 (Feb. 10, 2005); Nos. 05-05, 05-06 (Feb. 18, 2005) (Dep't Health & Human Servs. Office of Inspector Gen.).

DHHS OIG Approves Exclusive Contract for Ambulance Services Between Municipality and Ambulance Company That Provides for an In-Kind Exchange of Dispatch and Billing Services
The OIG concluded that an exclusive contract between a city and an ambulance company involving the exchange of dispatch and billing services would not be subject to administrative sanctions. Following an open, competitive bid process, the city awarded an exclusive, five-year contract to an ambulance company for emergency services. The arrangement involved an in-kind exchange of services: the city agreed to provide dispatch services (from an existing multi-city communications center) to the ambulance company; and the ambulance company agreed to provide billing and collection services to the city. The central issue was whether the ambulance company’s offer to provide “free" billing and collection services to the city in exchange for an exclusive contract was potentially abusive.

In concluding that it was not, the OIG focused on the following factors. First, the services exchanged were of equal value. As such, “[t]he parties have essentially bartered services of equal value, reducing the likelihood that the Ambulance
Company is providing services at no cost in exchange for Federal healthcare program business." Second, the use of the city-provided dispatch services would promote fast, efficient, and effective emergency response. Third, there was little risk of over-utilization of ambulance services or increased cost to Federal healthcare programs. Finally, an exclusive contract that was the result of an open, competitive process would provide limited opportunities to steer patients to particular hospitals.

Advisory Opinion No. 05-07 (Dep't Health & Human Servs. Office of Inspector Gen., February 18, 2005).

III. FOOD AND DRUG LAW

Ninth Circuit Says AG Exceeded Authority in Issuing Rule That Physician-Assisted Suicide Violates Controlled Substances Act

The Ninth Circuit invalidated Attorney General (AG) John Ashcroft's interpretive rule declaring that physician-assisted suicide violates the Controlled Substances Act (CSA). Oregon’s Death with Dignity Act allows for physician-assisted suicide by authorizing a physician to prescribe lethal doses of controlled substances for terminally ill patients. The court held that the AG's rule was intended to interpret and implement the CSA, which Congress enacted to deal with drug abuse. A court must look to Congress' intent in delegating power to the AG, said the appeals court, but generally an AG "may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care."

The court concluded that the AG’s rule violated the CSA because Congress did not authorize the AG to regulate physician-assisted suicide and the rule exceeded the AG's power to revoke a physician's privilege to write prescriptions. The CSA provides five factors the AG must consider before determining whether to revoke a physician's prescription writing privileges, and in this case, the AG only considered one factor in determining that physician-assisted suicide was inconsistent with the public interest. The AG ignored the plain language of the CSA, exceeded his delegated authority, and attempted to regulate an area in which he should have deferred to the states, according to the court.

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004).

This case limits the federal AG’s authority to issue rules interpreting the CSA contrary to state law in circumstances beyond those for which the CSA was intended to apply, i.e., controlling drug abuse.

D.C. Circuit Upholds DHHS Secretary’s Approval of State Initiative Requiring Prior Approval for Drugs Of Manufacturers That Do Not Sign Rebate Agreement

In 2001, the governor of Michigan formed the Pharmacy & Therapeutics Committee to formulate a list of drugs to be covered under a state low-cost state prescription drug coverage program. Any non-preferred drugs were subject to
prior approval for reimbursement unless the drug’s manufacturer agreed to rebate to the state the difference between the price of the drug and the price of the lowest-cost reference drug.

The D.C. Circuit held that the program as approved by DHHS did not violate the Medicaid statute. Plaintiffs argued the prior authorization provision violated the "formulary" provision of the Medicaid statute, 42 U.S.C. § 1396r-8(d)(4). The appeals court explained that the formulary provision of the Medicaid statute authorizes a state to create a list of covered drugs, which include covered outpatient drugs of any manufacturer that enters into a rebate program, and a covered drug may be excluded from the formulary if there is no clinical difference from other drugs in the formulary, but may be covered if prior authorization is obtained.

The appeals court concluded that the DHHS’ interpretation was reasonable and neither arbitrary nor capricious because it kept borderline beneficiaries that would otherwise be eligible for Medicaid in non-Medicaid programs. The appeals court rejected a commerce clause argument and determined that any effect the change in the price of a drug would have out of state was incidental. 


*This case holds that states can require rebates as conditions of inclusion in formularies under their Medicaid and non-Medicaid pharmaceutical programs*

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**U.S. Court in Massachusetts Holds Medicaid Rebate Statute Does Not Preempt State Fraud Claims**

Montana and Nevada brought state law fraud claims against various drug manufacturers, alleging that the pharmaceutical companies violated the “best price” terms in their Medicaid rebate contracts with the federal government by excluding from their reported prices certain discounts and other inducements offered to physicians to increase use of certain drugs. The pharmaceutical companies removed the suits to federal district court and moved to dismiss plaintiffs’ claims, arguing the Medicaid Rebate Statute preempts state law fraud claims alleging fraudulent “best price” reporting.

The U.S. District Court for the District of Massachusetts held that the Medicaid Rebate Statute does not preempt state fraud actions. In so holding, the court noted that the best price program involves "cooperative federalism" and that the statute provides that federal remedies are "in addition to other penalties as may be prescribed by law." The court also held the defendants failed to show an “actual conflict” between the state claims and the federal statute to overcome the presumption against preemption.  

This case is significant because it is the first action brought by states alleging harm by fraudulent best price reporting; the court held the claims were not preempted by the federal Medicaid Rebate Statute.

Connecticut Superior Court Finds That Learned Intermediary Doctrine Bars Failure to Warn Claims in Cardiac Pacemaker Battery Replacement Action

A patient with a pacemaker that was nearing the end of its life sued her physician and the pacemaker manufacturer, Medtronic, after the physician set the pacemaker rate lower to prolong its life while surgical decisions were being explored by the patient’s family. The patient suffered a cardiac event that resulted in permanent brain damage.

Medtronic claimed that: (1) all of plaintiffs' claims were pre-empted by federal law, specifically the pre-emption clause of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c, et seq.; (2) all of plaintiff’s "failure to warn" claims were barred by the learned intermediary doctrine, and (3) all of plaintiffs' failure to warn claims were also barred because plaintiff had actual knowledge of the hazard of which she now claimed Medtronic failed to warn her.

The Superior Court of Connecticut found that Medtronic was entitled to summary judgment based on the learned intermediary doctrine, holding that Medtronic had provided adequate warnings to the patient’s physician. The court further held that the patient's pacemaker was not defectively designed or manufactured and was accompanied by adequate warnings in the technical manual, which was approved by the FDA. Accordingly, the court granted Medtronic's motion for summary judgment.


The court noted that the "learned intermediary doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly."

Third Circuit Holds State Law Claims of Defective Design of Medical Device Were Pre-Empted by FDA Requirements

Surgeons implanted a device known as a HeartMate in plaintiff to provide circulatory support while plaintiff was awaiting a transplant. The HeartMate is surgically attached to the heart and helps to pump blood through the heart. After the surgery, the pump from the HeartMate became disconnected. Surgeons reattached the pump but air had entered the opening and caused a brain hemorrhage resulting in the plaintiff’s death. The plaintiff’s estate sued the manufacturer, who filed a motion for summary judgment on the ground that under the FDA's PMA process, plaintiff's state law claims were expressly preempted.

The district court applied the two-prong test of FDA preemption to determine if the FDA had established specific requirements that applied to the device and if
the state law claims are "different from, or in addition to, the specific federal requirements." The court determined that plaintiff's state common law claims were pre-empted, as the PMA process imposed specific requirements on the HeartMate device and any judgment on plaintiff's claims would be in direct conflict with the FDA's approval of the device. The Third Circuit affirmed the district court's judgment.

**Horn v. Thoratec Corp.**, 376 F.3d 163 (3d Cir. 2004).

*This case limits the availability of state law products liability remedies when a device has been approved under the FDA’s PMA process*

### IV. CRIMINAL LAW

**Physician Participating in Internet Pharmacy Guilty of Conspiracy to Distribute Controlled Prescription Drugs**

A physician and others created a website through which customers could order hydrocodone, a powerful and addictive painkiller. The evidence at trial showed that after customers completed a brief online questionnaire, the defendant physician signed thousands of prescriptions without ever seeing a customer. The prescriptions were then transmitted to and filled by a pharmacy operated by the physician's co-conspirators. The pharmacy billed the customer an inflated price for the drugs and paid the physician a fee for each of the prescriptions. The physician was paid nearly $200,000 wired to a bank in Antigua.

The physician appealed his conviction, asserting that the standard for conviction under 21 U.S.C. § 846 required that he have been found to have distributed the drugs both outside the usual course of his professional practice and without a legitimate medical purpose. He argued that the trial court erred by charging the jury disjunctively rather than conjunctively. The Tenth Circuit held that it is sufficient that the physician conspired either to have distributed the drugs outside his professional practice or to have distributed the drugs without a legitimate medical purpose.


*Physician was guilty of conspiracy to distribute prescription drugs as the Tenth Circuit held that it is sufficient that the physician conspired either to have distributed the drugs outside his professional practice or to have distributed the drugs without a legitimate medical purpose.*

**U.S. Supreme Court Holds U.S. Sentencing Guidelines Violate Sixth Amendment**

In a landmark decision, the Supreme Court held that the Sixth Amendment applies to the U.S. Sentencing Guidelines (Guidelines). In this case, the trial judge made additional findings of fact during the sentencing proceeding that increased the defendant's sentence under the Guidelines. The Seventh Circuit
held that the trial judge’s determination conflicted with the decision in Apprendi v. New Jersey, 530 U.S. 466 (2000), in which the Court held that any fact that increases a penalty for a crime beyond the statutory maximum must be submitted and proved to a jury. The trial judge found additional facts that were not presented or proved to the jury and then applied the Guidelines to increase the defendant's sentence beyond the statutory maximum.

The Supreme Court affirmed the Seventh Circuit's judgment, holding that using additional facts that were not presented to the jury to increase a defendant's sentence beyond the statutory maximum violates the Sixth Amendment. The Court also held that because the Sixth Amendment applies to the Guidelines, the provision of the Sentencing Reform Act making the Guidelines mandatory must be severed and excised, and as modified, the Guidelines are only advisory. United States v. Booker, 125 S.Ct. 738 (2005).

While the facts in this case involve the enhancement of a defendant’s sentence because the trial judge determined after trial that the defendant possessed a larger quantity of drugs than was proved to the jury, resulting in a sentence greater than the maximum statutory sentence, the implications of the Supreme Court's decision are far-reaching and potentially affect any defendant whose sentence has been enhanced under the Guidelines based on facts not proved to a jury. For healthcare providers, this development substantially affects the strategy of settlement and plea negotiations. An open question is how this decision impacts the new sentencing guidelines for organizations, which includes as one criteria whether a company has shown sufficient cooperation by waiving attorney-client privilege – an issue of concern raised by the American Bar Association and many other organizations.
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Philadelphia, PA
DHHS Summit on Health Information Technology and GAO Response

The Department of Health and Human Services (DHHS) held its first Secretarial Summit on Health Information Technology (the Summit) on July 21, 2004. DHHS Secretary Thompson released a report outlining a series of steps intended to foster promotion of widespread current electronic health records. Significantly, the report entitled, "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care" (the Report), lays out the first federal strategy to accomplish an ambitious change in health information technology and health services delivery. The Report is also significant in that it demonstrates the complexity and enormity of the intended undertaking, especially by an industry that has struggled with mixed success for eight years to adopt a standardized electronic claim. The Report is available at http://www.hhs.gov/healthit/documents/hitframework.pdf.

Shortly following the Summit, and in response to a request by the Senate Committee on Health, Education, Labor, and Pensions, the General Accounting Office (GAO) released an assessment of DHHS' efforts to promote the proliferation of electronic health records, as well as the legal barriers to such initiatives. The legal barriers identified by the GAO involve fraud and abuse, antitrust, federal taxation, intellectual property, liability and state licensing law issues. The assessment, “HHS’s Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption”, GAO-04-991R, can be found at http://www.gao.gov/new.items/d04991r.pdf.

ONCHIT Request for Information Regarding Electronic Health Records

Office of the National Coordinator for Health Information Technology (ONCHIT) issued a Request for Information (RFI) in the Federal Register on November 15, 2004. The RFI is significant because it indicates the size, scope and complexity of the federally led effort to make available to all Americans an interoperable electronic health record. The RFI seeks input on what should be included in a national health information infrastructure, what type of model should be deployed and what roles should be at the national level as opposed to a regional or local level. The RFI seeks information on the organizational and business framework of a national health information infrastructure, its policies and procedures, its financing and how it would comply with HIPAA’s privacy and security requirements. The RFI also asks how a national health information infrastructure would be managed and operated, including the proper role of competition, how to make it acceptable to healthcare providers, and its effect on health information technology markets in general. Finally, the RFI seeks input on financial and regulatory barriers, including legal barriers.
National Coordinator for Health Information Technology; Development and Adoption of a National Health Information Network, 69 Fed. Reg. 65599 (Dep’t Health and Human Servs. Request for Information Nov. 15, 2004).

The Role of Lawyers Under the Privacy Rules
On January 14, 2005, the Office for Civil Rights (OCR) published on its web site answers to frequently asked questions (FAQs) regarding the role of lawyers under the Health Insurance Portability and Accountability Act (HIPAA). In general, the FAQs address the use and disclosure of protected health information (PHI) in litigation. The FAQs are significant, however, for providing clarifications that are sometimes contrary to widely held views regarding the use and disclosure of PHI in litigation, such as how to meet the duty of satisfactory assurances.

In addition, the FAQs addressed subcontractor business associate agreements. Before January 2005, the only guidance to this question was language from the December 2000 preamble to the final rule explaining that an “expert witness” was not an “agent” to whom a lawyer would “delegate” legal service functions. However, the January 2005 FAQ answer suggests that the universe of “agents” is far broader and includes those who perform for the lawyer “in furtherance of” providing legal services, including jury experts, co-counsel, investigators and litigation support personnel. The FAQs may found at http://www.hhs.gov/ocr/hipaa/.

ONCHIT Issues Health Information Technology Leadership Panel Final Report
On May 11, 2005, ONCHIT issued the Final Report of the Health Information Technology Leadership Panel (the Panel), which was a spin off creation of earlier recommendations of ONCHIT. The Panel, consisting of representatives of very large corporations, reported three key imperatives: (1) Widespread adoption of interoperable HIT should be a top priority for the U.S. healthcare system; (2) The federal government should use its leverage as the nation’s largest healthcare payer and provider to drive adoption of HIT; and (3) Private sector purchasers and healthcare organizations can and should collaborate alongside the federal government to drive adoption of health information technology (HIT).

The Panel also adopted the following six principles to guide federal and private sector implementation of HIT: (1) Potential benefits of HIT far outweigh manageable costs; (2) HIT needs a clear, broadly motivating vision and practical adoption strategy; (3) The federal government should provide leadership, and industry will engage and follow; (4) Lessons of adoption and success of IT in other industries should inform and enhance adoption of HIT; (5) Stakeholder incentives must be aligned to foster HIT adoption; and (6) Among its multiple stakeholders, the consumer, including individual beneficiaries, patients, family members, and the public at large, is key to adoption of HIT and realizing its benefits.

**Analysis of HIPAA Preemption of Texas Laws**

On November 1, 2004, in response to state legislation mandating preemption analysis, the Attorney General of Texas issued a report regarding HIPAA preemption of Texas laws relating to privacy. The report provides specific legislative and administrative recommendations in instances in which state laws are preempted by HIPAA and in other instances in which compliance with both state law and HIPAA would be facilitated by clarification of the state law.


**I. LEGISLATION**

**California’s Legislature Attempts to Broaden Privacy Rights**

On August 23, 2004, California’s legislature passed a remarkably broad privacy long arm statute, S.B. 1451 (Statute), which would subject any recipient of any information protected by California law, including health information, to the jurisdiction of the California courts. In addition, the Statute would create a private right of action to enable individuals to enforce the same rights they would have against a California disclosing entity against protected information recipients. Governor Schwarzenegger declined to sign the Statute due to an ambiguity that could be interpreted to conflict with California’s financial laws. However, Schwarzenegger stated that once the ambiguity was resolved, he would be willing to sign such a measure into law, thereby creating the most far-reaching state regulation of health information.

**II. REGULATIONS**

**CMS Proposes Regulations Requiring Electronic Prescribing for Participants in the Part D Program**

The Centers for Medicare and Medicaid Services (CMS) published proposed standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that would require participants in the Part D program to have the capacity to support electronic prescribing. DHHS believes that it has identified several standards, called foundation standards, which have been used by the industry and may therefore be adopted without beta testing. In addition, the proposed regulations explain that federal law will preempt state laws that are contrary to the Medicare standards and relate to information used by that program; however,
DHHS rejected the contention that Medicare Part D preempts all state laws relating to all e-prescribing laws, rather than laws contrary to Medicare alone.

With respect to anti-kickback safe harbors and Stark exceptions, DHHS promised forthcoming developments but noted that, in the interim, existing safe harbors and exceptions must be utilized.  


CMS Takes Steps to Ensure Compliance With the HIPAA Security Rule  
On April 25, 2005, the HIPAA Security Rules became enforceable. The Security Rules require covered entities to adopt and implement administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of PHI. CMS has taken steps during the past few months to nudge the industry in the direction of compliance with the HIPAA Security Rule. Beginning with Security FAQs released in August 2004, CMS has attempted to provide technical support on security compliance. Additionally, in November 2004, CMS issued its first educational paper on security titled “Security 101 for Covered Entities.” On November 10, 2004, CMS convened a HIPAA Roundtable to describe the HIPAA Security Rule and answer questions. Finally, CMS issued additional FAQs regarding the Security Rules on May 5, 2005.

The technical assistance generally lacks the kind of bright line guidance the many stakeholders anticipated and tends to demonstrate the inherent complexity of achieving comparable levels of security across widely varying enterprise settings. Moreover, the questions and answers documented by CMS in its transcript of the roundtable suggest that while the healthcare industry wishes to comply with the HIPAA Security Rule, its understanding of the Security Rule and how its fits with the HIPAA Privacy Rule is a challenge that may not be overcome in a timely fashion.

DHHS Proposes Enforcement Rule Regarding Privacy  
On April 18, 2005, DHHS published an Enforcement Rule to amend and supplement the current interim final rule on enforcement of the Privacy Rules adopted two years ago. Although only a proposed rule, the proposed Enforcement Rule is significant because it provides further understanding regarding the enforcement of violations of the HIPAA regulations. From the important definition of who is a “person” subject to enforcement of the HIPAA rules, to how to calculate the amount of a civil monetary penalty, the proposed Enforcement Rule offers considerable guidance to long-standing ambiguities in the penalty sections of HIPAA. HHS proposes to add three subparts to Part 160 that will address: (i) compliance and investigations; (ii) imposition of civil monetary penalties; and (iii) procedures for hearings.
III. LITIGATION

First Criminal Conviction Under HIPAA
On August 19, 2004, a former cancer clinic employee, Richard W. Gibson, pleaded guilty in federal court in Seattle to wrongful disclosure of individually identifiable health information for economic gain. Under the plea agreement, Gibson admitted to obtaining demographic information about a cancer patient and disclosing that information, including the patient’s name, date of birth and social security number, in order to obtain four credit cards in the patient’s name.

Significantly, although the defendant was not a “covered entity” under HIPAA, the Department of Justice (DOJ) chose the HIPAA felony law to prosecute the defendant even though there are numerous other laws that could have been used to prosecute the identity theft.


Many see this first HIPAA guilty plea as a statement by the DOJ that HIPAA’s felony provision will reach well beyond covered entities.

New York Court Bars Use of Physicians’ Testimony and Expert Opinion Due to Lack of Valid HIPAA Authorization
A New York court barred the use of physicians as defense experts, as well as the use of their testimony, where defense counsel first issued subpoenas to the physicians and subsequently interviewed them on an ex parte basis. The court noted that the physicians were the treating physicians of the plaintiff and should have been interviewed only on the basis of a valid HIPAA authorization.


Defense counsel must have a valid HIPAA authorization before interviewing treating physicians on an ex parte basis.

New York Court Rules That HIPAA Does Not Allow Plaintiffs to Withhold Authorizations That Assist Defense Counsel
Defendants sought an order to compel plaintiff to execute a HIPAA compliant medical authorization enabling defense attorneys to meet with subsequent treating physicians. Plaintiff’s attorney refused to provide signed authorizations citing HIPAA and two recent New York trial court decisions, Browne ex rel. Estates of Browne vs. Horbar, 2004 WL 2827657 (N.Y. Sup. 2004), and
Keshecki v. St. Vincent’s Medical Center, 785 N.Y.S.2d 300 (N.Y. Sup. 2004), which the plaintiff argued prohibited ex parte discussions with plaintiff’s treating physicians.

The court found that HIPAA provides no impediment to the relief sought by defendants and that the regulations promulgated under HIPAA provide that in certain circumstances, “[a] covered entity may disclose protected health information in the course of any judicial or administrative proceeding.” While the court acknowledged that it is debatable whether the private interviews would constitute a “judicial or administrative proceeding” under HIPAA, the court emphasized the importance of “fundamental fairness” and further provided that “a plaintiff should not be allowed to simply refuse to provide an appropriate authorization to defendants yet seek to interview these same healthcare providers for potential testimony.”

Steele v. Clifton Springs Hospital and Clinic, 788 N.Y.S.2d 587 (N.Y. Sup. 2005)

New York court ruled that HIPAA does not authorize plaintiffs to refuse to provide medical authorizations that would allow defense counsel to meet with the patient’s subsequent treating physicians.

No Private Right of Action Under the Privacy Rules

Two cases continue a small line of decisions that uphold the view that there is no private right of action provided under the HIPAA Privacy Rules. In Bigelow v. Sherlock, a federal court in Louisiana granted a motion to remand to state court a state privacy action that had been removed to federal court by a defendant hospital contending that the complaint was an attempt to bring a claim under HIPAA. While the court confirmed that HIPAA does not provide a private cause of action, it stated that the complaint in the case was not a genuine attempt to raise such a claim and, therefore, remand to state court was appropriate.

In Johnson v. Parker Hughes Clinics, a federal court in Minnesota held that not only did HIPAA not provide a private right of action, the federal Declaratory Judgment Act was not available to circumvent the absence of a private right of action by asking the court to clarify the plaintiff’s right of access to PHI. Bigelow v. Sherlock, 2005 WL 283359 (E.D. Louis. 2005); Johnson v. Parker Hughes Clinics, 2005 WL 102968 (D.Minn. 2005).

Courts continue to hold that there is no private right of action under the HIPAA Privacy Rules.
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I. ALTERNATIVE DISPUTE RESOLUTION

California Appeals Court Holds Plaintiff Did Not Agree to Arbitration Provision When She Signed Admission Forms as Responsible Party and Not Agent

Goliger was admitted to a rehabilitation facility owned by defendant AMS. Upon admission, her daughter, Binshtock, signed on the line for “responsible party,” and left the line for “agent” blank. Binshtock did the same when she signed the arbitration agreement sections in the admissions forms. Golinger later died, and Binshtock sued on her mother’s behalf for personal injury, and on her own behalf for wrongful death. AMS moved to compel arbitration. The court refused to compel arbitration on the grounds that Binshtock had not agreed to arbitrate on behalf of her mother or herself. Although AMS argued Binshtock was acting as her mother’s agent when she signed the admission forms, the court held that there is no connection between Binshtock helping her mother with her medical matters, and acting as her agent to agree to arbitration.

_Goliger v. AMS Properties, Inc., 19 Cal.Rptr.3d 819 (Cal. App. 2004)._  

This case is significant because it distinguishes between the authority to act on behalf of a patient in medical matters and the authority to bind a patient to an arbitration provision.

California Appeals Court Holds Physician Alleging Tort Claims Against Medical Group Bound by Arbitration Clause in Employment Agreement

Physician Carl Buckhorn entered into an employment agreement with St. Jude Heritage Medical Group (Group). The employment contract included an arbitration clause. The St. Jude Heritage Health Foundation (Foundation), which provides healthcare facilities and administrative support in exchange for medical services rendered by the Group through a professional services agreement (PSA), was named as a third-party beneficiary of the employment contract. The PSA was subsequently amended to include a mandatory arbitration provision. Buckhorn sued the Group and the Foundation (collectively, Defendants) after he was terminated. In addition to his wrongful termination claims, Buckhorn also claimed defendants committed various torts after he was discharged, including defamation and interference with prospective economic advantage. Defendants moved to compel arbitration under the employment contract and the PSA. The trial court denied the motion. In its final order, the trial court found that Buckhorn was not bound by the arbitration clause in the PSA but did not refer to the arbitration clause in the employment agreement. Defendants appealed.
The California Court of Appeal, Fourth Appellate District, reversed, holding that the arbitration clause in the employment agreement applied to all of Buckhorn’s claims, including those alleging that Defendants engaged in tortious conduct against him after his termination. Buckhorn failed to show that his tort claims were “wholly independent” of the employment agreement; therefore, the appeals court held they should have been submitted to arbitration. **Buckhorn v. St. Jude Heritage Med. Group**, 18 Cal.Rptr.3d 215 (Cal. App. 2004).

*Arbitration clause in employment agreement applied to all of plaintiff physician’s claims, including those claims that arose after termination, as such claims were rooted in the contractual relationship.*

II. **FOOD AND DRUG LAW**

**U.S. Court in Massachusetts Holds Medicaid Rebate Statute Does Not Preempt State Fraud Claims**

Montana and Nevada brought state law fraud claims against various drug manufacturers, alleging that the pharmaceutical companies violated the “best price” terms in their Medicaid rebate contracts with the federal government by excluding from their reported prices certain discounts and other inducements offered to physicians to increase use of certain drugs. The pharmaceutical companies removed the suits to federal district court and moved to dismiss plaintiffs’ claims, arguing the Medicaid Rebate Statute preempts state law fraud claims alleging fraudulent “best price” reporting.

The U.S. District Court for the District of Massachusetts held that the Medicaid Rebate Statute does not preempt state fraud actions. In so holding, the court noted that the best price program involves "cooperative federalism" and that the statute provides that federal remedies are "in addition to other penalties as may be prescribed by law." The court also held the defendants failed to show an "actual conflict" between the state claims and the federal statute to overcome the presumption against preemption. **In re Pharmaceutical Industry Average Wholesale Price Litig.**, 321 F.Supp.2d 187 (D. Mass. 2004).

*This case is significant because it is the first action brought by states alleging harm by fraudulent best price reporting; the court held the claims were not preempted by the federal Medicaid Rebate Statute.*

**U.S. Court in New York Refuses to Dismiss Investors’ Action Against Bayer for Securities Fraud Following Withdrawal of Cholesterol-Lowering Drug**

Plaintiffs, a proposed class of purchasers of Bayer Corp. securities, asserted claims against Bayer under § 10(b) of the Securities Exchange Act of 1934 (Act) and against certain individual company executive officers under § 20(a) of the
Act. Following FDA pressure, Bayer voluntarily withdrew Baycol from the market in August 2001, citing increasing reports of side effects involving muscular weakness. As a result of the Baycol withdrawal, Bayer’s stock price dropped seventeen percent.

Defendants moved to dismiss the class action filed by the plaintiffs. The U.S. District Court for the Southern District of New York denied the motion to dismiss as to Bayer and two of its executives, but granted the motion as to two other officers and as to the claims brought by foreign purchasers of Bayer’s stock. The court held that defendants had a duty to disclose adverse event reports after August 2000 when they became aware of risks to the Baycol brand and their failure to do so was an actionable omission under § 10(b). The court found, however, that defendants had no duty to disclose before August 2000 because the adverse reports were not material before that time. The court further held that defendants’ statements describing Baycol’s strong sales record and predicting strong growth for Baycol were not actionable. Defendants were, however, under an obligation to update their forward-looking statements that Baycol would produce a sustained increase in the company’s operating margin and provide “strong potential for future growth” after they concluded that the brand was at risk in August 2000.


Adverse event reports, coupled with other evidence, put a pharmaceutical company on notice concerning a drug’s safety risks, triggering a duty to disclose under securities laws.

III. HOME HEALTHCARE

Federal Court in Arizona Requires State Agency Participating in Medicaid Program to Ensure Availability of Home Health Services

In this class action case, a group of Medicaid beneficiaries sued the Arizona Health Care Cost Containment System (AHCCCS) and other state agencies, alleging that the agencies did not provide adequate home- and community-based services to elderly and disabled Medicaid beneficiaries through the Arizona Long-Term Care System (ALTCS). The United States District Court for the District of Arizona observed that the ALTCS was having difficulty providing attendant care services to qualified Medicaid beneficiaries because of the low wages paid to home care workers (compared to rates paid by private paying clients) and because there was no contingency plan in place to address the unavailability of home care workers. The district court concluded that once a state agency elects to participate in the Medicaid program, it must ensure that adequate services are made available to Medicaid beneficiaries, who have a property right in the healthcare benefits for which they qualify. As such, the court ordered AHCCCS to provide adequate services to Medicaid beneficiaries; to develop contingency plans to address the unavailability of home care services; to pay home health
workers sufficient wages to promote the availability of services; to monitor the program to ensure that adequate services are available; and to implement a grievance procedure for reporting gaps in service.  

*This case is significant because it demonstrates the specific obligations of state agencies electing to participate in the Medicaid program even when state resources are scarce.*

## IV. INDIVIDUAL/PATIENT RIGHTS

**Minnesota Court Extends a Physician’s Duty of Care Regarding Genetic Testing and Diagnosis to Minor Patient’s Biological Parents**

Plaintiffs Kimberly Molloy (Molloy) and her husband, Glenn Molloy, sued three physicians for medical malpractice claiming they were negligent in failing to diagnose a genetic disorder in Molloy’s daughter. Plaintiffs claimed that the physicians' negligence caused Molloy to conceive another child with the same genetic disorder. Plaintiffs’ claim arose out of the medical treatment of Molloy’s daughter by the defendants. Molloy’s daughter suffered from Fragile X Syndrome, a serious disorder that had a high probability of being genetically transmitted and for which a reliable and accepted test was widely available. Plaintiffs argued that the defendant physicians should have foreseen that parents of childbearing years might have conceived another child in the absence of knowledge of the genetic disorder. The court held that the defendant physicians owed a duty of care regarding genetic testing and diagnosis, not only to the affected child, but also to her parents. This duty arose where it was reasonably foreseeable that the parents would have been injured if the advice was negligently given.  
**Molloy v. Meier**, 679 N.W.2d 711 (Minn. 2004).

*This case is significant because it extends a physician’s duty regarding genetic testing and diagnosis beyond the infant patient to the infant’s biological parents, who may be foreseeably harmed by a breach of that duty.*

**State and Federal Legislative Efforts to Circumvent Various Court Rulings Regarding Termination of Life-Prolonging Procedures Fail**

This high profile case involved Theresa Schiavo (Theresa), a woman in a permanent or persistent vegetative state since 1990. As the guardian for Theresa, her husband Michael Schiavo (Michael) obtained an order from the guardianship court authorizing the discontinuance of artificial life support. The guardianship court determined that there was clear and convincing evidence that Theresa was in a persistent vegetative state and that she would elect to cease life-prolonging procedures if she were competent. Theresa’s parents appealed this order and initiated various other actions challenging the guardianship court’s decision. Once all judicial challenges were exhausted, Theresa’s nutrition and
hydration tube was removed. Six days later, the Florida Legislature enacted a law authorizing the Governor to issue a one-time stay to prevent the withholding of nutrition and hydration (the Act). Subsequently, Theresa’s nutrition and hydration tube was reinserted pursuant to the Governor’s executive order. On the same day, Michael brought a declaratory judgment action arguing that the Act was unconstitutional.

The Florida Supreme Court held that the Act was unconstitutional as applied to Theresa and on its face. The court held the Governor’s executive order effectively reversed a properly rendered final judgment and amounted to an unconstitutional encroachment on the power reserved for the judiciary. The court further held the executive order inappropriately delegated legislative power to the Governor because the Act contained no guidelines or standards to limit the Governor from exercising completely unrestricted discretion with regard to the decision to withhold nutrition and hydration.

Subsequently, Congress enacted “An Act for the relief of the parents of Theresa Marie Schiavo” (Pub. L. No. 109-3), which authorized a Florida court to grant relief in the Schiavo case. Theresa’s parents then filed a petition for a temporary restraining order (TRO), which was denied by the United States District Court for the Middle District of Florida. The district court’s opinion was based upon the standard for granting a TRO. Specifically, the court concluded that the plaintiff’s failed to show a substantial likelihood of success on the merits of any of the five constitutional and statutory claims they raised. On appeal, the Eleventh Circuit Court of Appeals affirmed, concluding that the district court did not abuse its discretion in denying the TRO. The United States Supreme Court declined to review the cases.


This high profile case illustrates the controversial issues surrounding end of life decisions and the potential for emotions and political agendas to impact such cases.

Nebraska Supreme Court Holds Parents Cannot Raise Religious Objections to Statute Requiring Screening of Newborns for Diseases

A Nebraska statute requires that infants born in the state must be screened for several metabolic diseases within forty-eight hours of birth, or, if the birth is not attended to by a physician, registration of the birth. The parents in question did not bring their child in for tests because the test involved drawing blood from the baby’s heel and they believed that life is taken from the body if blood is removed from it. The county petitioned the court to compel the parents to have the tests done. The parents argued that the law violated their rights to freely exercise their religion under the First Amendment and their rights as parents to make decisions concerning their child’s upbringing. They also argued the issue was moot because the child was more than two months old and the law required testing
within forty-eight hours of the birth registration. The district court held that the state’s interest in having the children screened for diseases outweighed the parents’ interest in religious expression, and held that the issue was not moot because the tests could provide important information even if the child were older. The parents appealed and the Nebraska Supreme Court affirmed the district court’s judgment.


*State’s interest in newborn screening test results outweighed parents’ interest in religious expression; therefore, Nebraska court found no First Amendment violation.*

**New Jersey Court Permits Adult to Litigate Injury That Occurred During His Birth Twenty Years Earlier**

Twenty years after his birth, plaintiff sued his mother’s obstetrician alleging that the physician had a duty to discuss the possibility of cesarean section with the plaintiff’s mother. Because the obstetrician did not inform the plaintiff’s mother of the option of delivering via a cesarean section, the physician failed to obtain her informed consent, which resulted in an injury to plaintiff. The court held that New Jersey recognizes plaintiff’s independent cause of action against his mother’s obstetrician for prenatal injuries caused by his vaginal delivery arising out of the failure of the physician to obtain the mother’s informed consent prior to delivery. **Draper v. Jasionowski**, 858 A.2d 1141 (N.J. Super. A.D. 2004).

*This case is significant as it essentially extends the statute of limitations in New Jersey for a claim for medical negligence with respect to the delivery of a baby through the age of the child’s majority.*

V. **INSURANCE**

A. **Scope of Coverage**

**U.S. Court in New Hampshire Finds Term "Legal Action" Means Lawsuit, Not Administrative Appeal**

Plaintiff’s claim for health benefits under his employer’s health plan was denied. Plaintiff followed the administrative appeals process provided under the plan. After his appeals were ultimately denied, plaintiff filed suit against the plan asserting a claim for benefits under the Employment Retirement Income Security Act (ERISA).

The defendant health plan argued that plaintiff’s lawsuit should be dismissed because the plan contained a provision requiring that any “legal action” be brought against the plan within one year after the cause of action arose. The U.S. District Court for the District of New Hampshire agreed and held that plaintiff’s claims were time barred. In so holding, the court disagreed with plaintiff’s
argument that the term "legal action" is ambiguous because it does not clearly state that it means filing an action in court as opposed to following the health plan’s administrative process. 


This case is significant because it illustrates the need for careful drafting of private statute of limitations provisions in insurance contracts and health plans. Although the court ultimately enforced the limitation provision, the action may have been avoided entirely had the contract more clearly specified what the statute of limitation provision covered.

New York High Court Finds Insurance Company Not Required to Provide Same Benefits for Physical and Mental Disabilities
The group health plan covering plaintiff included disability insurance, but generally limited benefits based on mental disability to twenty-four months. Disability benefits paid under the plan to plaintiff, who suffered from a chronic psychiatric disability, were discontinued after approximately twenty-four months in accordance with the plan provisions. Plaintiff filed a complaint with the New York State Insurance Department (Department), claiming that the insurer violated N.Y. Ins. Law § 4224(b)(2), which prohibits an insurer from limiting the coverage available to an individual on account of a physical or mental disability unless permitted by law or regulation and statistically or empirically justified. After the Department dismissed her complaint, plaintiff filed suit. Both the trial court and the appellate court upheld the Department’s decision.

The New York Court of Appeals also affirmed the Insurance Department's decision. The court first noted that nothing in § 4224(b)(2) requires an insurer to offer the same benefits for all ailments unless statistically or empirically justified. The high court further noted that § 4224(b)(2) is similar to anti-discrimination laws in other states and "courts have generally declined to interpret these statutes to require equivalent coverages for mental and physical disabilities." After reviewing the legislative history of § 4224(b)(2), the high court found no evidence of intent to require parity of benefits for mental and physical disabilities. Accordingly, the high court affirmed the decision of the trial court and appellate court. 


This case is significant in New York because it ratifies a longstanding practice of some insurers of limiting benefits for mental disabilities. Also, the insurance law at issue in this case is similar to laws in other states and may be of interest to practitioners in those states as well.
B. Assignment, Subrogation, and Benefit Coordination

Ohio Supreme Court Says Contract That Gives Insurer Subrogation Right Over Insured's Third-Party Recoveries Regardless of Whether Insured Was Made Whole is Enforceable

The health plan sponsored by Lawson's employer included a reimbursement and subrogation provision that required an insured to reimburse the plan for any amounts later recovered from a negligent third party. The plan required participants to sign a subrogation agreement before the plan would pay any benefits. The plan paid benefits as a result of injuries Lawson's minor daughter suffered in an automobile accident. The provision was invoked with respect to a recovery obtained by Lawson from the negligent party in the accident and from Lawson's underinsured motorist coverage. However, Lawson refused to reimburse the plan for amounts it paid because Lawson's daughter was not made whole by the recovery she obtained from the negligent party and her own insurance.

The plan sued Lawson in state trial court, which granted summary judgment in Lawson's favor on the basis that the language in the subrogation agreement did not clearly specify that the plan's subrogation right would take priority over the participant's right to be made whole. The appeals court reversed, but recognizing that its ruling conflicted with other decisions, the court certified to the state high court the following question: is a subrogation clause that tries to give an insurer priority over an insured's claim against a third party against public policy and therefore unenforceable regardless of whether the insured is made whole?

The Ohio Supreme Court held that such an agreement between an insurer and an insured, if clear and unambiguous, is enforceable, regardless of whether the settlement or judgment fully compensates the insured's total damages. The high court found the agreement between Lawson and the plan was clear and unambiguous and upheld the decision of the appeals court.


This case demonstrates the need to clearly and unambiguously state in a subrogation agreement that reimbursement will be required regardless of whether the participant was made whole by his or her third-party recovery if the plan intends to recover in such circumstances.

New York High Court Says Insurer May Not Sue Tobacco Companies Under Deceptive Business Practices Law

Empire Blue Cross and Blue Shield (Empire) and other plans sued various tobacco companies in New York federal district court alleging that they engaged in deceptive practices designed to mislead the public about the effects of cigarette smoking. The complaint included a claim based on N.Y. Gen. Bus. Law
§ 349, a consumer protection statute intended to protect against deceptive acts or practices. A jury awarded Empire $17,782,702 on its § 349 claims.

The Second Circuit reversed the jury verdict on Empire's § 349 claims. However, citing unresolved questions of New York law, the Second Circuit certified two questions to the New York high court: (1) whether claims by a third-party payer of healthcare services provided to subscribers as a result of those subscribers being harmed by defendants' violation of § 349 was too remote to permit suit under the statute, and (2) if such an action was not too remote, whether individualized proof of harm to subscribers was required.

The New York Court of Appeals answered the first certified question in the affirmative, which rendered the second question moot. Section 349 gives "any person injured" by a violation of the statute a private right of action. Empire claimed here that it suffered actual damages because defendants misrepresented the truth about the dangers of smoking to subscribers, whose medical costs increased as a result. Under the common law, an insurer or third-party payer of medical costs may not recover derivatively for its insureds' injuries, but instead must rely on equitable subrogation. The high court rejected Empire's contention that the legislature intended to abrogate the common law rule and allow derivative recoveries in enacting § 349, finding nothing in the text or history of the statute to indicate the legislature intended such a result.


This case is significant in New York because it involves a previously unresolved question of law. It is also significant because of the potentially large amounts at stake.

C. Professional Liability Insurance Issues

Indiana Appeals Court Holds Liability Extends to Each Act of Malpractice in a Single Surgery

An Indiana Appeals Court held that a malpractice insurer was liable for payment for two separate acts of malpractice where the physician breached the duty of care twice during the same surgery and in each instance caused a significant injury to the patient. The Indiana Medical Malpractice Act (the Act) provides for a cap on damages, creation of the Indiana’s Compensation Fund (the Fund), and a splitting of damages between an insurer and the Fund. The court determined that the Act was ambiguous because, when addressing how much a patient may recover, it refers to recovery for “an act of malpractice”; however, when addressing how much an insurer must pay, the Act refers to “an occurrence of malpractice”. The court determined that the Act contained no language that excuses a healthcare provider for multiple, separate acts of malpractice during a single surgery. Thus, as the physician was liable for two acts of malpractice the insurer is liable for each act of malpractice.

This case puts Indiana physicians and malpractice insurers on notice that there is unlimited liability where a physician causes multiple injuries to a patient even if they occur during the same procedure.

VI. MEDICAL MALPRACTICE

A. New Causes of Action

New York Court of Appeals Rules That Expectant Mother Has Negligent Infliction of Emotion Distress Cause of Action Against Physician Who Negligently Caused Fetal Death

Plaintiff Broadnax delivered a stillborn fetus due to the alleged failure of her obstetrician to recognize abruptio placenta. Plaintiff Fahey prematurely delivered stillborn twins due to the alleged negligent failure of her obstetrician to recognize an incompetent cervix. Neither woman herself suffered any independent injury.

Based on New York case law, lower courts in each case awarded summary judgment to the defendant physicians in response to plaintiffs’ claims for negligent infliction of emotional distress. In a consolidated ruling, the New York Court of Appeals reversed, overturning previous case law and authorizing the women’s independent claims for negligent infliction of emotional distress to proceed. The court left intact New York law barring recovery for wrongful death when an act of negligence results in miscarriage or stillbirth. Broadnax v. Gonzalez, 809 N.E.2d 645 (N.Y. 2004).

This decision closed a gap in New York law that allowed recovery when a baby was injured due to prenatal negligence or when a mother was negligently injured during a stillbirth, but which prohibited recovery when a stillbirth was not accompanied by injury to the mother.

Supreme Court of South Carolina Rejects “Wrongful Life” as a Legally Cognizable Common Law Tort

Jennie Willis, mother and guardian of Thomas Willis, brought suit on his behalf against physician Wu for wrongful life. Plaintiff alleged that Wu failed to properly interpret a prenatal sonogram showing severe hydrocephalus at a time early enough (twenty-four weeks) for her to terminate the pregnancy under South Carolina law. Thomas was born severely and permanently developmentally retarded.

In an issue of first impression for South Carolina, the court’s survey of other jurisdictions revealed that twenty-seven do not recognize the tort of wrongful life and three recognize the tort, while twenty others have not considered the issue. After reviewing the various reasons a court might consider in deciding whether to
recognize wrongful life as an independent tort, the court concluded that it was unable to provide an answer to the question, “is a severely impaired life so much worse than no life at all that a child is entitled to damages?” The court distinguished the child’s claim for wrongful life from the mother’s claim for wrongful birth that had yet to be adjudicated and which is permissible under South Carolina law.  

This is a well-written opinion that carefully avoided premising its holding rejecting the tort of “wrongful life” in South Carolina entirely on theological or philosophical principles.

**B. Vicarious Liability**

**West Virginia Court Revives Negligence Claim Against Hospital Based on Apparent Agency**

Plaintiffs filed separate claims against West Virginia University Hospitals (WVUH), claiming WVUH was vicariously liable under a theory of apparent agency between WVUH and the physicians who provided the allegedly negligent care.

In both cases, the West Virginia Supreme Court found that WVUH could not be liable because the patients had signed consent forms and the hospital had not “through its actions or its conduct, held the physicians out to be its employees.” However, the court ruled that the patients should have been permitted to present evidence to support their claims that the physicians who treated them appeared to be hospital employees. The court found there was no evidence to support their claims that the physicians were actual agents of the hospital but the allegations in both lawsuits were adequate to allow the apparent agency claims to proceed.

Although WVUH relied on the disclaimers signed by the plaintiffs to support its claims that there could be no agency, the court found they did not unequivocally “inform [the plaintiffs] that the physicians treating them were not employees of the hospital.” The court concluded that “[t]he WVUH disclaimer provision presupposes that all patients can distinguish between ‘faculty physicians,’ ‘resident physicians’ and any other type of physician having privileges at the hospital. In other words, for this disclaimer to be meaningful, a patient would literally have to inquire into the employment status of everyone treating him or her.” Thus, the court held that plaintiffs were entitled to present evidence to support their apparent agency claims.  
**Burless v. West Virginia University Hospitals, Inc.**, 601 S.E.2d 85 (W.Va. 2004).

This case suggests that West Virginia hospitals will be facing an increasingly difficult task in avoiding agency liability for their independent contractor physicians in a non-emergency room setting.
Texas Supreme Court Holds That Claim Against Hospital for Negligent Credentialing is a Claim for Medical Liability

Original plaintiff, Rose, filed a medical malpractice claim against her surgeon, Fowler, for alleged injuries following cosmetic surgery performed at Garland Community Hospital. After learning of similar previous complaints against Fowler, Rose amended her complaint to include a claim for negligent credentialing against Garland. Under Texas law, "healthcare liability" claims require the submission of a supporting expert’s report. At issue for the court was whether the negligent credentialing claim was a healthcare liability claim requiring the mandated submission of such a report.

In answering in the affirmative, the court held that Garland's credentialing decisions prior to and contemporaneous with her surgery were "an inseparable part of the medical services Rose received" and inextricably intertwined with the patient's medical treatment and the hospital's provision of healthcare." Furthermore, the court noted that "without negligent treatment, a negligent credentialing claim could not exist." Thus, to comply with Texas law, a negligent credentialing claim must be supported by the testimony of an expert.


Other states have adopted the contrary view that hospital credentialing is a process apart from the provision of medical care. See e.g., Browning v. Burt, 613 N.E.2d 993 (Ohio 1993).

C. Elements of Claims

Claim Against Louisiana Blood Bank for Negligence in Drawing Donor’s Blood is Not a Claim for Medical Malpractice

Voluntary blood donor Delcambre suffered permanent arm injuries due to the alleged negligence of Blood Systems, Inc.'s (BSI) technician in inserting a phlebotomy needle. Delcambre filed a claim against BSI, who defended by stating that Louisiana's medical malpractice tort reform act (the Act) required initial submission of such claims to a medical review panel.

At issue before Louisiana's Supreme Court was whether, under the Act, such a claim was for negligence in the provision of "health care or professional services" rendered by a healthcare provider "to a patient." In ruling in the negative, the court agreed that while BSI was a "healthcare provider," Delcambre did not receive "healthcare services" nor was he a "patient." To qualify as a "patient" under the Act, a person must be in the process of receiving, or should have received, "healthcare." That in turn requires the provision of a medical service for the benefit of the claimant. Here, Delcambre, in voluntarily donating blood, received no treatment or diagnosis; moreover, he was self directed to BSI rather than by a physician. Any screening lab tests performed on him were for the
benefit of potential recipients of his blood. Thus, Delcambre’s claim did not fall under the Act and did not require prior submission to a review panel. **Delcambre v. Blood Systems, Inc.**, 893 So.2d 23 (Louis. 2005).

*In limiting the effect of Louisiana’s medical malpractice tort reform act’s on tort victims, the court’s decision also serves to shield plaintiffs from the act’s stringent damage caps.*

**Tennessee Appeals Court Rules That Patient’s Signed Consent is Vitiated by Misrepresentation and That Medical Battery Can be Identified by the “Simple Inquiry” Test**

Plaintiff Holt suffered from recurrent kidney stones, usually being treated only with IV fluids and analgesics. Thus, after being hospitalized by his urologist for another stone, he was surprised by an interventional radiologist, defendant Alexander, who asked him to sign a consent form for an invasive procedure to remove the stone. Holt complied and underwent the procedure after Alexander misrepresented that Holt’s urologist had authorized it.

Plaintiff sued Alexander for medical battery. Alexander defended by asserting that, in view of Holt’s consent, this was a claim for lack of informed consent and therefore required expert testimony to proceed. The court disagreed, noting that “under the ‘simple inquiry’ test, the court must ask whether the plaintiff was aware that the specific procedure was going to be done and whether the plaintiff authorized the procedure. If either question is answered in the negative, then the claim is one for medical battery.” Here, Alexander’s misrepresentation vitiated Holt’s signed authorization, permitting the case to go forward as a medical battery claim without the need for a medical expert. **Holt v. Alexander**, 2005 WL 94370 (Tenn. App. 2004).

*The court’s “simple inquiry” test is a useful tool to distinguish a medical battery claim from a lack of informed consent claim.*

**Oregon Appeals Court Declines to Apply Loss of Chance Doctrine to Wrongful Death Claim**

Decedent Joshi died of a second stroke after defendant physicians missed the diagnosis of a prior stroke and failed to administer treatments that might have prevented the second and fatal episode. Testimony of expert witnesses for his estate in its subsequent suit for wrongful death did not reach the level of certainty required by the classic “but for” test for proximate causation. Rather, plaintiff’s experts testified that each of several treatments, either singly or combined would only have provided decedent approximately a thirty percent chance of survival.

The court refused to adopt the view that proximate causation may be satisfied by use of the “substantial factor” test, reasoning that this would be contrary to the plain language of Oregon’s wrongful death statute. Furthermore, although several Oregon cases have recognized that a “lost opportunity” may be a
separate compensable harm, the court would not expand application of that concept to a case of wrongful death. 


*This decision is contrary to what is now the majority rule in those jurisdictions that have considered the issue, i.e., to allow wrongful death cases to proceed to trial even when expert testimony fails to show that the defendant’s negligence was more likely than not the cause of death.***

**Claim Against New Jersey Physician for Sexual Assault Cannot be Tried as a Claim for Either “Medical Negligence” or “Medical Malpractice”**

Hospital worker and plaintiff Wendy Zuidema knew defendant surgeon Pedicano when he informally examined the ganglion cyst on her wrist. Zuidema underwent Pedicano’s recommended surgery; at a postoperative visit, he allegedly sexually assaulted her. Initially, Zuidema filed a medical malpractice claim that was later amended to include the sexual assault but which lacked any allegations of improper medical care.

Through a series of judicial errors, the case reached a jury, which rejected the allegation of sexual assault but awarded $150,000 for “medical negligence.” Because plaintiff had no medical expert, the judge instructed the jury regarding “medical malpractice” based upon a New Jersey administrative code’s prohibition of physician-patient sexual conduct.

The New Jersey appellate court noted that “no authority in this State or from other jurisdictions allows a claim of sexual assault to support a claim for medical malpractice in a civil action as a matter of tort law.” Because evidence of an intentional act of sexual assault cannot support a claim of “medical negligence,” and the jury found no sexual assault, the verdict was reversed. 


*Significantly, the court pointed out that neither an administrative code nor rules of professional conduct alone may serve as the basis of a civil claim for negligence.*

**D. Discovery, Evidence, Trial Issues**

**Supreme Court of Minnesota Holds That Nurse Practitioner is Qualified to Render an Expert Opinion on Postoperative Care Only to the Extent it Involves Nursing Duties**

Following tracheal resection surgery at the Mayo Clinic, plaintiff Broehm developed skin necrosis of the forehead beneath a cloth restraint used to prevent early postoperative movement of the head and neck. Plaintiff subsequently developed permanent scarring of the forehead. Broehm filed suit against the hospital, alleging medical malpractice. In compliance with Minnesota’s tort reform act requiring submission of a detailed expert opinion averring medical negligence, Broehm submitted the affidavit of nurse practitioner Wick. Wick’s
expert disclosure cited four postoperative duties required of a hospital relevant to such surgery: obtaining informed consent for use of the restraint, proper construction of the restraint, periodic inspection of the underlying skin, and seeking appropriate consultation with a wound specialist.

Both the trial and appeals courts held that Wick was not qualified to render an expert opinion on any of the items of postoperative care she discussed. Thus, the case was dismissed for failure to comply with the Act’s expert witness requirements. The Minnesota Supreme Court reversed in part, concluding that Wick was qualified to render an expert opinion as to the hospital’s duty to periodically inspect the skin beneath the restraint. It affirmed the underlying courts as to Wick’s other proffered testimony.


*Nothing in this decision suggests that the expert opinion of a nurse practitioner carries any greater or lesser authority than that of a registered nurse without such qualifications.*

**Mother of Brain-Damaged Infant Plaintiff Can be Compelled to Provide Blood Sample Where Her Genetic Condition May Have Been a Causative Factor in Infant’s Condition.**

Randy Cruz, a minor, and his mother and guardian ad litem, Carmelita Cruz, sued the delivering physician for negligence in connection with Randy’s birth injuries, including brain damage. Defendant’s genetics expert provided a declaration that a simple blood test of Carmelita could provide evidence that her genetic condition was a causative factor in Randy’s injury. A California trial court ordered that the test be performed. Carmelita sought a writ vacating the order based on her claims that (i) a non-party cannot be compelled to undergo a medical test; (ii) the testing would be "painful, protracted, or intrusive;” (iii) relevant law limits testing to blood type only; (iv) the geneticist’s request for blood test was speculative.

In denying the mother’s motion, the appeals court first noted that, as the child’s mother, Carmelita was not truly a non-party and that both she and her child were under the care of the delivering physician. There was also no evidence that the requested blood test would be anything but routine. The court further noted that the relevant statute mentioned blood typing as an example, not a limitation. Finally, the court ruled that the mother’s assertions of “speculation” ran counter to the generally liberal standards for discovery.

**Cruz v. Superior Court**, 17 Cal.Rptr.3d 368 (Cal. App. 2004).

*In discussing the authorization of discovery requests, the court remarked that even “fishing expeditions are permissible in some cases.”*


**E. Defenses**

**Under Louisiana Law, Statute of Limitations for Birth Defect Runs From Date of Birth Even When Defect Has Been Identified by Prenatal Testing**

Plaintiff Bailey had been taking an anti-seizure/anti-psychotic drug, Depakote, when she became pregnant. None of Bailey’s physicians or pharmacies had ever warned her of Depakote’s known tetragenicity. A prenatal sonogram taken at two months showed a fetal neural tube defect and Bailey was informed of the cause of the defect (Depakote) at three months. Although Bailey considered termination of the pregnancy, she carried to term and the baby was born with multiple severe defects including spina bifida and hydrocephalus.

Bailey filed medical malpractice claims against her physicians and tort claims against the pharmacies within one year of the baby’s birth but more than one year after her prenatal discovery of the baby’s defects and their legal cause. Defendants responded that her claims were time barred and that the statute of limitations ran from the time of her prenatal discovery of the baby’s defects. In an issue of first impression for any jurisdiction, the Louisiana Supreme Court noted that a different rule might apply to her claims on behalf of herself and to those on behalf of her baby. As to the baby’s claims, while Louisiana law assigns a persona to an unborn fetus from the date of conception, the fetus has no capacity to file suit until its birth. Thus, the limitation period for its claims cannot begin to run until its birth.

Regarding the more problematic question of when the statute begins to run on the mother’s own claims, the court was concerned with the potential difficulties that might accrue to both a plaintiff and the courts if there were different commencement dates for each legal entity. Furthermore, under Louisiana’s discovery statute, discovery does not commence until the date on which the "tortious act actually produces damage." In the court’s mind, the damage did not occur until the baby was born. **Bailey v. Khoury,** 891 So.2d 1268 (Louis. 2005).

*In a case of first impression for any jurisdiction, the Louisiana Supreme Court ruled that the statute of limitations for birth defects runs from the date of birth for both mother and child even when the defect was identified by prenatal testing. The court aptly noted that recent advances in medical technology may “raise legal questions that never before required consideration.”*

**Maryland High Court Refuses to Expand Physicians’ Duties to Third Parties in Cases of “Wrongful Pregnancy”**

James Dehn was referred by his family physician, Edgecombe, to a surgeon for a vasectomy. Following the surgery, the surgeon gave Dehn detailed instructions for sperm count testing to insure his sterility. Dehn failed to undergo the tests but later discussed the tests with Edgecombe, who allegedly indicated they were
unnecessary. Eventually, after unprotected intercourse, Mrs. Dehn became pregnant.

The Dehns each filed claims against Edgecombe for wrongful pregnancy, seeking damages for care of the child. At trial, the jury found that Edgecombe was negligent in his advice to Mr. Dehn and that Mr. Dehn was contributorily negligent in not following his surgeon’s postoperative testing regimen. Under Maryland law, Mr. Dehn was denied any recovery. The trial court dismissed Mrs. Dehn’s claim, reasoning that there was no physician-patient relationship between herself and Edgecombe. An appeals court affirmed all of the trial court’s decisions.

The Maryland high court agreed, emphasizing the primary requirement of a physician-patient relationship before a duty could be imposed on Edgecombe to Mrs. Dehn. It refused to accept Mrs. Dehn’s argument that the foreseeable consequences of Edgecombe’s negligence resulted in a duty to her. The court further noted that creating such a duty could “expand beyond manageable bounds” to all potential sexual partners of Mr. Dehn. 

Dehn v. Edgecombe, 865 A.2d 603 (Md. 2005).

Maryland court refused to extend a physician’s duty for wrongful pregnancy to a patient’s spouse, as such expansion could include all potential sexual partners of the patient.

F. Damage Elements

Eighth Circuit Affirms but Reduces Punitive Damages Award in Nursing Home Medical Malpractice Case

Arkansas Nursing and Rehabilitation Center (ANRC) resident Stogsdill’s medical condition caused chronic constipation and her physician ordered that she be monitored for impaction. ANRC staff failed to properly check Stogsdill for impaction and, despite requests by her family, failed to notify her physician that she was not moving her bowels. The staff also ignored her distended abdomen, a situation that eventually resulted in colonic perforation and death.

Stogsdill’s husband, as administrator of her estate, sued ANRC’s owner, Healthmark Partners, for medical malpractice. A jury awarded $500,000 in compensatory damages and $5,000,000 in punitive damages. The Eight Circuit affirmed the award of punitive damages based on Arkansas’ criteria that the ARNC staff “knew, or ought to have known, in light of the surrounding circumstances, that their conduct would naturally and probably result in injury and that they continued such conduct in reckless disregard of the circumstances.” In analyzing a putatively excessive award, the court applied the current Arkansas standard using the three element due process analysis from BMW of North America v. Gore, 517 U.S. 559 (1996). Under this analysis, the court reduced the award to $2,000,000 or a four-to-one ratio between the
compensatory and punitive damages.  
**Stogsdill v. Healthmark Partners, LLC,** 377 F.3d 827 (8th Cir. 2004).

*Noting that Healthmark’s net worth was allegedly only $597,000, the court believed the original $5,000,000 punitive damages award was “conscience-shocking” and violated due process.*

**Loss of Chance for a Better Outcome Following a Stroke is a Compensable Tort Where Damages Should be Calculated on a Subjective Basis.**

Plaintiff Dr. Hargroder, a veterinarian, was treated in a rural Louisiana hospital on two successive days by on-call physician Unkel. Although plaintiff was a hypertensive diabetic with symptoms of a stroke, defendant treated him for a gastrointestinal disorder. Plaintiff was eventually diagnosed as having had a stroke and improved with the administration of heparin although he was left with some permanent deficits.

Plaintiff sued Unkel for negligent misdiagnosis and for the loss of chance of a better outcome had immediate treatment been instituted. A jury awarded him $150,000 following a directed verdict. A Louisiana appeals court affirmed the verdict, noting expert testimony that early treatment with tPA, heparin or steroids might have given Hargroder a chance for a fuller recovery. Thus, the loss of chance was “a distinct injury compensable as general damages.”

The court ruled, however, that these damages “cannot be calculated with mathematical certainty, and the fact finder should make a subjective determination of the value of that loss, fixing the amount of money that would adequately compensate the claimant for that particular cognizable loss.”

Believing that the jury erroneously awarded full compensation for the stroke, the court reduced the award to $75,000, noting that plaintiff’s chance of full recovery was never equal to or greater than even.  

*Viewing loss of chance as a separate compensable tort with damages dependent on the percentage lost likelihood of recovery simplifies analyses of these cases.*

**VII. PAYMENT ISSUES**

**Alabama Supreme Court Refuses to Limit Hospital’s Recovery Under Hospital Lien Law to Amount Paid in Settlement of Claims**

Bell, a bicyclist, was injured by a motorist, and was treated at Plaintiff University’s hospital. Following discharge, the hospital perfected a hospital lien under Alabama law. Although it had notice of the lien, Progressive Insurance Co. (Progressive), the motorist’s insurance company, paid Bell $6,000 for the release of any claims he might have against Progressive’s insured. After the hospital
learned of the settlement, it filed suit against Progressive seeking approximately $57,000 as reimbursement for the costs of caring for Bell. Progressive argued that even if it was liable for paying the settlement monies to Bell in violation of the lien, the most it should be liable for was $6,000, the amount it paid for the release. The Alabama Supreme Court disagreed, and held that the statute at issue, Alabama Code § 35-11-370, does not limit damages to the amount paid for the release and, therefore, Progressive was liable for the entire amount paid for Bell’s care.


This case demonstrates that insurers are responsible for the entire amount paid for the injured party’s care when a hospital perfects a lien rather than merely the amount the insurer paid for the release of any claims against it.
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I. ERISA ACTIONS

Seventh Circuit Affirms Holding That Medical Director Decision Not to Pay for Out-Of-Network Coverage Due to Religious Convictions Purely an Eligibility Decision Subject to ERISA

The Supreme Court addressed whether the Employee Retirement Income Security Act (ERISA) preempted a medical malpractice claim where a health maintenance organization (HMO) denied coverage to a subscriber who used an out-of-network surgeon in order to accommodate her religious beliefs. The HMO required participants to obtain treatment from a physician within the network unless none were available to provide the necessary treatment. Plaintiff was in need of a surgical revision to her hip; however, her religious beliefs as a Jehovah's Witness required the procedure to be performed without a blood transfusion. The HMO’s medical director authorized surgery to be performed by a network physician, but would not authorize coverage for an out-of-network surgeon to operate in accordance with her religious beliefs.

The Court affirmed the opinion of the district and appellate courts, holding that ERISA preempted plaintiff’s state law claims because the medical director’s decision not to pay for an out-of-network surgeon was purely an eligibility decision that must be challenged pursuant to ERISA. The Court found that, despite its belief that the plaintiff’s religious convictions were sincere, there was no dispute as to the appropriate medical treatment that was needed. Accordingly, the decision to deny coverage was purely based on the participant’s eligibility and must be challenged under ERISA.


ERISA preempts medical malpractice claim based on HMO’s failure to provide out-of-network coverage to address religious convictions.

Supreme Court Rules That ERISA Preempts State Law Claims Arising From Wrongful Denial of Healthcare Benefits by ERISA-Regulated Health Plans

Plaintiffs alleged that their HMOs violated the duty of care prescribed under the Texas Health Care Liability Act (THCLA) by refusing to cover services their physicians had found medically necessary. The Supreme Court found that the civil enforcement mechanism provided under ERISA § 502(a) has “extraordinary” preemptive power. Where an individual is entitled to coverage only by his or her relationship to an ERISA-governed employee benefit plan, claims based on denials of coverage fall within the scope of § 502(a)(1)(B). Accordingly, any such claims may only be pursued in federal court under ERISA, which does not
providing for punitive damages or other types of monetary relief that may be available under state law remedies.

The Court further noted that there is no legal duty under THCLA that arises independently of ERISA or the benefit plans' terms. THCLA imposes a duty to exercise ordinary care when making healthcare treatment decisions, but does not impose liability where the health plan does not provide for the coverage sought. Therefore, the Court determined that because the state law claim relied on interpretation of the terms of the ERISA-regulated health plan, the claims were preempted under § 501(a) of the act.

Aetna Health Inc. v. Davila, 542 U.S. 200 (2004); see Barber v. UNUM Life Ins. Corp. of America, 2004 WL 1964500 (3d. 2004); Mayeaux v. Louisiana Health Service and Indemnity Co., 376 F.3d 420 (5th Cir. 2004); Land v. CIGNA HealthCare of Florida, 381 F.3d 1274 (11th Cir. 2004), for application of the Davila standard.

Where an individual is entitled to coverage only by his or her relationship to an ERISA-governed employee benefit plan, claims based on denials of coverage must be pursued under ERISA.

District Court in New York Holds That ERISA Bars Plaintiff’s State Law Claims Against Claims Administrator

Plaintiff was admitted to the hospital with a diagnosis of major depression and recurrent psychotic phases. When plaintiff’s wife did not want him to return home, his physician asked that he remain in the hospital until alternative housing could be found. CIGNA denied coverage as not medically necessary for inpatient care beyond the date he could have been released but for his wife’s objection.

The court found the breach of contract claim preempted because the claim related to a breach of terms as defined in an ERISA-regulated benefit plan. The court similarly rejected the claims for bad faith and negligent and intentional infliction of emotional distress as claims arising from denial of ERISA-regulated coverage properly addressed under the remedial scheme of ERISA.


ERISA preempts state law claims including breach of contract, bad faith, and negligent and intentional infliction of emotional distress, because such claims arise from the denial of ERISA-regulated coverage.

Hospital’s State Law Claim for Breach of Contract is Based on a Duty Independent of ERISA and Thus Does Not Support Federal Question Jurisdiction

Pascack Valley Hospital (Hospital) sued United Food and Commercial Workers International Union Local 464A AFL-CIO Group Reimbursement Welfare Plan (Plan) in state court for breach of contract based on the terms of a managed care

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contract that provided if a plan failed to pay the hospital promptly, the negotiated
discount would revert to billed charges. The Hospital filed suit in the Superior
Court of New Jersey alleging the Plan breached its contract by improperly taking
a discount on the services provided to two eligible beneficiaries despite the
Plan’s failure to make timely payment. The Plan removed the case to district
court and moved for summary judgment. The Hospital cross-moved for removal
to state court. The district court, in granting the Plan’s motion for summary
judgment, held that the Hospital’s breach of contract claims against that Plan
were completely preempted by ERISA, and therefore, raised a federal question
supporting removal under 28 U.S.C. § 1441(a). The Third Circuit, however, held
that under the well pleaded complaint rule, the Hospital’s complaint did not
present a federal question supporting removal, as the Hospital’s complaint asserted a state law claim for breach of contract, and the federal common law of
ERISA does not provide an element, essential or otherwise, for such a claim. The
court noted that an action may only be removed if it falls within the narrow class
cases to which the doctrine of “complete preemption” applies.

Pascack Valley Hosp., Inc. v. Local 464A UFCW Welfare Reimbursement
Plan, 388 F.3d 393 (3d Cir. 2004).

The federal common law of ERISA does not support a claim for breach of
contract; therefore, removal to federal court is not appropriate.

A Multi-Employer Welfare Plan’s Decision Not to Cover Gastric Bypass
Surgery is Reasonable under ERISA

Plaintiff, a participant in an ERISA welfare plan (the Plan), brought suit after the
Plan’s trustees denied his request to cover the expense of a proposed gastric
bypass operation. The Plan trustees denied the procedure as an excluded
cosmetic service even though plaintiff suffered from many serious health
conditions. The district court dismissed the suit on the grounds that the Plan
trustees’ decision was not an unreasonable interpretation of the Plan. The court
recognized the Plan trustees had “discretionary and final authority in
making...decisions interpreting plan documents” and that judicial review of their
interpretations is deferential. On appeal, the Seventh Circuit stated that the
trustees of the multi-employer benefit plan acted reasonably under ERISA by
denying, under the plan’s cosmetic care exclusion, coverage for a gastric bypass
surgery sought for the morbidly obese participating Plan member, even though
the exclusion defined cosmetic as “having the primary effect of...improving the
physical appearance” and the plaintiff sought surgery primarily for health
reasons. The court found that the Plan’s exclusion “specifically and unqualifiedly
excluded gastric bypass surgery”.

Manny v. Central States, Southeast and Southwest Areas Pension and
Health and Welfare Funds, 388 F.3d 241 (7th Cir. 2004).

It is not unreasonable for Plan trustees to deny coverage for gastric bypass
surgery as an excluded cosmetic service, even though such surgery was sought
for health reasons, because the Plan’s exclusion was clear.
District Court Dismisses State Law Causes of Action Based on ERISA Preemption
Plaintiffs brought suit against an insurance brokerage firm and two former directors of the Transport Workers Union Retirees Association (Retirees Association). The Retirees Association offered a health benefits plan (the Plan) to plaintiffs and other members of the Retirees Association. Plaintiffs, as participants in the Plan, asserted that the defendants “grossly overcharged” for insurance benefits provided under the Plan. Plaintiffs also alleged breach of fiduciary duty under ERISA and New York State Insurance Law, as well as other state law claims.

The court denied the motion to dismiss on the breach of fiduciary duties claims and claims alleging breach of loyalty, care and duty to disclose, concluding that it was premature to determine the extent to which the “adjudications” called for the exercise of discretion over management of the Plan, or disposition of the Plan’s assets. The court observed that whether the defendants were fiduciaries under ERISA could not be definitively determined on a motion to dismiss.

Although the district court declined to dismiss plaintiffs’ breach of fiduciary duty claims, it did dismiss claims against all the defendants based on fraud, or fraudulent concealment, since, in the court’s view, the complaint failed to plead the fraud claims with particularity as mandated by Federal Rule of Civil Procedure 9(b).

The district court then addressed the causes of action under New York state law, stating that “[a]ny state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore preempted.”


This case is significant because it provides further insight into how a district court applies the preemptive force under ERISA for state law claims.

Supreme Court of Hawaii Rules That Hawaii’s External Review Law for Health Benefit Plans Was Preempted by ERISA
Enrollee sought coverage for a nonmyeloablative stem cell transplant to treat an enrollee’s cancer. The Hawaii Management Alliance Association (HMAA) denied coverage because the medical procedure was viewed as experimental, and not medically necessary. The enrollee sought internal review of that decision, which was upheld by HMAA’s medical director.

The enrollee sought expedited external review of the claim’s denial under Hawaii’s external review law, HRS § 432E-6, which allows for external review to be conducted by the State’s Insurance Commissioner. The Commissioner ruled
that the enrollee failed to prove that the decision by HMAA to deny coverage was improper, but ordered HMAA pay attorney fees and costs to the enrollee. HMAA appealed, and the appeals court ruled that the Commissioner did not err in awarding attorney fees and costs. The appeals court rejected HMAA’s argument that the external review procedure was preempted by ERISA. HMAA then appealed to the Supreme Court of Hawaii, which reversed the appeals court, and held that Hawaii’s external review law was preempted by ERISA. The high court thus vacated the Commissioner’s order awarding attorney fees and costs to the enrollee.

**Hawaii Management Alliance Ass’n v. Insurance Comm’r**, 100 P.3d 952 (Haw. 2004).

*This case is significant because it applies the body of ERISA law regarding preemption when construing a state’s external review provisions for appeal of coverage determinations under an ERISA employee health benefit plan.*

**U.S. Supreme Court Declines to Review Sixth Circuit Decision Stating That ERISA Did Not Permit Health Plan Fiduciary to Sue in Federal Court on Behalf of Plan Participant**

The Supreme Court declined to review the decision of the Sixth Circuit in *QualChoice v. Rowland* that found that ERISA did not permit a health plan fiduciary to sue in federal court to recover funds paid on behalf of a plan participant injured in an accident with a third party. The case involved a lawsuit brought by Robin Rowland, who participated in a health plan administered by QualChoice and who was injured in a car accident at an unguarded, unlit railroad crossing. Rowland incurred extensive medical bills resulting from the accident, which expenses were recovered in part from the railroad company. QualChoice then brought an action against Rowland to recover the amount it had advanced her under the plan to cover her medical expenses.

The United States District Court for the Northern District of Ohio dismissed the claim for lack of subject matter over the plan administrator’s action, since ERISA authorizes actions in equity but not those seeking legal restitution. The Sixth Circuit affirmed and the Supreme Court declined to review the lower courts’ rulings.


*This case illustrates the Supreme Court’s reluctance to grant certiorari for ERISA cases unless a controversy exists among the federal appeals courts.*
II. MANAGED CARE

Eleventh Circuit Affirms Class Certification of Physicians’ RICO Claims Against Managed Care Industry; Reverses Certification of State Law Claims

The Eleventh Circuit reviewed the district court’s certification of claims brought by physicians against the managed care industry under various state law claims and the Racketeer Influenced and Corrupt Organizations Act (RICO) charging HMOs with acts of conspiracy and fraud in an effort to systematically underpay physicians for their services. The case originated when lawsuits were filed in four federal judicial districts against Humana, Inc. The suits were consolidated by the Judicial Panel on Multi-District Litigation in the Southern District of Florida and later combined with other similar federal suits from across the country, In re Humana Managed Care Litig., 2000 WL 1925080 (Jud.Pan.Mult.Lit. 2000). Once the cases were consolidated, the plaintiffs filed an amended complaint against all defendants, requesting the district court certify three classes, including a global class, national class, and California subclass. The district court certified all three classes and the HMOs appealed.

The appeals court affirmed the certification of plaintiffs’ federal law claims, but reversed certification of the state law claims. The court found that the district court did not abuse its discretion in certifying the classes to litigate plaintiffs’ various RICO claims. Focusing on the class certification requirements of Federal Rule of Civil Procedure 23(b)(3), the court found a predominance of common questions of fact and law because the case “involves a conspiracy and joint efforts to monopolize and restrain trade”. However, the court “strongly urged” the district court to consider redefining the classes into subclasses based on whether the plaintiff’s reimbursement scheme was fee-for-service or capitation contract based. By contrast, the court reversed certification of plaintiffs’ state law claims, finding the individualized issues of law or fact to predominate over common, classwide issues.

Klay v. Humana, Inc., 382 F.3d 1241(11th Cir. 2004)

The Eleventh Circuit affirmed class certification for physicians’ MDL RICO claims against managed care industry; however, certification for state law claims was reversed.

Eleventh Circuit Affirms Decision Precluding Arbitration of Physicians’ Indirect-RICO Claims and Nonparticipating Provider Claims Against Managed Care Industry

Plaintiff physicians alleged that defendant HMOs adopted and utilized reimbursement policies and procedures that violated RICO and state prompt pay statutes, and used their market power to force physicians to accept harmful managed care practices.

In 2003, the Supreme Court ruled that insurance contracts requiring arbitration were enforceable even in the context of RICO claims and remanded the case to
the district court. *PacifiCare Health Sys. v. Book*, 538 U.S. 401 (2003). Following remand, plaintiffs amended their complaint. First, the district court ruled that direct RICO claims must be arbitrated, regardless of limitations on punitive damages under an arbitration agreement. Second, the court ruled that indirect RICO claims (claims of conspiracy among the defendant HMOs to violate RICO, and claims of aiding and abetting RICO violations) were nonarbitrable. Third, the court held that nonparticipating provider claims (non-par claims) are nonarbitrable if asserted by physicians where (i) there is no contract between the physician and the HMO regarding the services from which the claim arose, or (ii) there was absent an assignment to a physician of the claim by a subscriber who had a contract with the HMO. Finally, the district court ruled that nonarbitrable claims pending before the court would not be stayed pending arbitration of claims properly the subject of arbitration.

On appeal before the Eleventh Circuit, the defendant HMOs challenged the district court for its failure to require arbitration of all indirect RICO claims and non-par claims, and for not staying the litigation of nonarbitrable claims pending arbitration of the remaining claims. The Eleventh Circuit affirmed the district court’s ruling. In its decision, the court addressed whether indirect RICO claims should be subject to arbitration. It rejected the defendants’ argument, and held that under its prior rulings, and the law of the case doctrine, indirect RICO claims were not arbitrable. *Klay v. All Defendants*, 389 F.3d 1191 (11th Cir. 2004).

*This case is significant because it addresses important issues regarding the arbitration of claims physicians may raise regarding disputes with healthcare plans in their capacity as participating and non-participating providers.*

**Indiana HMOs Required to Exhaust Administrative Remedies Before Judicial Review Allowed Regarding Indiana Comprehensive Health Insurance Association Issues**

Three HMOs filed suit in Indiana against the administrator of Indiana’s high-risk insurance pool. The HMOs asserted that their mandatory membership in the Indiana Comprehensive Health Insurance Association (ICHIA) was unfair because they were not able to sufficiently benefit from a tax credit designed to offset losses from participating in the state’s high-risk insurance pool. ICHIA replied that taxation of HMOs is based on the HMO’s choice to do business under that particular business structure and that these grievances must be addressed administratively with ICHIA.

ICHIA was statutorily established to provide health insurance to those who could not otherwise afford it. The statute requires that every health insurer, HMO, limited-service HMO, and healthcare coverage self-insurer become a member of ICHIA. ICHIA also requires that participating members exhaust its own administrative remedies when challenging an assessment as opposed to seeking judicial review in state courts. However, the lower Indiana court held that
because ICHIA is not considered a state agency, HMOs are not required to exhaust their administrative remedies before seeking judicial review. The Indiana Supreme Court subsequently overturned the lower court, ruling that whether or not ICHIA is state agency, its administrative remedies must be exhausted before a member may resort to the state courts.

**M-Plan, Inc. v. Indiana Comprehensive Health Ins. Ass’n**, 809 N.E.2d 834 (Ind. 2004).

**HMO suit challenging state’s high-risk pool assessments dismissed for failure to exhaust administrative remedies.**

**California Court of Appeals Reverses Summary Judgment Granted to HMO on Issue of Whether HMO Provided Timely Treatment to Subscriber**

Plaintiff went to an urgent care facility as mandated under his healthcare plan with PacificCare of California (PacifiCare) when he began to have flu-like symptoms. After several weeks of appointments with his primary care physician (PCP), plaintiff requested a referral to a specialist. The PCP provided the referral; however, plaintiff was told by the specialist that his appointment would take six weeks since the specialist saw patients from PacificCare only one day a week. Plaintiff then sought treatment from an out-of-network specialist, who treated plaintiff’s condition. Plaintiff then sought reimbursement from PacifiCare, but was denied payment since the specialist was not part of PacificCare’s network. Plaintiff was unsuccessful in appeals pursued within the HMO.

The trial court granted defendant’s motion for summary judgment. On appeal, the California Court of Appeals agreed with the trial court that plaintiff’s treatment with the out of network specialist was not an “emergency medical condition” and thus was not reimbursable under his healthcare plan. Applying the definition of “emergency medical condition” under the plan, and the facts surrounding plaintiff’s condition, the court of appeals concluded that plaintiff’s condition did not rise to the level of an emergency.

The court then addressed whether there was a breach of contract since, as alleged by plaintiff, treatment was not afforded under the plan within a reasonable time period. The court ruled that a triable issue existed as to whether or not PacifiCare had fulfilled its implied-in-fact duty to provide plaintiff timely treatment by an appropriate specialist. Thus, the court concluded that summary judgment should not have been granted in favor of the defendants for plaintiff’s breach of contract and bad faith claims.


This case is significant because it provides insight on how the court construed “emergency medical condition” under the terms of the healthcare plan for coverage purposes. Furthermore, this case highlights the standard applied in California in judging the reasonableness of time for treatment afforded a subscriber under a healthcare plan.
California Court of Appeals Rules That Mandatory Arbitration of Claims Raised by Insureds of Healthcare Service Plans Was Constitutionally Permissible

Plaintiff insureds filed suit against the California Department of Managed Care (the Department) for approving healthcare service contracts entered into between the plaintiffs and HMOs. Those contracts were approved by the Department pursuant to its authority under the Knox-Keene Act. Health & Saf. Code § 1340, et seq. Plaintiffs argued that the Department erred in approving those contracts since they embodied clauses mandating binding arbitration of disputes between the HMO and its insureds. Plaintiffs contended that those contracts where contracts of adhesion, and that the mandatory arbitration provisions denied the insureds of their constitutional right to a civil trial by jury, and denied them due process. The trial court ruled that the binding arbitration provisions were constitutional where the agent for the employee-insureds (namely, the employer) has waived the right to a jury trial.

The appeals court affirmed, rejecting plaintiffs’ arguments and concluding that, as announced in Madden v. Kaiser Foundation Hospitals, 17 Cal.3d 699 (1976), the right to a jury trial can be waived, through an agreement for binding arbitration, by an employer who enters into a healthcare plan on behalf of its employees. The court stated that as long as there was adequate disclosure of the binding arbitration clause, approval by the Department of the agreement between the HMOs and plaintiff-insureds’ employers was permissible.

Viola v. Dep’t of Managed Health Care, 23 Cal.Rptr.3d 821(Cal. App. 2005).

In California, an employer has the implied authority as the agent of its employees to agree to binding arbitration of disputes arising under a health services plan that it negotiates as part of an employee benefit package.

Health Net and Prudential Settle National Physician Class Action

Health Net, Inc. (Health Net) and Prudential Financial, Inc. (Prudential) announced that they have settled a national class action brought by nearly 700,000 physicians who alleged that Health Net and Prudential, along with other managed care companies, had violated federal racketeering and state prompt-pay laws in processing claims. Under the settlements, which must be approved by the United States District Court for the Southern District of Florida, Health Net will make a guaranteed cash payment of $60 million, and will invest $80 million (over a four-year term) in various administrative changes. Prudential (which owned Prudential Health Care until it was acquired by Aetna in 1999) agreed to a $22.2 million settlement with the physicians.

The agreements with Health Net and Prudential follow settlements between the same physician plaintiffs and two other named defendants, Aetna, Inc. and Cigna HealthCare Plan, in 2003. Litigation remains pending between the physician plaintiffs and WellPoint, United Healthcare, Humana, and PacifiCare.
In re Managed Care Litig., MDL Case No. 1334 (S.D. Fla., settlement announced May 3, 2005).

Physician plaintiffs achieve yet another victory in their fight to change practices of the managed care industry.

Illinois Court Rules That Health Plan May be Required to Reimburse Out-Of-Network Provider Who Reasonably Relied on Plan’s Assurances
The Illinois Appeals Court ruled that a health plan may have to reimburse out-of-network providers who reasonably relied on the assurances of the health plan that the providers’ treatment of plan members would be covered. The case arose out of claims filed by Chatham Surgicore Ltd. (Chatham) for podiatric outpatient services rendered to individuals covered by a Blue Cross Blue Shield of Illinois (Blue Cross) administered plan. Chatham was not a network provider with Blue Cross and, therefore, had not agreed to negotiated rates or other contract terms for providing services to Blue Cross members. Chatham alleged that before treating each Blue Cross plan beneficiary, Chatham called Blue Cross to verify coverage, and that during these conversations, Blue Cross, without disclosing any limitations, represented that its members were covered for the services provided at Chatham. Chatham further alleged that after providing treatment to Blue Cross’ insureds, it promptly sent a request for payment pursuant to an assignment from the Blue Cross members entitling Chatham to receive payments directly from Blue Cross, but that Blue Cross had never processed the claims. Under theories of promissory estoppel and fraud, Chatham sued Blue Cross.

The appeals court, in reversing the trial court’s decision, found that Blue Cross knew or should have known that its statements would induce Chatham to treat patients; therefore, its statements satisfied the promise element for purposes of stating a promissory estoppel claim. However, the court sustained the decision of the trial court that Chatham had failed to plead the specific allegations needed to support a theory of fraud.


Out-of-network providers who reasonably relied on health plan’s statements regarding insureds may be entitled to reimbursement for the services rendered to the health plan’s insureds.

III. INSURANCE

Seventh Circuit Rules FEHBA Preempts State Law on Subrogation Claim
Insured was injured in an automobile accident and was enrolled under Service Benefit Plan (Plan) of Blue Cross and Blue Shield of Illinois (Blue Cross). The Plan was provided for government employees and their dependents under the Federal Employees Health Benefits Act (FEHBA). Blue Cross paid for the
insured’s medical care from the injuries sustained from the accident. The insured sued the other party in the accident and recovered money in excess of his medical expenses in a settlement agreement. The insured and Blue Cross could not agree on the amount of money the Plan should be reimbursed from the settlement. The insured brought suit against Blue Cross in state court under state law theories. Thereafter, while the state court action was pending, Blue Cross brought suit against the insured under the Statement of Benefits in the Plan, demanding reimbursement for the benefits paid on behalf of the insured. The district court dismissed the suit brought by Blue Cross and Blue Shield against the insured for lack of subject matter jurisdiction.

The Seventh Circuit reversed, stating that the district court had subject matter jurisdiction over the action brought by Blue Cross under 29 U.S.C. § 1331. The court further stated that even where a statute does not explicitly create a cause of action, a claim may arise under federal law if the statute completely preempts state law in a particular arena.

Blue Cross and Blue Shield of Illinois v. Julia Cruz, 396 F.3d 793 (7th Cir. 2005).

This case is significant because it provides insight on how the Seventh Circuit construes the preemption language under the FEHBA.

New York High Court Finds Insurance Company Not Required to Provide Same Benefits for Physical and Mental Disabilities

The group health plan covering plaintiff included disability insurance, but generally limited benefits based on mental disability to twenty-four months. Disability benefits paid under the plan to plaintiff, who suffered from a chronic psychiatric disability, were discontinued after approximately twenty-four months in accordance with the plan provisions. Plaintiff filed a complaint with the New York State Insurance Department (Department), claiming that the insurer violated N.Y. Ins. Law § 4224(b)(2), which prohibits an insurer from limiting the coverage available to an individual on account of a physical or mental disability unless permitted by law or regulation and statistically or empirically justified. After the Department dismissed her complaint, plaintiff filed suit. Both the trial court and the appellate court upheld the Department’s decision.

The New York Court of Appeals also affirmed the Insurance Department's decision. The court first noted that nothing in § 4224(b)(2) requires an insurer to offer the same benefits for all ailments unless statistically or empirically justified. The high court further noted that § 4224(b)(2) is similar to anti-discrimination laws in other states and "courts have generally declined to interpret these statutes to require equivalent coverages for mental and physical disabilities." After reviewing the legislative history of § 4224(b)(2), the high court found no evidence of intent to require parity of benefits for mental and physical disabilities. Accordingly, the high court affirmed the decision of the trial court and appellate court.

This case is significant in New York because it ratifies a longstanding practice of some insurers of limiting benefits for mental disabilities. Also, the insurance law at issue in this case is similar to laws in other states and may be of interest to practitioners in those states as well.

New York Court Rules That No Payments From Insurers Required for Illegally Structured Medical Enterprises
As a result of a certified question from the United States Court of Appeals for the Second Circuit as to whether New York’s “no-fault” insurance laws would permit insurers to withhold payment for medical services provided by fraudulently incorporated enterprises, the New York Court of Appeals ruled that insurance carriers may withhold payment for services provided by fraudulently incorporated medical enterprises even if the care received by the patient was appropriate and within the scope of the licenses of the persons providing the treatment. The court further held that non-physician medical professionals who had evaded state law prohibiting non-physicians from sharing ownership in medical service corporations could not obtain payments from carriers under the state’s no-fault insurance statute.


This decision is important because it illustrates that the professional service corporation laws will be vigorously enforced in New York, and that failure to comply will result in the denial of payment for services rendered, even if the care was necessary and appropriate.

IV. MISCELLANEOUS

Fourth Circuit Affirms District Court’s Dismissal of American Chiropractic Association’s Claims That Trigon Healthcare and Various Physicians Engaged in Anti-Competitive Conspiracy
The Fourth Circuit affirmed the district court’s dismissal of American Chiropractic Association Incorporated Inc.’s (ACAI) claims against Trigon Health Care Incorporated (Trigon). ACAI filed an eight-count complaint and Trigon moved to dismiss the action in its entirety. The district court dismissed two counts for failure to state a claim. After discovery in the case, Trigon filed a motion for summary judgment to dismiss the remaining claims. The district court granted Trigon’s motion for three counts, holding the intracorporate immunity doctrine precluded any conspiracy between Trigon and the medical doctors that served on one of its committees, and ACAI produced no evidence of a conspiracy. Upon appeal, in affirming the lower court, the Fourth Circuit disagreed with ACAI that Trigon and its MCAP, a committee established by Trigon, created false referral guidelines meant to limit the use of chiropractors for the treatment of low back pain and to keep reimbursement from chiropractors. The court held that Trigon lacked the legal capacity to conspire with medical doctors on MCAP and,
therefore, lacked the capacity to conspire with the meaning of § 1 of the Sherman Act. On November 11, 2004, the U.S. Supreme Court denied certiorari without comment.


District Court of New Jersey Permits Class Action Against Health Net to Proceed
Plaintiffs from two different employee benefit health plans offered by Health Net of New Jersey (Health Net) that were consolidated sought class certification for Health Net beneficiaries in a nationwide action to address alleged misconduct by Health Net. Plaintiffs claimed Health Net failed to disclose data and other relevant information that comprises the Prevailing Health Care Charge System (PHCS) or other similar databases, and alleged the databases were flawed. Health Net filed a motion to dismiss for failure to exhaust administrative remedies.

In denying Health Net’s motion to dismiss, the court held exhaustion of administrative remedies is not required to assert a claim for breach of fiduciary duty or with breach of contract claims where it was futile or when Health Net did not maintain adequate administrative claims procedures. The court also determined that the federal law requirements regarding class certification were or could be satisfied.


Exhaustion of administrative remedies is not required to assert claims for breach of fiduciary duty or breach of contract where it is futile or adequate administrative claims procedures do not exist.

Specialty Hospital Files Antitrust Action Against Acute Care Hospitals and Insurers
Heartland Surgical Specialty Hospital, LLC (Heartland), a specialty surgical hospital, filed an antitrust action in the United States District Court of Kansas against traditional acute care hospitals and several major insurance carriers for the carriers’ refusal to enter into managed care contracts with Heartland. The lawsuit alleges that the named insurance carriers, Blue Cross and Blue Shield of Kansas City, Coventry Health Care of Kansas, United Healthcare, Inc., Humana Health Plan, Inc., Aetna Inc., and Cigna Healthcare of Ohio, Inc., conspired with major hospitals (also named as defendants) to direct patients’ to the traditional hospitals to the exclusion of Heartland for acute care hospital services and spine and upper extremity services. In denying the allegations, defendants maintain that their network contracting decisions were appropriate and had been made independently.

Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc., No. 05-CV-2164 (complaint) (D. Kan. April 26, 2005).
This case is significant because it demonstrates the ongoing battle between specialty hospitals and “traditional” hospitals for patients and revenue.
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I. CONTRACTS

Court Decides Hospital May Not Exclude Physicians With Staff Privileges

Three physicians with staff privileges at Monongalia County General Hospital (Hospital) who also were employees and shareholders of Monongalia Anesthesia Associates, Inc., which previously provided anesthesia services to the Hospital, challenged the Hospital’s exclusive contract with another provider that covered virtually all general anesthesia services.

The West Virginia Supreme Court rejected the physicians’ position that they had a property interest in their staff privileges and also held that the hospital’s medical staff bylaws did not constitute a contract with the physicians. It distinguished the scope of judicial review in cases involving public and private hospitals, saying that, in public hospitals, physicians do not practice at the will of the hospitals’ governing authorities, but are “entitled to practice,” so long as they stay within the law and conform to all “reasonable” rules and regulations. The court then examined whether the hospital’s decision to enter into the exclusive contract was reasonable, concluding that “the total exclusion of physicians from their hospital practices, and the concomitant complete deprivation of patient choice, simply cannot be justified “by the ends the hospital sought to achieve.

Although the court acknowledged that its decision was contrary to prevailing authority upholding exclusive contracts, it disagreed with those precedents. It found that a preferential contract would have allowed the lead plaintiff access to hospital facilities to treat patients when he was requested, allowed the hospital management the discretion to contract to secure a primary provider of medical services to solve scheduling and staffing problems, and also would have preserved patient choice.


West Virginia Supreme Court set a new precedent disallowing exclusive provider agreements because such agreements unfairly excluded other physicians, hindered a patient’s right to choose his or her physician and were aimed at solving a problem that could have been addressed by less restrictive means.

Wisconsin Court Holds Company Retained to Provide Records Release Service Did Not Breach Contract With Health System

All Saints Healthcare System, Inc. (All Saints), entered into a contract with Midwest Medical Records Associates (MMRA) in which MMRA would provide release of information (ROT) services for All Saints, including maintaining All Saints’ medical records and responding to requests for copies of medical records

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A class action lawsuit was filed against All Saints claiming that it was charging unreasonable and exorbitant fees for certain services in violation of a Wisconsin statute allowing a patient to obtain copies of their medical records at a reasonable cost. All Saints cross-claimed against MMRA. The trial court granted summary judgment to MMRA, and All Saints appealed.

The appeals court found that the Contract itself specified the prices to be charged by MMRA for providing copies of medical records, and MMRA could not be in breach of the Contract for charging those prices. The court also rejected All Saints’ argument that by warranting that it would comply with all applicable regulations, MMRA in effect warranted that the fee schedule in the Contract complied with the law. The Contract provided that MMRA could not change the rates without All Saints’ consent, thus the Contract could not be “construed to include a warranty that MMRA would charge rates other than those specified in the contract.” The court also noted that All Saints was under no obligation to agree to the rates in the Contract and could have demanded other rates if it deemed the proposed rates to be unreasonable.

*Cruz v. All Saints Healthcare Sys., Inc.*, 690 N.W.2d 25 (Wis. App. 2004).

*Hospital sued in class action for high patient record retrieval fees could not sustain breach of contract claim against medical records management company it hired because the rates the company agreed to charge were set in the contract and the hospital could have contracted for a different amount.*

### II. EMPLOYMENT ISSUES

**Attending Physicians Are Not Exempt, as Managers, From Illinois State Labor Law**

Cook County Hospital (Hospital) claimed the activities of its attending physicians’ committee, the attending physicians participation in department meetings, and their development of individual care plans that involved issuing orders and directing other hospital personnel, were evidence of the physicians’ managerial status. The ALJ found that the attending physicians did not meet the definition of managerial employees because they were not engaged predominantly in executive and management functions. The Illinois Appellate Court noted that for employees to be classified as managerial under the Illinois Public Labor Relations Act, they must be “predominantly engaged in executive and management functions” and they must “exercise responsibility for directing the effectuation of management policies and procedures.” Managerial status requires “sufficient independent authority and discretion to broadly effect a department’s goals or means of achieving its goals,” the court concluded, adding that “[h]ere, the only discretion the attendings exercise is in providing patient care and results from their professional and technical expertise.” The court stated that even if the attending physicians' work on committees and in department meetings rose to the level of executive and management functions, the doctors “do not engage
predominately in such executive and management functions as required for exclusion under the Act." Rather, the work appears to comprise approximately ten percent of the attending physicians' work time. **County of Cook v. Illinois Labor Relations Bd.-Local Panel,** 824 N.E.2d 283 (Ill. App. 2004).

This case established that under Illinois labor relations law, attending physicians may not be considered exempt as "supervisors" because, although they do perform some managerial functions, they do not possess enough administrative responsibility for the state to consider such responsibility to be a major component of their employment.

**Missouri Appeals Court Finds Hospital Protected by HCQIA in Suspension of Anesthesiologist**

Keshav Joshi, M.D., worked for St. Luke's Episcopal Presbyterian Hospital (Hospital) as an anesthesiologist from 1989 to 1996. The peer review committee at the Hospital reviewed multiple incidents in which Joshi allegedly rendered poor patient care. In addition, several nurses complained about Joshi's care.

The Hospital's Chief of Anesthesiology reviewed all of the complaints against Joshi and recommended a summary suspension because he believed that Joshi posed an imminent threat to patients. Joshi's attorney requested a preliminary hearing at which a decision was rendered to continue the suspension pending a full hearing. Before the hearing took place, Joshi resigned. Joshi then sued the Hospital, the Chief of Anesthesiology, and others (Defendants) seeking damages and injunctive relief. Defendants moved for summary judgment claiming that they were entitled to immunity under the Health Care Quality Improvement Act (HCQIA). The trial court granted defendants summary judgment, but denied their request for attorneys' fees.

Rejecting Joshi's argument that Defendants did not make a reasonable effort to find the facts of the matter, the appeals court found the totality of the evidence showed that Defendants' efforts to obtain the facts were more than reasonable. The appeals court further found that adequate notice and a full and fair hearing were provided to Joshi. Lastly, the appeals court held that the numerous complaints about Joshi, along with various reports, demonstrated a reasonable belief that the action was warranted. Accordingly, the appeals court affirmed the trial court's judgment. **Joshi v. St. Luke's Episcopal Presbyterian Hosp.**, 142 S.W.2d 862 (Mo. App. 2004).

This case is important because it demonstrates that courts continue to recognize the viability and necessity of HCQIA immunity.
Ninth Circuit Says Physician’s Complaint Alleging Discrimination Was Sufficient to Survive Motion to Dismiss

Plaintiff, an African-American anesthesiologist, claimed Sunrise Hospital (Hospital) discriminated against him based on race by not disciplining any other hospital staff that violated hospital rules during the two incidents at issue, and by not providing him with standard procedural protections that were provided to non-black staff members during the Hospital’s hearing. The district court dismissed the complaint on the ground that the allegations of racial discrimination were merely conclusory statements that were unsupported by any facts.

The Ninth Circuit reversed and remanded the district court’s judgment, stating that plaintiff’s complaint satisfied pleading requirements. In Swierkiewicz v. Sorema, NA., 534 U.S. 506 (2002), the Supreme Court determined that a complaint alleging employment discrimination claims only need to include a brief statement of the facts and did not have to allege specific facts to establish a prima facie case of discrimination. The Ninth Circuit found the district court’s approach was inconsistent with Swierkiewicz and remanded the case to the district court for a determination of whether plaintiff’s complaint satisfied the simple pleading requirements.

Maduka v. Sunrise Hosp., 375 F.3d 909 (9th Cir. 2004).

Ninth Circuit held that hospital employee alleging discrimination did not have to allege a prima facie case of discrimination in his complaint, as Supreme Court had previously held that conclusory allegations of discrimination were sufficient to move forward with employment discrimination claims.

California Court Finds Hospital May Summarily Suspend Physician Who is Imminent Threat to Patients

Dr. Penny Pancoast is a physician with an internal medicine practice who obtained medical staff privileges at Sharp Memorial Hospital (Sharp). Pancoast’s privileges at Sharp were suspended because she had not completed a number of medical records. In the next few months, various attempts to contact Pancoast failed and her psychiatrist and other associates informed Sharp that Pancoast was stressed and possibly suicidal. Pancoast sued Sharp and its chief of staff, alleging that Sharp acted improperly in suspending her privileges and in failing to provide her with a hearing. The trial court granted Pancoast a writ of mandate directing the hospital to either restore her privileges or provide a hearing.

The California Court of Appeal, Fourth District, directed the trial court to vacate its writ. The court first turned to the issue of whether by allowing suspension where there is likely harm to prospective patients, Sharp’s bylaws go beyond the scope of California Business and Professions Code § 809.5. The court found that, read in light of the public interest in protecting patient safety, the statute protects prospective as well as identified patients. Next, the appeals court found that Sharp had an adequate basis upon which to conclude that Pancoast was an imminent threat to patients. Pancoast argued that she did not intend to begin
admitting patients to Sharp as soon as her medical records suspension was over; therefore, she was not an imminent threat to patients. However, the appeals court found that the record contained a “great deal” of proof that Pancoast did intend to begin admitting patients. 

**Medical Staff of Sharp Mem’l Hosp. v. Superior Court,** 16 Cal.Rptr.3d 769 (Cal. App. 2004).

*California court held that doctor whose privileges were summarily suspended by hospital could not maintain action because hospital had adequate basis for finding that doctor posed an imminent threat to patients and, as such, was justified in suspending her privileges without a hearing.*

**South Carolina Appeals Court Asserts Employment Contract Could be Inferred From Employee Handbook**

When plaintiff began her employment as a nurse at Aiken Regional Medical Centers (Aiken), she was given an employee handbook that contained an express provision that it was not an employment contract. Plaintiff signed a card acknowledging she had read and understood the handbook. In 1995, Universal Health Services, Inc. (Universal), bought Aiken, and plaintiff remained employed at Aiken until she was terminated in January 1997 due to insubordination for refusing to meet with hospital officials. Plaintiff sued Universal alleging she was wrongfully terminated. Following the trial, the trial court granted Universal’s motion for judgment notwithstanding the verdict (JNOV) on the grounds that plaintiff’s employment was at-will and there was no evidence that there was an employment contract. Plaintiff appealed.

The Court of Appeals of South Carolina reversed the trial court’s order and remanded the case for the jury verdict to be reinstated. According to the appeals court, there are exceptions to the doctrine of at-will employment, and an employment contract may be inferred from an employee handbook. The presence of disclaimer language in the employee handbook was not dispositive of the issue, for if the language of the disclaimer is ambiguous, it may be open to more than one interpretation. In addition, Universal had a written policy in the employee handbook regarding the handling of disciplinary problems and terminations of employees; such language infers that it is part of an employment contract. Because there was evidence an employment contract existed, the trial court erred in granting the motion for JNOV on the issue, said the appeals court. 

**Burns v. Universal Health Servs., Inc.,** 603 S.E.2d 605 (S.C. App. 2004).

*South Carolina Court held that hospital employee could infer an employment contract from language found in an employee handbook and that disclaimer language in the handbook was not enough to dispose of the issue.*
Missouri Appeals Court Allows Employee’s Negligence Claim Against Hospital for False Drug Test Result
St. John’s Regional Health Center (St. John’s) performed a drug test on an employee, which tested positive for amphetamines. Three days later, another sample was taken from the employee, and it tested negative for amphetamines. The employee filed suit against St. John’s seeking a declaratory judgment that the drug test was incorrect and falsely showed that she had drugs in her system and alleging negligence and res ipsa loquitor against St. John’s because it had a duty to use a drug screen that was reliable. The trial court dismissed the employee’s claim for declaratory judgment and found her other claim time-barred under the two-year statute of limitations for medical malpractice.

The Missouri appeals court found that any controversy that existed could be addressed in the negligence claim; therefore, the appeals court affirmed the trial court’s dismissal of the declaratory judgment count. In addition, the appeals court held that in order for the negligence claim to fall under the two-year statute of limitations, St. John’s would have to be a healthcare provider under the statute and the drug screen would have to be a healthcare service. After examining case law from Missouri and other states, the appeals court concluded that “a drug screen test performed by a hospital is not a healthcare service if such is not performed within the confines of the physician-patient relationship." Accordingly, the court found that a negligence claim could exist that was not time-barred. Meekins v. St. John’s Reg’l Health Ctr., 2004 WL 2367101 (Mo. App. 2004).

Missouri appeals court allowed a negligence claim by a hospital employee who falsely tested positive during a hospital-administered drug test to proceed, as it did not fall under the state’s medical malpractice statute.

III. LIABILITY ISSUES

Court Finds Physician May Sue as Beneficiary of Trauma Services Contract
Baptist Health (Baptist) and Arkansas Trauma Surgeons, PLLC (ATS), entered into a services agreement (Agreement) under which ATS and its physicians provided on-call coverage for Baptist. A surgeon member of ATS sued Baptist for breach of contract when Baptist sought to have ATS remove the surgeon from the on-call schedule. At issue was whether the surgeon was entitled to sue as a third-party beneficiary of the Agreement.

While the Agreement between the parties did not directly speak to whether the individual physicians of ATS were intended third-party beneficiaries, the surgeon specifically alleged that the agreement and the formation of the ATS stemmed from a discussion between Baptist and the individual physicians and, therefore, that ATS "was formed for the benefit of Baptist and the Services Agreement was entered into for the benefit of the individual physicians." The court noted that the terms of the ATS operating agreement were negotiated with and approved by
Baptist and included a designation of Baptist as a third-party beneficiary thereto. In addition, the selection of physicians for membership in ATS was subject to Baptist's prior approval, while the Agreement provided that each member of ATS would be compensated based upon the number of times each provided call coverage for Baptist. The court stated that "[h]ere, [the surgeon] not only pled that he benefited from the Services Agreement, but he also pled sufficient facts from which a reasonable inference can be drawn that ATS and Baptist intended to benefit him and other individual physicians."


Arkansas court found that physician who was indirect beneficiary under provider agreement for services provided by small practice group was allowed to sue hospital for breach of contract even if he was not specified as a third party beneficiary because he did indeed benefit from the services agreement.

**Court Revives Negligence Claims Against Hospital Based on Apparent Agency**

Plaintiffs filed separate claims against West Virginia University Hospitals (WVUH), claiming WVUH was vicariously liable under a theory of apparent agency between WVUH and the physicians who provided the allegedly negligent care.

In both cases, the West Virginia Supreme Court found that WVUH could not be liable, because the patients had signed consent forms and the hospital had not "through its actions or its conduct, held the physicians out to be its employees." However, the court ruled that the patients should have been permitted to present evidence to support their claims that the physicians who treated them appeared to be hospital employees. It found that there was no evidence to support their claims that the physicians were actual agents of the hospital but the allegations in both lawsuits were adequate to allow the apparent agency claims to proceed.

Although WVUH relied on the disclaimers signed by the plaintiffs to support its claims that there could be no agency, the court found they did not unequivocally "inform [the plaintiffs] that the physicians treating them were not employees of the hospital." The court concluded that "[t]he WVUH disclaimer provision presupposes that all patients can distinguish between ‘faculty physicians,’ ‘resident physicians’ and any other type of physician having privileges at the hospital. In other words, for this disclaimer to be meaningful, a patient would literally have to inquire into the employment status of everyone treating him or her." Thus, the court held that plaintiffs were entitled to present evidence to support their apparent agency claims.


This case suggests that West Virginia hospitals will be facing an increasingly difficult task in avoiding agency liability for their independent contractor physicians in a non-emergency room setting.
Court Finds That Hospital is Not Liable for Negligent Hiring Despite Poor Employee Screening Process
Plaintiff argued that, but for its failure to exercise due care, Universal Health Services, Inc. (d/b/a Anchor Hospital Behavioral Health Systems) (Universal), would not have hired Shawn Love as a mental health assistant and plaintiff would not have been injured. Love allegedly made inappropriate comments and sexual advances to her and finally, after incapacitating her with medication, raped her. During the investigation, information was discovered that revealed that Love’s employment and education history was incomplete and/or inaccurate.

Despite such inaccurate or incomplete employment and education information in Love’s application, the Georgia Supreme Court held that the trial court correctly granted summary judgment to Universal. Universal had no reason to question the accuracy or thoroughness of the information provided by the private investigation agency, ChoicePoint, and ChoicePoint’s seven-year criminal record search on Love in the jurisdiction where he indicated he had lived and worked revealed no record of criminal activity. The other problems with his application and the hospital’s interview process presented no indications that Love posed any risk of personal harm to others. Accordingly, the court held that evidence “uncontrovertedly establishes” that Universal did not disregard any indication of a propensity to inflict physical harm that should have aroused suspicion and further investigation.

**Munroe v. Universal Health Servs., Inc., 605 S.E.2d 928 (Ga. 2004).**

*Health system was not liable for sexual assault committed by its employee even though he had previous criminal record because the background search firm used by the provider had not included the information in the results it gave to the health system; furthermore, the previous criminal acts would not have given the health system an indication that the employee was prone to commit physical violence.*

Federal Court Holds Each Financial Report Submitted to Government Could Subject Hospital Conducting Federally Funded Vaccine Trials to False Claims Liability
Stephen B. Cantrell, D.D.S., M.D. (Relator) brought a qui tam action under the False Claims Act (FCA) against New York University (NYU) alleging that its School of Medicine and Hospitals Center defrauded Medicare by “upcoding” certain services provided in connection with its federally funded clinical trials to test the efficacy of vaccines for malignant melanoma. Relator also alleged that NYU received “program income” from outside sources including the patients’ private insurers that it failed to report to the government, amounting to a “reverse false claim” under the FCA.

The U.S. District Court for the Southern District of New York addressed the issue of whether each receipt of an item of alleged “program income” from the vaccine
trial constituted a separate false claim, finding that each grant application or amendment, progress report, and periodic financial report could support an FCA claim. The court declined to find, however, that the individual receipt of an alleged program payment constituted a separate false claim under the statute. The court also held that bills sent to private insurers by the hospital were not actionable as individual claims under the FCA.


*This case is significant because the court held that each financial report submitted by a hospital could be considered a potential claim for purposes of the False Claims Act if it failed to include income from certain fees or services performed by the provider; however, the relator must establish that the provider was required to disclose such information in order to constitute an FCA violation.*

**Pennsylvania Court Holds Negligent Supervision Claims Against Hospital Did Not Constitute Professional Liability**

St. Joseph Medical Center and its parent company, Catholic Health Initiatives (collectively, St. Joseph), sought a declaration in state court that it was entitled to excess coverage from the Medical Professional Liability Catastrophe Loss Fund (Fund) in connection with two settled medical malpractice actions alleging that a St. Joseph employee sexually assaulted patients. According to St. Joseph, the two underlying actions involved “professional liability” claims pursuant to the Healthcare Services Malpractice Act, thereby entitling it to excess coverage under the Fund. The Fund argued that St. Joseph’s alleged negligent supervision of the employee did not involve “professional liability” or the “furnishing of medical services that were or should have been provided” because preventing an employee from sexually assaulting patients does not require “medical skill associated with specialized training.” Both St. Joseph and the Fund moved for summary judgment.

The Pennsylvania Commonwealth Court granted summary judgment to the Fund, holding that professional liability only arises in connection with providing or failing to provide medical services. Specifically, the court agreed with the majority of jurisdictions that “professional liability policies do not provide coverage for healthcare practitioners who sexually assault their patients.”


*Pennsylvania court held that claims for negligent supervision based on sexual assault brought against hospital did not qualify as professional liability claims under the Medical Professional Liability Catastrophe Loss Fund and, therefore, hospital was not entitled to any funds for settling cases.*

**New York Court Holds Hospital Has Duty to Maintain Safe Waiting Room**

Plaintiff, a fifteen-month-old child, was brought by his mother to the emergency room of Bronx Lebanon Hospital Center (Hospital). While awaiting treatment,
plaintiffs were directed to wait in an open area where several unsupervised children were running around. Although a nurse was present and advised the children to stop running, plaintiff child was pushed over by another child and broke his elbow.

The New York Supreme Court, Appellate Division, reversed the grant of summary judgment to the Hospital. The court noted that a hospital has a duty to protect its patients from injury and an owner of property has a duty to maintain that property in a reasonably safe condition. The court found that the Hospital failed to maintain the area where the accident occurred in a safe manner and further noted that nurses were clearly aware that unruly children were present but failed to call security or take any other measures to protect plaintiff from harm. **Rodriguez v. 1201 Realty, LLC, 781 N.Y.S.2d 328 (N.Y. App. 2004).**

_In New York, a hospital has a duty to maintain safe conditions in a waiting room area and a nurse who warned unruly children in the area to behave but did not call security or take other protective measures did not satisfy that duty._

**Michigan Court Holds Plaintiff Failed to Show Decedent Believed Doctor Was Agent of Hospital**

Plaintiff, as the personal representative of her husband James’ estate, sued Providence Hospital Medical Centers, Inc. (Hospital), for the alleged negligent acts of a doctor who performed surgery on James. James died shortly after the surgery and plaintiff alleged the Hospital was liable for the doctor’s negligent treatment of James. The doctor was an independent contractor, but plaintiff argued he was the Hospital’s ostensible agent.

The Michigan Court of Appeals affirmed the trial court’s judgment granting the Hospital’s motion for a directed verdict. Plaintiff argued that the evidence of the Hospital’s control of the facility where James was examined and treated, the Hospital’s name on the surgery consent forms James signed, and the Hospital’s sign in its facility represented that the doctor was an employee of the Hospital.

The Michigan Court of Appeals affirmed the trial court’s judgment granting the Hospital’s motion for a directed verdict, finding that it was James’ belief in the doctor’s status, and not plaintiff’s belief, that is relevant. Although plaintiff admitted that the doctor did not indicate to James that he was an employee of the Hospital, plaintiff claimed James would have believed the doctor was the Hospital’s ostensible agent because the doctor’s office was in the Hospital’s building, which included signs and logos of the Hospital. However, the court found no evidence to support a finding that James believed the doctor was the Hospital’s ostensible agent, or that such a belief was reasonable; therefore, no agency relationship existed. **Inglis v. Providence Hosp. and Med. Ctrs., Inc., 2004 WL 1908120 (Mich. App. 2004).**
To prove ostensible agency in the physician-hospital context, plaintiff must establish that the patient reasonably believed that the physician was an agent of the hospital.

California Appeals Court Says Psychotherapist Could be Liable for Failing to Warn Third Party of Threat Posed by Patient

Cal and Janet Ewing sued Northridge Hospital Medical Center (Northridge), a mental health facility, for wrongful death after their son Keith was killed by Geno Colello, who had been briefly hospitalized at the facility. Colello, a Los Angeles police officer with a history of emotional problems, shot Keith because he was dating his former girlfriend.

Reversing the grant of non-suit to Northridge, the appeals court concluded that whether the threat was communicated directly to the psychotherapist by the patient or indirectly by the patient’s family was irrelevant to the liability determination for failure to warn. Rather, the critical inquiry is whether the psychotherapist actually believed or predicted the potential harm.

The court also held that expert testimony is not required to establish the psychotherapist’s negligence because a breach of the applicable standard of care is not an element of the statutory duty to warn. Further, the court held that the patient does not have to convey a threat of physical violence to a third party directly to the psychotherapist for liability to attach under statute. A therapist’s duty to warn is triggered when he or she actually believes or foresees a patient poses a risk of inflicting serious physical harm on a reasonably identifiable person. Because the basis for a therapist’s belief or prediction is irrelevant, the trial court erred in granting Northridge’s motion on the ground that the patient did not tell the therapist directly of his intentions.


California court held that a therapist has a duty to warn a third party of potential risk of harm when he or she believes or foresees a patient may pose a danger to the party regardless of whether or not the patient informs the therapist of the threat directly or the therapist learns of it through another source.

IV. TAX ISSUES

Michigan Court of Appeals Upholds Denial of Tax Exemption to Medical Center, Physician Practice Groups

The Michigan Court of Appeals concluded a medical center and two independent physician practice groups did not qualify as hospitals serving public health needs that would be eligible for exemption from ad valorem property tax assessments imposed by two cities. The court found that mere acceptance of Medicare and Medicaid patients was insufficient to justify treatment as a charitable institution. The court further stated that the center and practice groups’ provision of a
negligible amount of free care undermined their contention that they were charitable institutions that served a public health purpose.

The original tribunal and the appeals court said their decisions were governed by *ProMed Healthcare v. Kalamazoo*, 64 N.W.2d 47 (Mich. App. 2002), which found that the charitable activities of an entity claiming tax exemption must be more than an incidental part of its operations. One of the practice groups in the instant case argued that it was exempt because its healthcare services at the subject property were “available to the general public without restriction, regardless of the ability to pay, and lessen[ed] the burdens of government.” The court found that argument insufficient, holding that the center “failed to present evidence that its ‘provision of charitable medical care constituted anything more than an incidental part of its operations.’” The court further stated that the center and practice groups needed to show that their activities, taken as a whole, constituted either a charitable gift for the benefit of the general public without restriction or were undertaken for the benefit of an indefinite number of persons. *McLaren Regional Medical Center v. Owosso*, 2004 WL 1882645 (Mich. App. 2004).

*This case sets a high standard for what can be considered charitable care by a hospital for tax exemption purposes and declares that simple acceptance of Medicare and Medicaid patients alone is not sufficient to justify a hospital’s assertion of charitable purpose.*

**Government and St. David’s Agree to Settle Texas Hospital Joint Venture Litigation**

Less than a month after the federal government signaled its intent to appeal a jury verdict that had allowed a Texas nonprofit healthcare system to keep its tax exemption, the system announced the litigation will soon come to an end. Carol C. Clark, interim president of St. David’s Health Care System (St. David’s), said that the Department of Justice (DOJ) had withdrawn its appeal of a March jury verdict that rejected the Internal Revenue Service’s (IRS’s) position that the nonprofit system’s whole hospital joint venture with for-profit HCA Inc. compromised its charitable mission and required it to forfeit its tax exemption under I.R.C. §501(c)(3).

The government withdrew its appeal of the jury’s verdict in exchange for the system’s agreement not to seek attorneys’ fees in the case. On March 4, 2004, a jury in the U.S. District Court for the Western District of Texas decided that Austin, Texas-based St. David’s should retain its nonprofit status, even though the IRS claimed the system forfeited its exemption when it entered into a whole-hospital joint venture in 1996.

The government's decision not to follow through with an appeal ends a long dispute. The IRS revoked St. David's tax exemption in 2000, arguing that it no longer operated exclusively for charitable purposes because of the then four-
year-old partnership with HCA; the case has been in the courts since. Had St. David’s lost, it could have owed nearly $40 million in back taxes, interest and penalties, Clark said. The DOJ declined to comment on the matter.

The ongoing litigation regarding St. David’s Hospital’s disputed tax exempt status was brought to an end when the hospital and the government agreed to a confidential settlement, thus ending the federal government’s appeal of an earlier jury verdict in favor of St. David’s. Nevertheless, tax-exempt hospitals must be careful when structuring whole-hospital joint ventures not to cede operational control to a non-exempt party concerning certain charitable and clinical matters.

Ohio Supreme Court Says Fitness Center Did Not Have Charitable Purpose and Thus Was Not Exempt From Real Property Tax

Plaintiff Bethesda Healthcare, Inc., a non-profit corporation, owns the TriHealth Fitness and Health Pavilion, which it leases in part to itself for a fitness center and also to physician practice groups. Plaintiff owns Bethesda Hospital, Inc., and uses part of the pavilion for hospital departments. Plaintiff applied for a real property tax exemption for the space it used. The Tax Commissioner (Commissioner) granted an exemption in part for the space used for the hospital’s departments, but not for the fitness center. Plaintiff appealed the determination, and the Board of Tax Appeals (BTA) held the fitness center was not exempt because it was a private facility with paying members and had no charitable purpose that would qualify it for an exemption. Plaintiff appealed.

The Ohio Supreme Court affirmed the Commissioner’s determination. The high court determined that the charging of a fee did not necessarily negate consideration of the fitness center as having a charitable purpose; rather, it was the overall purpose of the fitness center that determined whether it was operated for a charitable purpose. Of 5,400 members, the fitness center only provided a small number of free or reduced price memberships, supporting a finding that the services rendered by the fitness center did not have a substantial charitable purpose.


Fitness center that was located in a tax-exempt hospital location was not a tax-exempt entity because it was operated separate from the hospital and did not share the hospital’s charitable purpose.

Florida Hospital Loses Fight Over FICA Taxes; Court Decides Medical Residents Covered

The U.S. District Court for the Southern District of Florida concluded that medical residents in training at a South Florida hospital and their employer must withhold and pay employment taxes under the Federal Insurance Contribution Act (FICA). The court stated that medical residents working at hospitals have never qualified as “students” exempt from payment of employment taxes under the Social Security Act.
The court based its decision on the federal government’s action to recover over $2.4 million in FICA tax refunds it had paid to Mt. Sinai Medical Center of Florida, Inc., between March 1996 and December 1999. The court found the government proved that it had refunded the money erroneously and that it was entitled to recover the funds, plus interest, from the hospital.

The decision follows the IRS’ adoption of regulations, proposed in February 2004, to clarify the definition of “school, college, or university” and student status requirements for FICA tax liability purposes. The court acknowledged these regulations, and others interpreting §3121 (b)(10) of the Internal Revenue Code, but said the regulations applied only to services performed on or after April 1, 2005, and were not applicable to the time period at issue in the case. 


Court found that medical residents were not students for purposes of FICA and thus, hospital was responsible for FICA contributions for the medical residents it employed.

V. PAYMENT ISSUES

Ninth Circuit Finds Hospital is Not Entitled to Additional Payments Under Medicare Because it Could Not Show DSH Status

The Provider Reimbursement Review Board (PRRB) ruled that the Medicare intermediary properly adjusted the cost reports of University Medical Center of Southern Nevada (Hospital) after finding the Hospital was not eligible for Medicare disproportionate share hospital (DSH) reimbursement, reducing the Hospital’s total reimbursement by $6.8 million. To determine disproportionate share qualification, the PRRB used the “Pickle Amendment” test, which is based on the relationship of net inpatient care revenues from state and local government sources to total inpatient care revenues. Such proportionate amount must exceed thirty percent for eligibility.

The Ninth Circuit concluded that the hospital’s argument that the word “such” referred to “net inpatient care revenue,” was not supported by the statutory language. By ignoring the noun “total,” it violated “the principle that every word in a statute must be given effect whenever possible.” Although the original statute clearly supported the Secretary’s interpretation that the relevant state and local funding must exceed thirty percent of total net inpatient care revenue without any deduction for Medicare and Medicaid, the legislative history surrounding the 1987 amendment was more equivocal. The conference report’s exclusion of Medicare and Medicaid supported the hospital’s position, but it was not the deciding factor. The court said that subsequent legislative history was an unreliable guide to legislative intent, particularly where the discussion of existing law did not
accompany a related amendment to the pertinent statutory provision. It wrote that “[b]ecause the Secretary’s interpretation reflects a permissible construction of the statutory language, it is entitled to deference,” affirming the district court’s judgment in favor of the Secretary.

_University Medical Center of Southern Nevada v. Thompson_, 380 F.3d 1197 (9th Cir. 2004).

The Ninth Circuit deferred to the interpretation of the DSH qualification statute put forth by DHHS and found that the hospital did not provide sufficient evidence to maintain its DSH status.

**Federal Court Concludes Trainers May Perform Physical Therapy**

A whistleblower argued that Fairview Health System (Hospital) violated the FCA by submitting claims to Medicare and Medicaid because physical therapy services could not be delegated to athletic trainers under state law and physical therapy performed contrary to state law is not subject to reimbursement from the federal government programs. That meant the claims were false because the Hospital demanded payment from the programs while violating Minnesota’s law under an “implied false certification” theory of FCA liability. The government declined to intervene.

The U.S. District Court for the District of Minnesota dismissed the action, concluding that the argument that athletic trainers could not perform physical therapy services was incorrect because state law provides that an athletic trainer may provide physical therapy services while working under direct supervision of a physical therapist. However, the court rejected the Hospital’s request for attorneys’ fees, costs, and disbursements because the action was not brought by the government, but was a qui tam action brought by a private plaintiff in which the government declined to intervene.


_FCA lawsuit alleging hospital fraudulently submitted claims for physical therapy because the service was provided by an unauthorized personal trainer was dismissed by the court because it found that under Minnesota state law, personal trainers were qualified to perform certain physical therapy services._

**Court Finds Lower Court Ruling Did Not Order CMS to Convey SCH Status to Hospital Who Challenged Secretary’s Interpretation of Regulation**

CMS (as its predecessor, the Health Care Financing Administration) determined that Heartland Hospital (Hospital) was in an urban area, but was less than thirty-five miles from the nearest like hospital, thereby failing to qualify for sole community hospital (SCH) status. The Hospital appealed the determination to the PRRB, which held it did not have jurisdiction and granted plaintiff’s request for expedited judicial review. The Hospital filed suit in the U.S. District Court for the District of Columbia, which granted Hospital’s motion regarding the use of alternatives to the Metropolitan Statistical Area (MSA). The court remanded the
case to CMS, which issued a final rule giving its reasoning for adopting the urban area definition and the use of the MSA. Based on the final rule, CMS again denied the Hospital’s request to be designated as a SCH. The Hospital brought suit again, seeking reimbursement as an SCH. DHHS moved to dismiss on the ground the Hospital was seeking judicial review of DHHS’ decision on remand.

The district court denied the Hospital’s motion, stating that its prior judgment did not mandate that the Hospital be granted SCH status; rather, such judgment held the regulation invalid until CMS evaluated the alternatives and provided its rationale for using the MSA. The court also concluded that the Hospital’s requested relief was inappropriate because a court should not substitute its judgment for that of an agency when there has been a procedural flaw in an administrative matter.


*Court held that its prior ruling remanding hospital's SCH determination to CMS for reconsideration did not guarantee hospital would be granted SCH status.*

**California Supreme Court Rules Against Hospital’s Right to Recover Costs From Patients Through Liens**

Plaintiff, Parnell, brought a lawsuit after San Joaquin Community Hospital (Hospital) filed notice of a lien against a settlement Parnell received from the driver of a vehicle that struck a taxi in which he was a passenger. At the time of the accident, Parnell was covered by medical insurance through the Wholesale Beer Distributor Industry Trust Health Plan, which contracted with Community Care Network (CCN), a preferred provider organization, for discounts on medical care for its beneficiaries. The Hospital, which treated Parnell for his injuries, was a preferred provider in CCN’s network. CCN reimbursed the Hospital the amount specified in the provider agreement. Those reimbursements, along with deductible and copayment amounts paid by Parnell, constituted “payment in full” to the hospital, according to the provider agreement.

Nevertheless, the Hospital asserted a lien against Parnell’s settlement with the third party to recover the difference between the actual cost of the medical services provided to Parnell, and the negotiated amount received under the provider agreement. The trial court found for the Hospital, but the appeals court reversed.

The California Supreme Court held that a lien under the Hospital Lien Act, Cal. Civ. Code §§ 3045.1-3045.6, requires an underlying debt owed by the patient to the hospital. While the court had no wish to exacerbate the financial crisis of hospitals, “our job is to construe our statutes in accordance with the Legislature’s intent and the controlling case law. As such, hospitals may look to the Legislature for relief from these financial pressures, but not to this court,” the court said.

**Parnell v. Adventist Health System/West,** 26 Cal.Rptr.3d 569 (Cal. 2005).
This California Supreme Court ruling will constrain the ability of hospitals to recover from patients treated following the patients’ involvement in an accident by limiting their ability to place a lien on the patient’s accident-related recoveries.

DHHS OIG Issues Six Concurrent Advisory Opinions Approving Similarly-Structured Gainsharing Arrangements Between Physicians and Hospitals. The OIG, through six separate Advisory Opinions, approved gainsharing arrangements between hospitals and physicians that examined a similar fact pattern. In each opinion, the OIG stated that it would not prosecute the participants under either the Anti-kickback Statute or the civil monetary penalties statute.

The OIG concluded that it would not pursue sanctions under the civil monetary penalties statute, although technical violations of the statute were likely. The safety mechanisms inherent in the arrangements were key to this result. The most important safety mechanism in the arrangements appeared to be the "transparency" of the arrangements created by distinct and separate measures producing the gainsharing. The OIG also noted that the there was "credible medical support" for the proposition that none of the arrangements would adversely affect patient care. It also recognized that the cost savings generated by the arrangements would not disproportionately derive from procedures financed by government programs; that excessive decreases in services would be prevented by the historically-based utilization "floor" below which no savings may be accrued; that the disclosure to patients of the arrangements would permit them to scrutinize the effect of the cost saving measures; that the amount and duration of the savings to be distributed to the physicians was limited; and that the savings to participating physicians would be distributed on a basis that did not take into account individual utilization.

The OIG also concluded that it would not pursue sanctions under the Anti-kickback Statute, although technical violations of the statute were likely. The OIG noted that none of the arrangements would likely attract additional physicians, increase referrals, or provide a means to reward referrals because participation in the arrangements was limited to existing staff members, there is a cap on the number of procedures eligible for inclusion in each of the arrangements, and each arrangement lasts for only one year. In addition, the OIG conceded that the shared gain resulting from the savings will properly compensate the participating physicians for their effort in producing the savings and the added liability risk they will assume by implementing the changes to produce the savings.

Advisory Op. No. 05-01 (January 28, 2005); Nos. 05-02, 05-03, and 05-04 (February 10, 2005); Nos. 05-05, 05-06 (February 18, 2005 (Dep’t Health & Human Servs. Office of Inspector Gen).

Specific linkage between cost savings and particular cost reduction measures, safety to patients, and unlikelihood of payments for referrals prevent OIG from imposing sanctions for gainsharing arrangements.
Tenet Announces Proposed Settlement of Litigation Alleging Patient Over-charges
Tenet Healthcare Corp. (Tenet) announced that it had reached an agreement providing for a nationwide settlement of certain class-action lawsuits regarding prices that uninsured and some underinsured patients were charged for prescription drugs and other medical products and services at hospitals owned and operated by Tenet subsidiaries. The proposed settlement was announced in a press release from the for-profit hospital company.

Class-action lawsuits are pending against Tenet and certain of its hospitals in Alabama, California, Florida, Louisiana, Missouri, Pennsylvania, South Carolina, Tennessee, and Texas. “If a nationwide settlement is approved by the California court, those class action lawsuits will be subject to dismissal,” the press release said.

According to the press release, the company has agreed to provide a reimbursement mechanism for uninsured patients who received medically necessary services at any of its hospitals between June 15, 1999, and December 31, 2004, the period covered by the lawsuits, and who paid more than a certain percentage of the hospital’s gross charges.

The press release is available at http://www.tenethealth.com/TenetHealth/PressCenter/PressReleases/TenetPricingClassActionSettlement.htm

Tenet Health System agreed to settle class action cases filed by uninsured patients alleging overcharges for care in several states by providing a number of mechanisms aimed at providing fair and discounted charges for services to patients who did not have insurance.

Ninth Circuit Says Plaintiffs Waived Arguments About Outlier Payments by Failing to Raise Them During Rulemaking
Plaintiffs, seventy-nine hospitals and two healthcare corporations, alleged that DHHS had failed to make the correct adjustments to the calculation of outlier payments under Medicare and sought reimbursement for alleged shortfalls in the outlier payments they received for fiscal years 1991 and 1996. Plaintiffs argued the DHHS’ outlier thresholds for 1991 to 1996 were arbitrary and capricious because DHHS did not make the correct calculations of the thresholds. The district court granted DHHS’ motion for summary judgment and held plaintiffs failed to raise any arguments during the comment period.

The Ninth Circuit affirmed the district court’s judgment that the arguments were waived because they were not raised during the administrative rulemaking procedure. The appeals court noted that in Exxon Mobil v. EPA, 217 F.3d 1246 (9th Cir. 2000), it held that plaintiffs’ arguments were waived because they did not
raise them during the administrative rulemaking procedure. Plaintiffs argued that Exxon was on point, but that it lacked discussion or analysis of the issue and was inconsistent with the appeals court’s authority and should not be followed. Rejecting plaintiffs’ arguments, the appeals court said it was bound by its holding in Exxon and the terseness of the opinion was irrelevant. Universal Health Servs., Inc. v. Thompson, 363 F.3d 1013 (9th Cir. 2004).

Court found that health systems waived arguments regarding DHHS’ improper use of an outlier formula because they failed to assert such arguments when provided the opportunity to do so during an administrative rulemaking procedure.

VI. MISCELLANEOUS

Court Finds Fetus Is Not a Person With Equal Protection Rights Under Texas Law

Plaintiff went to the emergency room in her seventh month of pregnancy complaining of a quick pulse and dizziness. Doctors determined that she had a high pulse rate and high blood pressure and sent her to the labor and delivery room for further observation. At several points during the night, doctors monitored the heart tones of the fetus, which were difficult to detect. The next morning, the doctors determined that the fetus would be stillborn. Plaintiff claimed the hospital should have delivered her baby by Caesarean section.

The Texas Supreme Court stated that it has repeatedly affirmed its 1987 decision in Witty v. American General Capital Distributors, Inc., 727 S.W.2d 503 (Tx. 1987), which held that the Texas Legislature did not intend the words “individual” or “a person” to include an unborn fetus. The Witty decision also prohibited damages for prenatal injuries if the fetus did not survive birth. The court noted that in 2003, the Texas Legislature did grant the parents of a stillborn child a cause of action under the Texas Wrongful Death Act. However, that statute expressly states it does not apply to claims for the death of an individual who “is an unborn child that are brought against a physician or other healthcare provider licensed in Texas if the death is caused by, associated with, arises out of, or relates to a lawful medical or healthcare practice or procedure of the physician or healthcare provider”. The court also observed that the U.S. Supreme Court has held that the unborn are not included within the protection of the Fourteenth Amendment and the Equal Protection Clause. Fort Worth Osteopathic Hosp. v. Reese, 148 S.W.2d 94 (Tx. 2004).

The Texas Supreme Court reiterated that under state and federal law, certain causes of action that are extended to an individual or person do not, by definition, include an unborn fetus; therefore, the parents of a fetus that did not survive birth could not bring an action against a healthcare provider.
Federal Court Rejects Doctors’ Attempt to Block Publication of Settlements
The U.S. District Court for the District of New Jersey found that neither federal law nor the U.S. Constitution bars the release of information on medical malpractice payments submitted to the state by malpractice insurers to comply with a 1989 state law, rejecting arguments by physicians that publication of medical malpractice claim settlements would void the confidentiality provisions of existing settlement contracts.

The ruling clears the way for the state to enforce a disputed provision of the New Jersey Health Care Consumer Information Act, which was enacted in 2003. At issue is the requirement in the act for the New Jersey Division of Consumer Affairs, in consultation with the State Board of Medical Examiners, to develop and make available to the public over the Internet and through a toll-free telephone number profiles of all the state’s licensed physicians and podiatrists.

The court stated that the legislation serves a significant and legitimate consumer protection interest that overrides any disservice to existing contracts. In light of the legitimate public purpose behind the statute and the fact that the state is not a party to the medical malpractice agreements, “this Court must respect the New Jersey Legislature’s policy-making authority with regard to the necessity and the reasonableness behind disclosure of statutorily mandated medical malpractice information.”


Information about medical malpractice settlements required under New Jersey’s Health Care Consumer Information Act was not protected by state or federal law and the State Board of Medical Examiners, which was required to provide the information by law, was not bound by the confidentiality provisions found in the settlement agreements themselves.

Court Upholds Preliminary Injunction Enjoining County From Closing Hospital and Reducing Services
The Los Angeles County Board of Supervisors (Board) voted to close Rancho Los Amigos National Rehabilitation Center (Rancho) and reduce the services at Los Angeles County-USC Medical Center (LAC-USC) in an effort to reduce expenditures. Plaintiffs, chronically ill indigent patients who rely on county health services, sued the Board seeking injunctive relief against the closure of Rancho and the reduction of services at LAC-USC. The district court granted the requested relief and the Board appealed.

The Ninth Circuit affirmed the district court’s judgment and held plaintiffs had standing to bring the suit and had alleged sufficient harm to support the injunction. Plaintiffs demonstrated that, if the two facilities were closed or their services were reduced, the county would have greater difficulty in providing them with timely and appropriate care as required by law. The court further stated that
plaintiffs do not have to wait for the two facilities to close or reduce their services to prove that they will be injured.

The court then addressed the likelihood of plaintiffs’ success on the merits of their various claims. The court concluded that a county budget crisis was not a valid defense to plaintiffs’ state law claims that the county is statutorily required to provide appropriate health services to the state’s needy. The appeals court noted the state’s interpretation of the relevant statute and prior court cases have both concluded that a budget shortfall is not a defense to providing statutorily required healthcare to residents.


*California court granted preliminary injunction forcing public hospital that was scheduled to cease operations to remain open and held that a state budget shortage could not release a county from its statutory responsibility to provide appropriate health services to the needy.*

**Nevada Court Upholds Temporary Guardianship of Minor Child Whose Parents Refused to Consent to Blood Transfusion Because of Religious Beliefs**

Valley Hospital (Hospital) petitioned the state trial court ex parte for temporary guardianship of a child pursuant to Nev. Rev. Stat. § 159.052 so they could provide medically necessary blood transfusions in emergency situations absent parental consent. The court granted temporary guardianship on an emergency basis for the purpose of consenting to blood transfusions and to other medical care. At a hearing regarding guardianship, the parents argued that the child’s condition was stable and that an immediate medical emergency did not exist. The parents also contended that Valley Hospital should have brought the petition under a Nev. Rev. Stat. ch. 432B, which pertains to protecting children from abuse and neglect and requires a state investigation, notice, a hearing, and appointed counsel.

The Nevada Supreme Court held that the temporary guardianship did not violate the parents’ substantive due process rights because the state’s interest in protecting the welfare of the child outweighed the parents’ care and custody interest and religious freedom. The court also reasoned that absent the temporary guardianship, there would not be enough time to obtain a court order in an emergency. The court further held that ch. 432B did not provide offsetting additional protections in the instant case. Instead, the high court held that the lower court properly applied the temporary guardianship statute.


*A child whose parents refused to consent to necessary medical treatment because of their religious beliefs could be taken into temporary state custody under state law without violating substantive due process because the interest in*
the safety of the child outweighed the interests of the parents or their religious beliefs.

**District Court in Colorado Holds No Private Right of Action Under HIPAA**

University of Colorado Hospital Authority (Hospital) filed an action in state court seeking an injunction against Denver Publishing Company (DPC) preventing it from publishing or using any information contained in a report prepared as part of a Hospital peer review proceeding that DPC had obtained from an unnamed source and requiring DPC to return the report. DPC removed the case to federal court because the Hospital had alleged that DPC’s publishing of the report would violate the Health Insurance Portability and Accountability Act (HIPAA).

The U.S. District Court for the District of Colorado denied the Hospital’s motion for a temporary restraining order; meanwhile, DPC published the contents of the report while the case was pending. Because this rendered Hospital’s original complaint moot, Hospital amended its complaint to assert additional claims. DPC moved to dismiss on the ground that no private right of action exists under HIPAA. The court found that “[n]either § 1320d-6, [HIPAA’s penalty provision] nor any other section of HIPAA, contains any language conferring privacy rights upon, or identifying as the intended beneficiary of § 1320d-6, any specific class of persons.” The court also noted that other federal courts have consistently refused to find a private right of action under HIPAA. Finally, the court rejected the Hospital’s argument that a failure to recognize a private right of action would “effectively frustrate” the purpose of HIPAA. Absent a congressional intent to provide the right, the court held that courts may not imply a cause of action in a statute.


*The court held that there was no private right of action found in the language of the federal HIPAA statute; furthermore, courts could not imply such a right without evidence of congressional intent.*

**Florida Appeals Court Holds No Privacy Limitation on State’s Ability to Obtain Patient’s Medical Records Via Search Warrant**

After police in Florida obtained search warrants to obtain certain medical records of Rush Limbaugh as part of an investigation into whether he violated the state “doctor shopping” statute by obtaining prescriptions for controlled substances from various physicians over a five-month period, the state placed the records under seal and notified Limbaugh that his records had been seized. Limbaugh objected to the seizure, asserting a right of privacy in his personal medical affairs under the Florida Constitution. A state trial court denied Limbaugh’s request to quash the search warrants. Limbaugh appealed.

The appeals court held that the constitutional right of privacy in medical records is not implicated by the seizure of such records when seized pursuant to a valid
search warrant, nor is the patient entitled to prior notice and a hearing in connection with the search warrant. Moreover, the appeals court noted, nothing in the search warrant statutes limit the use of search warrants for medical records. Here, the state had the burden of showing probable cause existed that Limbaugh’s medical records were relevant to the commission of a crime in which he might be involved. Search warrants typically do not require prior notice and a hearing because of the potential that the evidence being sought, particularly in a criminal investigation, may be compromised. State prosecutors were within their discretion to determine that, for this reason, a search warrant rather than a subpoena was necessary in this case.


_Court found that a patient’s right to privacy in medical records is not violated by the retrieval of records pursuant to a valid search warrant and Florida search warrant statute does not limit its use for medical records; thus, patient does not have to be notified of the record’s retrieval nor can the patient challenge such an action on privacy grounds._

_Resident Physicians’ Antitrust Class Action_

On May 7, 2002, three former resident physicians, Paul Jung, M.D., Luis Llerena, M.D., and Denise Greene, M.D., filed an antitrust class action lawsuit against the National Resident Matching Program (NRMP), and its five sponsors, the Accreditation Council for Graduate Medical Education, and twenty-nine hospitals that sponsor residency programs. Under §1 of the Sherman Act, plaintiffs alleged that defendants used the NRMP match system to limit competition by sharing salary and other confidential information, fixing wages and restricting opportunities for residents. Plaintiffs alleged that these actions led to lower wages and longer working hours for residents than would have occurred in a competitive situation.

In response to the threat of litigation, the defendants obtained from Congress a special exemption to the antitrust laws stating that the NRMP match system does not violate antitrust law, and that the match system cannot be used as evidence in an antitrust case. The district court granted the Association of American Medical Colleges’ motion to dismiss the case, citing the April 2004 legislation as a deciding factor. The named plaintiffs appealed to the U.S Court of Appeals for the District of Columbia.

On January 25, 2005, the U.S. District Court for the District of Columbia denied a motion brought by the named plaintiffs for alteration or amendment of judgment to allow for an amended complaint, finding that the passage of the April 2004 legislation did not support amendment. The court further found that futility precluded any amendment to the complaint.

Plaintiffs cannot claim that the April 2004 legislation is a “change in controlling law” as the decision was issued after the legislation was passed and, therefore, may not amend their complaint.

Ohio Appeals Court Rules That Peer Review Statute Precluded Trial Court From Requiring Hospital to Identify Documents in Its File
Hospital that was sued over its credentialing of a physician objected to the production of peer review documents. After an in camera review, the trial court sustained the objection but ordered the hospital to produce a list identifying the documents contained within its peer review committee records that could be obtained from the original source. The hospital appealed.

The Ohio Court of Appeals ruled that the order violated the clear intent of the Ohio Peer Review Statute, which makes all information considered by a peer review committee privileged and non-discoverable from the hospital. The court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files.


*Ohio court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files.*
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I. ALTERNATIVE DISPUTE RESOLUTION

California Appeals Court Holds Noncompliance With Disclosure Requirements Renders Health Plan’s Arbitration Provision Unenforceable

Suzanne and Michael Malek were enrolled in a Blue Cross of California (Blue Cross) health plan. The enrollment form that they signed as well as other plan documents contained an arbitration clause. The Maleks sued Blue Cross in state trial court alleging it had improperly denied benefits for infertility treatment and Blue Cross moved for arbitration. The trial court denied Blue Cross’ petition to compel arbitration.

The California Court of Appeal affirmed, holding that the Blue Cross enrollment form violated both the prominence and placement requirements of Cal. Health & Safety Code § 1363.1. The court concluded that the penalty, unenforceability of the arbitration agreement, was not disproportionately harsh in relation to the gravity of the violation. Thus, the court held that a health plan’s failure to meet statutory disclosure requirements for arbitration provisions included on its enrollment form renders the arbitration agreement unenforceable. To hold otherwise, the court said, would defeat the statutory purpose of the disclosure requirements to alert healthcare consumers that they are binding themselves to arbitration and waiving their right to a jury.


A health plan must disclose arbitration provisions on enrollments forms in the statutorily prescribed manner in order to enforce such arbitration requirements.

Arizona Supreme Court Says Employment Agreements are Exempt From Arbitration Act

Team Physicians of Arizona, Inc. (TPA) sued a number of physicians and physician assistants (collectively, defendants) who had left their employment with TPA to form a competing company to provide emergency medical services to area hospitals. TPA moved to compel arbitration pursuant to arbitration provisions in defendants’ employment contracts. Defendants argued that Ariz. Rev. Stat. § 12-1517 exempts employment contracts from the Uniform Arbitration Act (the Act). However, the trial court held that § 12-1517 only applied to collective bargaining agreements and, accordingly, granted TPA’s motion to compel arbitration. Defendants appealed.

Rejecting defendants’ remaining arguments regarding statutory construction, the Arizona Supreme Court vacated the trial court’s ruling mandating arbitration and remanded for further consistent proceedings. When the Arizona legislature
adopted the Act, it did not include specific language that would have made the Act applicable to all employer-employee arbitration agreements, the court noted. The court acknowledged the strong public policy favoring arbitration, but concluded that the plain language of § 12-1517 “carves out an exception to that policy.”


Uniform Arbitration Act does not apply to employer-employee arbitration agreements in Arizona.

California Appeals Court Holds Physician Alleging Tort Claims Against Medical Group Bound by Arbitration Clause in Employment Agreement

Physician Carl Buckhorn entered into an employment agreement with St. Jude Heritage Medical Group (Group). The employment contract included an arbitration clause. The St. Jude Heritage Health Foundation (Foundation), which provides healthcare facilities and administrative support in exchange for medical services rendered by the Group through a professional services agreement (PSA), was named as a third-party beneficiary of the employment contract. The PSA was subsequently amended to include a mandatory arbitration provision. Buckhorn sued the Group and the Foundation (collectively, Defendants) after he was terminated. In addition to his wrongful termination claims, Buckhorn also claimed defendants committed various torts after he was discharged, including defamation and interference with prospective economic advantage. Defendants moved to compel arbitration under the employment contract and the PSA. The trial court denied the motion. In its final order, the trial court found that Buckhorn was not bound by the arbitration clause in the PSA but did not refer to the arbitration clause in the employment agreement. Defendants appealed.

The California Court of Appeal, Fourth Appellate District, reversed, holding that the arbitration clause in the employment agreement applied to all of Buckhorn’s claims including those alleging Defendants engaged in tortious conduct against him after his termination. Buckhorn failed to show that his tort claims were “wholly independent” of the employment agreement and, therefore, they should have been submitted to arbitration, the appeals court held.


Arbitration clause in employment agreement applied to all of plaintiff physician’s claims, including those claims that arose after termination, as such claims were rooted in the contractual relationship.

Indiana Appeals Court Says Plaintiff Was Required by Nursing Home Contract to Arbitrate Claims

Dortha Bagley was a resident of Castleton Health Care Center (Castleton). Her daughter, Cheryl Sanford, acted as her legal representative based on a limited
durable power of attorney. Sanford signed the contract for Bagley’s admission to Castleton, which included a provision for dispute resolution by mediation and arbitration. Subsequently, Bagley underwent hip surgery, but died. Sanford, as the personal representative of her mother’s estate (Plaintiff), sued Castleton on survival and wrongful death claims. Castleton moved to compel arbitration. The trial court issued an order compelling plaintiff to submit the claims to mediation and, if necessary, arbitration. Plaintiff appealed.

The Indiana Court of Appeals affirmed the trial court’s order, noting that judicial inquiry into an arbitration provision is limited to determining the validity of the contract containing the provision. Rejecting plaintiff’s argument that the nursing home contract was unconscionable because the arbitration clause was “buried” in the contract, the court concluded that the arbitration clause was obvious, and as Bagley’s legal representative, it was assumed plaintiff read the agreement before signing it.

Plaintiff also argued that the arbitration clause conflicted with the Federal Arbitration Act (FAA), which provides with respect to nursing home admissions that a facility may not accept any “other consideration” as a condition of admission. The court rejected plaintiff’s reading of the FAA and determined that because the phrase “other consideration” was followed by a specific list of terms including, “gift, money, or donation,” the arbitration clause was not consideration. The court then turned to plaintiff’s argument that the arbitration clause was unconstitutional because it deprived plaintiff of the right to a jury trial. The court held that plaintiff knowingly waived any right to a jury trial by signing the contract and she could not claim otherwise when the arbitration provision clearly states the waiver of the right.


Arbitration provision in nursing home admission contract was enforceable because it was obvious within the contract and did not conflict with the FAA; moreover, the provision was constitutional, as plaintiff knowingly waived the right to a jury trial.

Maryland Appeals Court Says Medical Malpractice Claim Must Be Remanded for Arbitration

William Frew and his wife (plaintiffs) sued Dr. Ralph Salvagno, the Altizer-Salvagno Center for Surgery, and others that were involved with Frew’s treatment (defendants) for medical malpractice based on an injury to Frew’s foot, which allegedly occurred when Salvagno improperly applied a tourniquet to Frew’s ankle during surgery.

Under the Maryland Health Care Malpractice Claims Act (the Act), any claim for medical malpractice seeking damages in excess of $5,000 must initially be submitted for arbitration for the purpose of determining liability and damages before any action can be sought in court. The claim must be filed with the Health
Claims Arbitration Office (HCAO). A certification by a qualified expert that the actions of the defendant departed from the accepted standard of care must be filed. The certificate of a qualified expert must be filed within ninety days of the filing of the claim. In the case of a claim for lack of informed consent, however, these procedures do not have to be followed.

The chairperson of the arbitration panel dismissed two counts on the ground plaintiffs had over two years to name expert witnesses and failed to do so. The chairperson also determined plaintiffs failed to show a prima facie case of lack of informed consent. Plaintiffs filed a petition in court to nullify the decision. The trial court granted plaintiffs’ motion to nullify, vacated the dismissal by the chairperson, and denied defendants’ motion to dismiss. Defendants appealed.

The Maryland Court of Special Appeals ordered the case to the remanded to HCAO for arbitration. The court concluded that the Act does not bar the use of expert testimony by an adverse witness for a lack of informed consent claim. Because the Act does not require a certificate for an informed consent claim, the court held plaintiffs were allowed to arbitrate their claim without naming an independent expert. Therefore, the trial court did not err in denying defendants’ motion to dismiss the complaint. The court then turned to defendants’ argument that the trial court erred in holding that the chairperson exceeded her authority in dismissing plaintiffs’ claims. The chairperson should not have dismissed the case, said the appeals court, because the dismissal in the absence of a liability determination had the effect of being a non-decision and the chairperson should have granted summary judgment.


Alabama High Court Says Plaintiff Did Not Avail Herself of Contract and Thus Was Not Required to Arbitrate Claims

Melda McCurdy (plaintiff) was admitted to Springhill Senior Residence (Springhill) after being discharged from the hospital for rehabilitation after a stroke. Plaintiff sued Springhill, its administrator, and other employees of Springhill (defendants) on a claim of negligence in failing to provide her with proper care. Plaintiff amended her complaint to include a breach of contract claim. Defendants filed a motion to compel arbitration and argued the admissions contract contained an arbitration clause and plaintiff had alleged a breach of contract claim, which indicated plaintiff admitted there was a contract. Plaintiff claimed she did not sign an admission contract and no representative of Springhill discussed with her what would happen if a dispute arose. The trial court granted plaintiff’s motion to dismiss the breach of contract claim and denied defendants’ motion to compel arbitration. Defendants appealed.

The Supreme Court of Alabama affirmed the trial court’s judgment, stating that plaintiff was not seeking any benefit under the contract at the time the trial court ruled on the motion to compel arbitration. Defendants argued they did not attempt to enforce the arbitration agreement until plaintiff amended the complaint
to include the breach of contract claim. Disagreeing with defendants that plaintiff’s breach of contract claim manifested an assent on plaintiff’s part to the admissions contract, the high court concluded plaintiff received no benefit from the admissions contract. Under the circumstances in this case, the high court held plaintiff had not availed herself of any benefit under the admissions contract, and therefore the trial court’s judgment had to be affirmed. 


In cases where plaintiff does not avail herself of any benefit under an admissions contract, an arbitration provision in the admissions contract cannot be enforced.

**Connecticut Appeals Court Reinstates Arbitration Award, Says Physician Was Completely Rehabilitated**

Dr. Albert Torres (Defendant) accessed credit card information from patient files and made several telephone calls to an adult entertainment service. Defendant’s misconduct was discovered, and he was fined $5,000 by the state Department of Health, voluntarily surrendered his medical license in New York, and was arrested and charged with larceny, criminal impersonation, and computer crimes. The criminal charges were dismissed after Defendant completed required counseling. Defendant was not discharged nor suspended from practice. Plaintiff Private Healthcare Systems, Inc. (PHS), had a preferred physician agreement with Defendant, which consisted of a one-year term with automatically renewable successive terms. PHS terminated Defendant based on his misconduct, and Defendant invoked the contract’s appeal procedures, which included arbitration. Following a hearing, the arbitrator concluded Defendant was rehabilitated and did not pose a risk to patients, and ordered PHS to reinstate defendant. PHS petitioned the trial court to vacate the arbitration award on the ground the award violated public policy and established state law on theft. The trial court vacated the arbitration award on the ground it violated public policy against theft. Defendant appealed.

The Connecticut Appellate Court reversed the trial court’s judgment vacating the arbitration award. In **State v. AFSCME, Council 4, Local 387, AFL-CIO,** 777 A.2d 169 (Conn. 2001), the Connecticut Supreme Court held that a violation of a criminal statute was not a “per se public policy violation sufficient to justify vacating an arbitrator’s decision.” The appeals court determined there was no clear public policy against allowing a surgeon who had committed criminal conduct as a result of mental illness and who had been rehabilitated, to be reinstated. Thus, the appeals court held the arbitration award had to be reinstated. However, the Supreme Court of Connecticut granted PHS’ appeal on the issue of whether the appeals court properly determined that the arbitrator’s reinstatement of Defendant did not violate Connecticut’s public policy. **Private Healthcare Sys., Inc. v. Torres,** 855 A.2d 987 (Conn. App.), *petition for certification of appeal granted,* 861 A.2d 513 (Conn. 2004).
Under Connecticut law, there is no clear public policy that prevents a physician who committed criminal acts due to mental illness but was later rehabilitated, from being reinstated to his preferred physician contract.

California Court of Appeals Rules That Mandatory Arbitration of Claims Raised by Insureds of Healthcare Service Plans Was Constitutionally Permissible

Plaintiff insureds filed suit against the California Department of Managed Care (the Department) for approving healthcare service contracts entered into between the plaintiffs and HMOs. Those contracts were approved by the Department pursuant to its authority under the Knox-Keene Act. Plaintiffs argued that the Department erred in approving those contracts since they embodied clauses mandating binding arbitration of disputes between the HMO and its insureds. Plaintiffs contended that those contracts where contracts of adhesion, and that the mandatory arbitration provisions denied the insureds of their constitutional right to a civil trial by jury and denied them due process. The trial court ruled that the binding arbitration provisions were constitutional where the agent for the employee-insureds (namely, the employer) has waived the right to a jury trial.

The court of appeals affirmed, concluding that, as announced in Madden v. Kaiser Foundation Hospitals, 131 Cal.Rptr. 882 (Cal. 1976), the right to a jury trial can be waived, through an agreement for binding arbitration, by an employer who enters into a healthcare plan on behalf of its employees. The court stated that as long as there was adequate disclosure of the binding arbitration clause, approval by the Department of the agreement between the HMOs and plaintiff-insureds’ employers was permissible.

Viola v. Dep’t of Managed Health Care, 23 Cal.Rptr.3d 821 (Cal. App. 2005).

In California, an employer has the implied authority as the agent of its employees to agree to binding arbitration of disputes arising under a health services plan that it negotiates as part of an employee benefit package.

Texas Supreme Court Orders Arbitration Between Pharmacies and PBM Pursuant to Unsigned Arbitration Clause in Provider Agreement

The Texas Supreme Court found that a provider agreement’s arbitration clause between AdvancePCS Health (PCS), a pharmacy benefits management company, and several pharmacies in its network was enforceable under the Federal Arbitration Act (FAA) and Texas law. Although the pharmacies did not sign the provider agreements, the high court said neither the FAA nor Texas law requires arbitration clauses to be signed, so long as they are written and agreed to by the parties. Moreover, the arbitration clause need not be included in all the contracting documents.

Because PCS had established the existence of an arbitration clause governing the dispute, the burden shifted to the pharmacies to raise an affirmative defense
to arbitration. The high court rejected the pharmacies’ argument that PCS could cancel the agreement at will, rendering it illusory and without consideration. Here, the arbitration clause was not a stand-alone agreement but part of an underlying contract. Even considered alone, the arbitration clause was not illusory because PCS could not have avoided arbitration by terminating the agreement if the pharmacies had invoked the arbitration clause rather than filing suit. Next, the high court denied the pharmacies’ contention that the arbitration clause was unconscionable because they were forced to accept it. Lastly, the high court found insufficient evidence to support the pharmacies’ claims the PCS disclosed the provider agreement only after the pharmacies joined its network. Accordingly, the high court held the trial court abused its discretion in failing to compel arbitration and concluded the PCS was entitled to mandamus relief.


*This case is significant because it states that arbitration clauses do not have to be signed to be enforced so long as they are written and agreed to by the parties.*

II. INDIVIDUAL/PATIENT RIGHTS

**South Carolina High Court Holds That Informed Consent Does Not Create Agency Relationship Between Physician and Hospital**

The South Carolina Supreme Court held that an attending physician does not establish an actual agency relationship with a hospital just from obtaining informed consent from the patient. The plaintiff argued that the hospital’s rules, which required medical staff to obtain informed consent, created the agency relationship. The court rejected this argument, reasoning in part that obtaining informed consent is a matter solely for the attending physician and is between the physician and the patient.


*Hospital rules requiring medical staff to obtain informed consent do not establish an agency relationship between the hospital and the attending physician.*

**Massachusetts High Court Holds Plaintiff Could Not Claim Violation of Consumer Protection Act for Physician’s Failure to Obtain Informed Consent**

Plaintiff Georgia Darviris sued surgeon James G. Petros in state trial court alleging he had performed a hemorrhoidectomy on her without her consent. Plaintiff signed, but did not read, a consent form authorizing Petros to perform a fissurectomy or other “operations, procedures, or treatment” that he may, in his medical judgment, be considered necessary. Plaintiff asserted claims for failure to obtain informed consent, negligent infliction of emotional distress, and unfair and deceptive practices in violation of Mass. Gen. Laws. ch. 93A. Granting Petros summary judgment on her ch. 93A claim, the state trial court held that “an
unfair or deceptive act requires more than a finding of negligence.” The appeals court affirmed the judgment. Plaintiff appealed.

The Massachusetts Supreme Judicial Court affirmed. Although Petros may have been negligent in not discussing the hemorrhoidectomy procedure with plaintiff, his conduct was not unfair or deceptive, particularly in light of the consent form that plaintiff signed. According to the high court, the legislature enacted a comprehensive medical malpractice statute to “cover the field” of medical malpractice litigation. “Allowing a plaintiff to restate a claim, otherwise subject to the medical malpractice act, as a violation of [Mass. Gen. Laws. ch. 93A], would undermine the careful policy choices articulated by the Legislature,” the high court observed.


**As a matter of policy, plaintiffs may not sue a physician for medical malpractice under Massachusetts’s unfair or deceptive practices act.**

**Texas Court Finds Fetus Is Not a Person With Equal Protection Rights Under Texas Law**

Plaintiff went to the emergency room in her seventh month of pregnancy complaining of a quick pulse and dizziness. Doctors determined that she had a high pulse rate and high blood pressure and sent her to the labor and delivery room for further observation. At several points during the night, doctors monitored the heart tones of the fetus, which were difficult to detect. The next morning, the doctors determined that the fetus would be stillborn. Plaintiff claimed the hospital should have delivered her baby by Caesarean section. The Texas Supreme Court stated that it has repeatedly affirmed its 1987 decision in *Witty v. American General Capital Distributors, Inc.*, 727 S.W.2d 503 (Tx. 1987), which held that the Texas Legislature did not intend the words “individual” or “a person” to include an unborn fetus. The *Witty* decision also prohibited damages for prenatal injuries if the fetus did not survive birth. The court noted that in 2003, the Texas Legislature did grant the parents of a stillborn child a cause of action under the Texas Wrongful Death Act. However, that statute expressly states it does not apply to claims for the death of an individual who “is an unborn child that are brought against a physician or other healthcare provider licensed in Texas if the death is caused by, associated with, arises out of, or relates to a lawful medical or healthcare practice or procedure of the physician or healthcare provider”. The court also observed that the U.S. Supreme Court has held that the unborn are not included within the protection of the Fourteenth Amendment and the Equal Protection Clause.

**Fort Worth Osteopathic Hosp. v. Reese,** 148 S.W.2d 94 (Tx. 2004).

*The Texas Supreme Court reiterated that under state and federal law, certain causes of action that are extended to an individual or person do not, by definition,*
include an unborn fetus; therefore, the parents of a fetus that did not survive birth could not bring an action against a healthcare provider.

**Nebraska Supreme Court Holds Parents Cannot Raise Religious Objections to Statute Requiring Screening of Newborns for Diseases**

A Nebraska statute requires that infants born in the state must be screened for several metabolic diseases within forty-eight hours of birth, or, if the birth is not attended to by a physician, registration of the birth. The parents in question did not bring their child in for tests because the test involved drawing blood from the baby’s heel and they believed that life is taken from the body if blood is removed from it. The county petitioned the court to compel the parents to have the tests done. The parents argued that the law violated their rights to freely exercise their religion under the First Amendment and their rights as parents to make decisions concerning their child’s upbringing. They also argued the issue was moot because the child was more than two months old and the law required testing within forty-eight hours of the birth registration. The district court held that the state’s interest in having the children screened for diseases outweighed the parents’ interest in religious expression, and held that the issue was not moot because the tests could provide important information even if the child were older. The parents appealed and the Nebraska Supreme Court affirmed the district court’s judgment.


*State’s interest in newborn screening test results outweighed parents’ interest in religious expression; therefore, Nebraska court found no First Amendment violation.*

**State and Federal Legislative Efforts to Circumvent Various Court Rulings Regarding Termination of Life-Prolonging Procedures Fail**

This high profile case involved Theresa Schiavo (Theresa), a woman in a permanent or persistent vegetative state since 1990. As the guardian for Theresa, her husband Michael Schiavo (Michael) obtained an order from the guardianship court authorizing the discontinuance of artificial life support. The guardianship court determined that there was clear and convincing evidence that Theresa was in a persistent vegetative state and that she would elect to cease life-prolonging procedures if she were competent. Theresa’s parents appealed this order and initiated various other actions challenging the guardianship court’s decision. Once all judicial challenges were exhausted, Theresa’s nutrition and hydration tube was removed. Six days later the Florida Legislature enacted a law authorizing the Governor to issue a one-time stay to prevent the withholding of nutrition and hydration (the Act). Subsequently, Theresa’s nutrition and hydration tube was reinserted pursuant to the Governor’s executive order. On the same day, Michael brought a declaratory judgment action arguing that the Act was unconstitutional.
The Florida Supreme Court held that the Act was unconstitutional as applied to Theresa and on its face. The court held the Governor’s executive order effectively reversed a properly rendered final judgment and amounted to an unconstitutional encroachment on the power reserved for the judiciary. The court further held the executive order inappropriately delegated legislative power to the Governor because the Act contained no guidelines or standards to limit the Governor from exercising completely unrestricted discretion with regard to the decision to withhold nutrition and hydration.

Subsequently, Congress enacted “An Act for the relief of the parents of Theresa Marie Schiavo” (Pub. L. No. 109-3), which authorized a Florida court to grant relief in the Schiavo case. Theresa’s parents then filed a petition for a temporary restraining order (TRO), which was denied by the United States District Court for the Middle District of Florida. The district court’s opinion was based upon the standard for granting a TRO. Specifically, the court concluded that the plaintiff’s failed to show a substantial likelihood of success on the merits of any of the five constitutional and statutory claims they raised. On appeal, the Eleventh Circuit Court of Appeals affirmed, concluding that the district court did not abuse its discretion in denying the TRO. The U.S. Supreme Court declined to review the cases.


This high profile case illustrates the controversial issues surrounding end of life decisions and the potential for emotions and political agendas to impact such cases.

III. MEDICAL MALPRACTICE

West Virginia Supreme Court Rules That Apparent Agency Could Exist Even Though Patients Signed Consent Forms Indicating Otherwise

The West Virginia Supreme Court considered the issue of apparent agency in two consolidated cases. In both cases, the patients received outpatient and inpatient services and signed consent forms acknowledging that the treating faculty physicians and residents were not employees of the teaching hospital. The court acknowledged that no actual agency relationship existed. However, the court determined that apparent agency could exist, even outside an emergency room treatment situation, if the hospital committed an act or failed to take action that would cause a reasonable person to believe the physician in question was an agent of the hospital and the plaintiff relied on the apparent agency relationship. The court determined that the hospital’s failure to provide meaningful written notice could constitute a failure to take action, as the court found that the hospital’s reference to “faculty physicians and resident physicians” was not unambiguous since it presumed a patient could distinguish among these physicians and other physicians.

West Virginia Supreme Court ruled that an apparent agency relationship could exist if a hospital committed an act or failed to take action that would cause a reasonable person to believe that the physician in question was an agent of the hospital and the plaintiff relied on the apparent agency relationship.

Florida Constitutional Amendments Likely to Significantly Impact Medical Malpractice Cases
The Florida electorate approved three amendments to the state constitution that will likely have significant impact on medical malpractice cases, and issues concerning professional rights. The first, which has become widely known as “Amendment 7” or the “Patient’s Right to Know About Adverse Medical Incidents” amendment and which will be included in Article X of the Florida Constitution as Section 22, provides that any patient or potential patient has the right to access and obtain copies of records of a healthcare facility or provider’s “adverse medical incidents.”

The second, which has become generally known as “Amendment 8” or the “Public Protection from Repeated Medical Malpractice” amendment and which will be included in Article X of the Florida Constitution as Section 20, provides that “no person who has been found to have committed three or more incidents of medical malpractice shall be licensed or continue to be licensed by the State of Florida.”

Finally, “Amendment 3” or the “Medical Liability Claimant’s Compensation” amendment, which will be included in Article X of the Florida Constitution as Section 26, limits an attorney’s contingency fee in a medical malpractice action.

Trial courts across the state have ruled inconsistently on the issue of retroactivity of Amendment 7, and on the issue whether it is “self-executing” or requires legislative implementation. There is no appellate decision to date, although trial court orders have been appealed. At least one appellate court has stayed an action for declaratory judgment concerning the enforceability of Amendment 8 pending the conclusion of the current legislative session. There have been no appellate decisions regarding Amendment 3.

U.S. Court in Kansas Finds Immunity for Emergency Medical Workers Does Not Extend to Their Employers
A patient who was being transferred by an air ambulance service, Eagle Med, and attended by the defendants, Landgraf and McGowan, who were registered nurses and mobile intensive care technicians, died after an incident during transport. Eagle Med moved for summary judgment, asking the court to rule that the immunity for emergency medical workers under Kansas law extends to employers of the immune emergency medical workers. In a matter of first impression, the U.S. District Court for the District of Kansas ruled that the
immunity granted under Kansas law to emergency medical workers does not extend to the employers of those workers, as the plain language of the statute only encompasses certain emergency medical workers, not their employers. The court also noted that public policy weighed in favor of not extending the immunity because “vicarious liability represents a policy choice that, as between an innocent victim and the otherwise innocent employer of a tortfeasor, the latter should bear the risk that the tortfeasor is incapable of satisfying any judgment arising from his negligence.” Lastly, the court determined that the law of agency was personal to the emergency medical workers and did not extend to employers of those workers. Accordingly, the court denied Eagle Med’s motion for summary judgment.


*Immunity for emergency medical workers does not extend to their employers under Kansas law.*

**IV. MEDICAL RECORDS**

**Court Rules That HIPAA Protections Apply to Records That Predate HIPAA’s Effective Date**

In a qui tam action, the U.S. District Court for the District of Columbia applied the privacy protections of the Health Insurance Portability and Accountability Act (HIPAA) in a protective order request to protect records request by the qui tam relator even though the records predated the effective date of HIPAA. The court stated that it would not allow “any disclosures that may violate federal or state law,” rejecting the government’s argument that records existing prior to HIPAA’s effective date should not be protected.


*This case is significant because it applies HIPAA’s privacy protections to records that predate its effective date; interestingly, the government argued against such protection.*

**D.C. Circuit Holds District Court Must Weigh Privilege Before Ordering Production of Medical Records**

Plaintiffs, two mentally retarded adult men, are wards of the District of Columbia Mental Retardation and Developmental Disabilities Administration (MRDDA). For several years they lived in a group home where they alleged they were sexually assaulted by the defendant, another resident of the group home and also a ward of MRDDA. Plaintiffs sued the District for violating their civil rights and under other causes of action including negligence. During pre-trial proceedings, plaintiffs moved to compel production of all of the defendant’s medical records. The district court granted the motion. Defendant’s guardian ad litem moved for reconsideration and a more extensive protective order. The district court denied
the motion and denied a second request to modify the order. The D.C. Circuit vacated the district court’s order and remanded the case. The court found that the Supreme Court recognized a federal psychotherapist–patient privilege in *Jaffee v. Redmond*, 518 U.S. 1 (1996). Accordingly, the court held that any “conversations between” defendant and a licensed psychotherapist or social worker are protected from disclosure. Because the district court’s order would subject defendant’s records to disclosure without screening in any way to make sure that they did not contain confidential communications, the appeals court found the district court abused its discretion. The appeals court did not address directly any District of Columbia statutes that afford privileges that would bar disclosure, but held that the district court should look at those provisions and weigh them in its consideration of whether to compel production of the records under Federal Rule of Civil Procedure 26.

*In re Sealed Case (Medical Records)*, 381 F.3d 1205 (D.C. Cir. 2004).

Courts may not compel production of a defendant’s medical records without first determining whether those records are subject to a federal privilege and weighing the probative value of each non-privileged document against the intrusion into the appellant’s legitimate privacy interest.

**Florida Appeals Court Holds No Privacy Limitation on State’s Ability to Obtain Patient’s Medical Records Via Search Warrant**

After police in Florida obtained search warrants to obtain certain medical records of Rush Limbaugh as part of an investigation into whether he violated the state “doctor shopping” statute by obtaining prescriptions for controlled substances from various physicians over a five-month period, the state placed the records under seal and notified Limbaugh that his records had been seized. Limbaugh objected to the seizure, asserting a right of privacy in his personal medical affairs under the Florida Constitution. A state trial court denied Limbaugh’s request to quash the search warrants. Limbaugh appealed.

The court held that the constitutional right of privacy in medical records is not implicated by the seizure of such records when seized pursuant to a valid search warrant, nor is the patient entitled to prior notice and a hearing in connection with the search warrant. Moreover, the appeals court noted, nothing in the search warrant statutes limit the use of search warrants for medical records. Here, the state had the burden of showing probable cause existed that Limbaugh’s medical records were relevant to the commission of a crime in which he might be involved. Search warrants typically do not require prior notice and a hearing because of the potential that the evidence being sought, particularly in a criminal investigation, may be compromised. State prosecutors were within their discretion to determine that, for this reason, a search warrant rather than a subpoena was necessary in this case.

Court found that a patient’s right to privacy in medical records is not violated by the retrieval of records pursuant to a valid search warrant and Florida search warrant statute does not limit its use for medical records; thus patient does not have to be notified of the record’s retrieval nor can the patient challenge such an action on privacy grounds.

California Appeals Court Says Hospital Report of Patient’s Fall Was Privileged
Richard Johnson underwent surgery at Sutter Davis Hospital (Sutter). While Richard was in the Intensive Care Unit and under doctor’s orders that his bed rails be left up and that he be under direct supervision, he fell and broke his hip. Donna Johnson, Richard's wife, sued Sutter following Richard’s death on claims of elder abuse, negligence, and intentional and negligent infliction of emotional distress stemming from Sutter’s failure to follow the orders of Richard’s doctor. Cindy Goss, a registered nurse that was on duty when Richard fell, testified at a deposition that she had filed an accident report about Richard’s fall. Johnson filed a motion to compel production of the report, but Sutter opposed the motion, stating that the report was privileged under Cal. Evid. Code § 1157, which provides that records of a medical staff committee are privileged. Sutter filed a motion for a protective order pursuant to § 1157. The trial court denied Sutter’s motion for a protective order on the grounds Sutter failed to show either a peer review body or a committee of the medical staff reviewed the report.

The California Court of Appeal, Third District, held that the report was privileged under § 1157, concluding that there was sufficient evidence to support a finding that the report was privileged as part of the medical staff’s review of quality issues, and the trial court erred in denying Sutter motion. The court further stated that the Legislature enacted § 1157 to further the public policy of encouraging candor in the use of patient records to improve patient care.


This case demonstrates that courts are reluctant to hold reports regarding quality of care issues unprivileged because of the desire to encourage candor in the use of patient records to improve patient care.

New York Court Rules That HIPAA Does Not Allow Plaintiffs to Withhold Authorizations That Assist Defense Counsel
Defendants sought an order to compel plaintiff to execute a HIPAA compliant medical authorization enabling defense attorneys to meet with subsequent treating physicians. Plaintiff’s attorney refused to provide signed authorizations citing HIPAA and two recent New York trial court decisions, *Browne ex rel. Estates of Browne vs. Horbar*, 2004 WL 2827657 (N.Y. Sup. 2004), and *Keshecki v. St. Vincent’s Medical Center*, 785 N.Y.S.2d 300 (N.Y. Sup. 2004), which the plaintiff argued prohibited ex parte discussions with plaintiff’s treating physicians.
The court found that HIPAA provides no impediment to the relief sought by defendants and that the regulations promulgated under HIPAA provide that in certain circumstances, “[a] covered entity may disclose protected health information in the course of any judicial or administrative proceeding” (45 CFR § 164.512[e]). While the court acknowledged that it is debatable whether the private interviews would constitute a “judicial or administrative proceeding” under HIPAA, the court emphasized the importance of “fundamental fairness” and further provided that “a plaintiff should not be allowed to simply refuse to provide an appropriate authorization to defendants yet seek to interview these same healthcare providers for potential testimony.”

**Steele v. Clifton Springs Hospital and Clinic**, 788 N.Y.S.2d 587 (N.Y. Sup. 2005)

New York court ruled that HIPAA does not authorize plaintiffs to refuse to provide medical authorizations that would allow defense counsel to meet with the patient’s subsequent treating physicians.

**U.S. Court in Minnesota Says Wife’s Claim to Deceased Husband’s Medical Records Under HIPAA Was Not Sufficient to Confer Jurisdiction**

Mary Johnson decided to sue Parker Hughes Cancer Center (Parker Hughes) and retained an attorney to investigate and pursue a civil action. As her husband’s surviving spouse, she requested that Parker Hughes provide copies of the medical and billing records pertaining to her husband’s treatment. Parker Hughes denied the request, claiming she was not in compliance with HIPAA. She argued the state law allowed her to act on behalf of her deceased husband and Parker Hughes argued that HIPAA preempts state law. Johnson brought an action seeking declaratory relief clarifying her rights under HIPAA and Parker Hughes moved to dismiss the complaint for lack of subject matter jurisdiction. The U.S. District Court for the District of Minnesota granted the motion to dismiss, noting that Johnson did not bring a cause of action under HIPAA, but instead sought an order interpreting HIPAA. The court found Johnson’s claim was insufficient to confer subject matter jurisdiction. The court concluded that because there was no private cause of action under HIPAA and there was no other basis to invoke a federal question, subject matter jurisdiction was inappropriate. Accordingly, the court dismissed the complaint for lack of subject matter jurisdiction.


The case reinforces the concept that there is no private right of action under HIPAA.

**Mississippi High Court Finds Law Firm Lacks Standing to Object to Prices Charged for Medical Record Retrieval**

The Supreme Court of Mississippi held that a law firm lacked capacity to bring an antitrust claim against hospitals and a medical records company for charging excessive fees to the law firm’s clients for the retrieval of medical records. Owen
& Galloway, LLC, (the Firm) filed a lawsuit against Smart Corporation, a medical records company (Smart), Gulf Coast Community Hospital, Inc. and Hancock Medical Center (collectively, the Hospitals), alleging that excessive and inconsistent fees were charged by Smart to the Firm for retrieval of medical records with the knowledge of the Hospitals in violation of Mississippi’s antitrust laws. The trial court granted summary judgment to the defendants, finding that the Firm lacked standing because “as a matter of law [the Firm] had no independent right to purchase medical records of its clients.” The Firm appealed. The Supreme Court of Mississippi affirmed, stating that the Firm’s only right to purchase copies of medical records was in its capacity as agent for its clients. The court found that the real party in interest is the clients, not the Firm.


Only patients/clients, not law firms acting as their agents, have standing to object to any fees associated with the retrieval of their medical records.

V. MEDICAL STAFF ISSUES

Court Decides Hospital May Not Exclude Physicians With Staff Privileges

Three physicians with staff privileges at Monongalia County General Hospital (Hospital) who also were employees and shareholders of Monongalia Anesthesia Associates Inc., which previously provided anesthesia services to the Hospital, challenged the Hospital’s exclusive contract with another provider that covered virtually all general anesthesia services.

The West Virginia Supreme Court rejected the physicians’ position that they had a property interest in their staff privileges and also held that the hospital’s medical staff bylaws did not constitute a contract with the physicians. It distinguished the scope of judicial review in cases involving public and private hospitals, saying that, in public hospitals, physicians do not practice at the will of the hospitals’ governing authorities, but are “entitled to practice,” so long as they stay within the law and conform to all “reasonable” rules and regulations. The court then examined whether the hospital’s decision to enter into the exclusive contract was reasonable, concluding that “the total exclusion of physicians from their hospital practices, and the concomitant complete deprivation of patient choice, simply cannot be justified “by the ends the hospital sought to achieve.

Although the court acknowledged that its decision was contrary to prevailing authority upholding exclusive contracts, it disagreed with those precedents. It found that a preferential contract would have allowed the lead plaintiff access to hospital facilities to treat patients when he was requested, allowed the hospital management the discretion to contract to secure a primary provider of medical services to solve scheduling and staffing problems, and also would have preserved patient choice.

Court set a new precedent disallowing exclusive provider agreements because such agreements unfairly excluded other physicians, hindered a patient’s right to choose his or her physician and were aimed at solving a problem that could have been addressed by less restrictive means.

**Court Finds Hospital May Summarily Suspend Physician Who is Imminent Threat to Patients**

Dr. Penny Pancoast is a physician with an internal medicine practice who obtained medical staff privileges at Sharp Memorial Hospital (Sharp). Pancoast’s privileges at Sharp were suspended because she had not completed a number of medical records. In the next few months, various attempts to contact Pancoast failed and her psychiatrist and other associates informed Sharp that Pancoast was stressed and possibly suicidal. Pancoast sued Sharp and its chief of staff, alleging that Sharp acted improperly in suspending her privileges and in failing to provide her with a hearing. The trial court granted Pancoast a writ of mandate directing the hospital to either restore her privileges or provide a hearing.

The California Court of Appeal, Fourth District, directed the trial court to vacate its writ. The court first turned to the issue of whether by allowing suspension where there is likely harm to prospective patients, Sharp’s bylaws go beyond the scope of California Business and Professions Code § 809.5. The court found that, read in light of the public interest in protecting patient safety, the statute protects prospective as well as identified patients. Next, the appeals court found that Sharp had an adequate basis upon which to conclude that Pancoast was an imminent threat to patients. Pancoast argued that she did not intend to begin admitting patients to Sharp as soon as her medical records suspension was over; therefore, she was not an imminent threat to patients. However, the appeals court found that the record contained a “great deal” of proof that Pancoast did intend to begin admitting patients.

**Medical Staff of Sharp Mem’l Hosp. v. Superior Court**, 16 Cal.Rptr.3d 769 (Cal. App. 2004).

*Court held that doctor whose privileges were summarily suspended by hospital could not maintain action because hospital had adequate basis for finding that doctor posed an imminent threat to patients and, as such, was justified in suspending her privileges without a hearing.*

**VI. PROFESSIONAL RIGHTS**

**Court Rules DHHS Bound by HIPAA When Reviewing NPDB Reports But Physician’s Action Challenging Record Was Time-Barred**

St. John’s Mercy Medical Center (St. John’s) in St. Louis, Missouri filed an adverse action report with the National Practitioner Data Bank (NPDB) after it summarily suspended an unidentified physician (Plaintiff) for an indefinite period
of time as required by the Health Care Quality Improvement Act (HCQIA). Plaintiff objected to the reference to a “positive” psychiatric evaluation in the revised report and asked DHHS to amend the records pursuant to HIPAA. DHHS informed Plaintiff that his only administrative remedy was through the procedures for disputing information contained in the NPDB under 45 C.F.R. § 60.14. Applying the regulation, the DHHS Secretary concluded that the revised report was inaccurate and amended it to indicate that Plaintiff “was not suffering from any type of psychiatric disorder.” However, Plaintiff still objected, arguing that pursuant to HIPAA, the NPDB records should make no reference whatsoever to a psychiatric evaluation.

The U.S. District Court for the District of Columbia held that HIPAA, which requires an agency to “make reasonable efforts” to assure the accuracy, completeness, relevance, and timeliness of records disseminated about an individual, provides more protection than the DHHS regulations for challenging a record submitted to the NPDB. However, the court found that Plaintiff’s HIPAA claims were time-barred under the applicable two-year statute of limitations. The court rejected Plaintiff’s contention that a new cause of action was initiated every time DHHS disseminated the report after he notified the agency of the problem. The critical time period, said the court, is when Plaintiff knew or should have known of the alleged inaccuracy in the NPDB report. Accordingly, the court granted summary judgment in the Secretary’s favor on the ground that the action was time-barred.


*This case is significant because it explains when HIPAA’s statute of limitation begins – when the plaintiff become aware of the privacy violation. Furthermore, it explains that the government must adhere to HIPAA’s requirements in processing disputes regarding disputed National Practitioner Data Bank reports because HIPAA is more protective.*

**Connecticut Supreme Court Holds State Qualified Immunity Law in Connection With Review of Physician Abrogates Common Law Absolute Immunity**

Charlotte Hungerford Hospital (Hospital) contacted the Connecticut State Medical Society’s impaired physician program in March 1997 about Mohinder P. Chadha’s ability to safely practice medicine. In May 1997, the State Department of Public Health (Department) filed a statement of charges against Chadha. Several physicians submitted affidavits to the Department expressing concerns about Chadha. The State Medical Examining Board (Board) summarily suspended Chadha’s license pending a final determination. In November 1997, the Hospital submitted a report about Chadha to the NPDB. The Board subsequently entered a final determination suspending Chadha’s license.

Chadha sued the hospital and physicians, claiming defamation against the Hospital for submitting a false report to the NPDB and malicious submission of
false affidavits to the Department against the physicians. The physicians asserted special defenses, including qualified immunity under state law and common law absolute immunity for statements made in connection with a judicial or quasi-judicial proceeding. The Hospital and physicians moved for summary judgment. The trial court held that the state’s qualified immunity provisions abrogated the common law absolute immunity and that the physicians had failed to counter Chadha’s assertions of malice for purposes of granting summary judgment. The physicians appealed and the Connecticut Appellate Court affirmed the trial court’s judgment. The Connecticut Supreme Court found that the only reasonable interpretation of the qualified immunity provisions was that they trumped the absolute immunity afforded under common law.  


*Connecticut court ruled that the state’s qualified immunity regarding physician peer review abrogates absolute immunity under common law.*

**Alabama Supreme Court Finds That Non-Profit Hospital Corporation Was Not Required Under Its Medical Staff Bylaws to Follow Fair-Hearing Panel’s Recommendation**

After hiring consultants to study its oncology program, the Providence Hospital (Hospital) board decided to transfer ownership of its oncology center to Seton Medical. The Hospital board notified all radiation oncologists with privileges at the Hospital. Radiation Therapy Oncology, P.C., physicians (RTO Physicians) requested a hearing before the fair-hearing panel, which found that the transfer would adversely affect the clinical privileges of the RTO Physicians. The Hospital board considered the panel’s decision but reaffirmed the Hospital board’s resolution to transfer the cancer program to Seton Medical. RTO and the RTO Physicians sued. The trial court granted summary judgment in favor of the Hospital.

The Supreme Court of Alabama affirmed, finding that a medical staff does not have the power to overrule a valid business decision made by a hospital’s board. Moreover, the high court rejected the argument that a genuine issue of material fact existed as to the reason that the board declined to adopt the fair-hearing panel’s decision because the board had considered matters other than patient care. Finally, the high court rejected their argument that the transfer was a sham and that denying the RTO Physicians access to oncology equipment constituted a breach of the medical staff bylaws.  


*Hospital’s medical staff does not have the authority to overrule a valid business decision made by the hospital’s board.*
VII. LICENSING AND PROFESSIONAL DISCIPLINE

Pennsylvania Commonwealth Court Finds Board May Revoke License of Physical Therapist Based on Discipline From Other States
Wageed Abdel Malek Girgis had his license to practice physical therapy revoked by the Pennsylvania Bureau of Professional and Occupational Affairs, State Board of Physical Therapy (Board) under Pa. Stat. § 1311(a)(8) on the basis of discipline imposed by other jurisdictions. Girgis appealed, claiming the Board is not authorized to discipline him with no finding that he was incompetent, negligent, or abusive, and the Board is not authorized to discipline him where there is no finding that Girgis’ actions in the other jurisdictions harmed patients. The Pennsylvania Commonwealth Court affirmed the Board’s decision, noting that between April 1997 and June 1999, eight disciplinary actions were taken against Girgis in seven jurisdictions other than Pennsylvania. Turning to Girgis’ argument that the Board could not discipline him without finding that he was incompetent, negligent, or abusive, the court held that the plain language of § 11(a)(8) does not require such a finding. In fact, said the court, the section explicitly permits discipline to be imposed based on a finding that an individual’s license to practice physical therapy in other states was “suspended, revoked, or otherwise disciplined.” The court also found that under Johnson v. State Bd. Of Med. Educ. And Leisure, 410 A.2d 103 (Pa. Cmwlth. 1980), the underlying reason for the actions in the other states was irrelevant. Therefore, the court affirmed the Board’s revocation of Girgis’ license.


Professional licensing boards in Pennsylvania may revoke a license based on disciplinary actions taken in other states.

Kansas Appeals Court Holds Board May Enjoin Use of M.D. by Unlicensed Individual
Plaintiff was a licensed dentist in Kansas, who later graduated with a Doctor of Medicine degree. However, he never completed his post-graduate training program or completed any licensing examinations necessary to practice medicine. Nevertheless, plaintiff attaches the designation of M.D. to his name in his dentistry practice. The Kansas State Board of Healing Arts (Board) brought suit seeking to enjoin plaintiff’s use of M.D. and to declare the use of this designation unlawful under the circumstances. Plaintiff won at the trial level, but the state court of appeals reversed and remanded for an injunction.

The court reasoned that plaintiff’s use of M.D. would tend to mislead or confuse the public because an M.D. degree is commonly associated with a certain course of training, which plaintiff did not completely receive. At the same time, however, the court found that the governing state statute was facially overbroad because it also seeks to ban uses of the M.D. designation that are not misleading. Even the Board conceded that the Plaintiff should be allowed to use the M.D. designation in “academic or social settings.” The court held that the statute should only be
The M.D. designation may not be used in a professional context by an individual in Kansas who is not licensed by the state.

Alabama High Court Finds Revocation of Physician's License Supported by Substantial Evidence
The Medical Licensure Commission of Alabama (Commission) revoked the medical license of Oscar Almeida, an obstetrician/gynecologist, based on testimony that he engaged in sexual misconduct while rendering professional services. Almeida filed a motion of appeal and a motion to stay the revocation. The trial court granted the motion to stay and subsequently reversed the Commission’s order, finding it did not have “substantial evidence” to justify the revocation. The court of appeals affirmed; however, the Alabama Supreme Court reversed and remanded the case.

The high court first turned to whether the Commission’s decision to revoke Almeida’s license was supported by substantial evidence. The high court noted that the Commission first heard testimony from four former patients, some of which was corroborated by one of Almeida’s former employees, and from a sales representative who also observed sexually inappropriate conduct and expert testimony from a psychiatrist and a psychologist who opined that Almeida had demonstrated inappropriate behavior. Thus, the high court found that the Commission’s decision was in fact supported by substantial evidence.

Next, the high court turned to whether Almeida was afforded due process. The Commission said in its order that it did not require the Board to produce written statements of the complaining witnesses because those statements were the work product of the Board’s attorneys and were therefore not discoverable. Agreeing with the Commission’s order, the high court found no due process violation because Almeida was “aware of the identity of the complaining witnesses…had the opportunity to depose those persons and…tape-recorded statements made by those parties during the Board’s investigation…[were] transcribed and made available to Almeida.”

Ex parte Medical Licensure Comm’n of Alabama, 897 So.2d 1093 (Ala. 2004).

Alabama court found no due process violation in case where medical board was not required to produce written statements of the complaining witnesses.
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I. LABOR ISSUES

Supreme Court Expands the Anti-Cutback Rule of the Employee Retirement Income Security Act
Plaintiff was a retired participant in a pension plan administered by the defendant pension fund (Plan). The Plan prohibited its participants from engaging in certain employment after retirement. If Plan participants accepted any prohibited employment, their monthly payments would be suspended. When plaintiff originally retired, the Plan specifically prohibited employment as any job as a construction worker. Plaintiff subsequently took a job working as a construction supervisor. The Plan later expanded its definition of a prohibited job by including any employment in the construction industry. After his pension payments ceased, plaintiff sued to recover the suspended payments alleging that the Plan had violated ERISA's anti-cutback rule.

The U.S. Supreme Court stated that the purpose of ERISA is to protect employees' expectations of benefits promised to them by employers. The anti-cutback rule prohibits any amendment that reduces early retirement benefits. The Court held that the new restrictions placed on the participants of the Plan did, in fact, reduce the value of the benefits by diminishing plaintiff's opportunities for post-retirement employment; therefore, the Plan's amendment was a violation of the anti-cutback rule.


This case broadens the anti-cutback rule of ERISA to provide more protections against amendments to employee benefit plans.

National Labor Relations Act Is Not Violated When Picketers Are Asked to Disassemble Because of Public Safety Concerns
The International Union of Operating Engineers (Union) filed an unfair labor practice complaint with the National Labor Relations Board (NLRB) claiming that the Greenbrier, a resort, interfered with the Union's right to picket a construction company performing work at the resort in violation of the National Labor Relations Act (NLRA). After the Union discovered that the construction company working on the resort had violated its collective bargaining agreement with the Greenbrier, the Union picketed the resort. The picketing took place in front of the Greenbrier along a stretch of dangerous highway. The Greenbrier contacted the police, stating that it was concerned with public safety. The Union then filed a grievance with the NLRB claiming that the Greenbrier had interfered with their right to picket. The NLRB ruled that the Greenbrier interfered with the Union's right to picket on private property because its motive in contacting the police was
for the removal or arrest of the picketers. The Fourth Circuit disagreed and held that the Greenbrier did not violate the Union’s right under the NLRA by reporting its concern with traffic safety to the police. Because of the potentially dangerous situation, the Greenbrier was justified in contacting to police and asking them to assess the situation.


*An union’s right to picket on private property without interference is not absolute when such picketing presents a potentially dangerous situation.*

**Third Circuit Holds Labor Management Relations Act Bars Malpractice Actions Against Attorneys Employed by Unions**

Plaintiff filed a complaint against the defendant attorney (Attorney) for legal malpractice in connection with the representation of the plaintiff in a labor grievance proceeding she had brought against her employer. The plaintiff had been terminated from her employment because of alleged professional misconduct. The union hired the Attorney on behalf of plaintiff, who later alleged that the Attorney deceived her into settling her labor grievance and giving up her right to arbitrate. On a question of first impression for the Third Circuit, the court held that the Labor Management Relations Act (LMRA) barred malpractice actions against attorneys representing union members in matters pursuant to collective bargaining agreements. The court reasoned that when a union hires an attorney, such attorney does not enter into an attorney-client relationship with the union member it represents, but instead performs as an agent of the union. The court compared the attorney to a union representative, who, under the LMRA, is not personally liable to third parties for actions taken on the union’s behalf. Therefore, the plaintiff’s action against the Attorney was properly dismissed by the lower court.

**Carino v. Stefan,** 376 F.3d 156 (3rd Cir. 2004).

*The Labor Management Relations Act immunizes an attorney hired by a union to perform services on behalf of an individual union member from suit for malpractice by the individual member.*

**Third Circuit Rules Purchaser of Hospital System Not Liable for Accrued Sick Leave**

Tenet HealthSystem (Tenet) purchased four hospitals from Allegheny Health Education and Research Foundation (AHERF). In the purchase agreement, Tenet agreed to assume certain AHERF contractual obligations, including the collective bargaining agreements with the National Union of Hospital and Health Care Employees. The Third Circuit held that employees’ accrued sick leave was an obligation arising before the closing date of the purchase and thus was not the responsibility of Tenet. The court viewed the sick leave as a “contingent obligation” but, nonetheless, an accrued obligation. The court held, however, that Tenet assumed the existing collective bargaining agreements and, therefore, could not bargain for new terms for the balance of the existing agreements.

A hospital buyer that is not responsible for obligations of the hospital prior to sale is not liable for employees’ accrued sick leave, despite being bound by existing collective bargaining agreements.

NLRB Rules Unfair for Hospitals to Refuse to Hire Nurses Striking Other Area Hospitals
The NLRB held that seven Minneapolis-area hospitals (Hospitals) violated the NLRA by refusing to hire nurses on strike against other hospitals. The Hospitals entered into a coordinated bargaining agreement prior to negotiations with the Minnesota Nurses Association (Union) in which they agreed, if the nurses struck at one of the hospitals, the others would refuse to hire the nurses on a per-diem basis, previously, a common practice. The NLRB found the Hospitals lacked a “legitimate and substantial business justification” for failing to employ the striking nurses. Moreover, the NLRB refused to let the hospitals expand a bilateral labor dispute “by introducing a new front of economic warfare.”


Hospital employer not facing labor dispute with union may not refuse to hire union members on strike against other employer.

Bargaining Unit Cannot Combine Regular and Leased Employees Without Consent
The NLRB held that a representation election involving both temporary and permanent workers requires the consent of both the supplying employer and the using employer. The NLRB reversed its decision in M.B. Sturgis, 331 NLRB 1298 (2000) and reasoned that for a bargaining unit to include employees of two different employers, the consent of both employers would be required. In this case, some of the members of the proposed bargaining unit were employees solely of the company utilizing the services of the employee leasing company and some were jointly employed by the leasing company and the user employer. The NLRB concluded that the inclusion of solely employed employees and jointly employed employees in the same bargaining unit creates a multi-employer unit, which, in accordance with the NLRA, may be appropriate only with the consent of both parties.

H.S. Care LLC, d/b/a Oakwood Care Center, 343 NLRB 76 (2004).

In a significant victory for employers using temporary or leased workers, such workers can only be incorporated in bargaining units with permanent workers with the employer’s consent.
D.C. Circuit Rules Attempt to Escape Coverage of Multi-Employer Bargaining Association Fails

Resort Nursing Home (Resort) desired to secede from a multi-employer bargaining association (Association); therefore, it ceased paying dues to the Association and handled its own grievance and arbitration proceedings, but took no steps to inform the Association or any union that it no longer chose to delegate bargaining authority to the Association. In the meantime, the Association negotiated a new three-year agreement with a local of the Service Employees International Union (Union). The Union filed an unfair labor practice charge with the NLRB against Resort when it refused to honor the new collective bargaining agreement.

The D.C. Circuit upheld the NLRB’s determination that there are only limited circumstances that permit a party to withdraw from multi-employer bargaining during negotiations and that such unusual circumstances did not exist in this case. Although negotiations commenced eight months before the current contract expired, Resort was still obligated to notify the Association and the Union prior to the commencement of negotiations that it was withdrawing from the Association.


*Parties must officially withdraw from multi-employer bargaining associations before new negotiations commence; if they do not, they must honor the new agreement.*

II. FAIR LABOR STANDARDS ACT

Department of Labor Issues Final Regulations for White Collar Exemptions

The Department of Labor (DOL) released final regulations concerning the exempt status of “white collar” employees under the Fair Labor Standards Act (FLSA). The regulations took effect on August 23, 2004. The revised rules update the salary levels and the duties and salary basis tests that white collar employees must meet to be exempt from the FLSA’s requirements for minimum wage and overtime compensation. The new regulations are the first overhaul of the white-collar duties tests since 1949, and the first increase in the minimum salary requirements for exempt employees since 1975.

Under the new regulations, an employee must earn a minimum salary of $455 per week or $23,660 per year and meet the duties tests for either an executive, administrative, professional, outside sales, or computer employee to be considered an exempt employee. This change is not likely to affect most exempt employees, many of whom already earn more than $23,660 per year. Highly compensated employees who were previously non-exempt, on the other hand, may now be exempt under a streamlined duties test provided for in the new regulations. Employees performing office or non-manual work and paid total
annual compensation of $100,000 or more (which must include at least $455 per week paid on a salary or fee basis) qualify as exempt employees if they customarily and regularly perform at least one of the duties of an exempt executive, administrative, or professional employee.

**Defining and Delimiting the Exemptions for Executive, Administrative, and Professional, Outside Sales and Computer Employees:** 29 C.F.R. § 541 et seq.

*All employers should review the classification of their exempt employees in light of these new regulations, as the DOL has stated there will be no grace period for compliance.*

### III. DISCRIMINATION ACTIONS

**Supreme Court Holds Constructive Discharge is a Tangible Employment Action**

Plaintiff alleged that her supervisor’s conduct was so severe that she was forced to resign, and therefore, was constructively discharged in violation of Title VII of the Civil Rights Act of 1964. The Supreme Court granted certiorari in this case to resolve the question of whether a constructive discharge qualifies as a tangible employment action that precludes the employer from asserting the affirmative defense set out in the Court’s earlier decision in *Burlington Industries, Inc. v. Ellerth*, 524 U.S. 742 (1998). The *Ellerth* case held that an employer is strictly liable for supervisor harassment that ends in a tangible employment action, but if no tangible employment action is taken, the employer may raise an affirmative defense if the employer can show that it used reasonable care in implementing a policy to prevent and correct sexual harassment, and that the employee unreasonably failed to take advantage of the policy. In the present case, the Court held that because a constructive discharge is the equivalent of a formal discharge for remedial purposes, an employer does not have the ability to raise the *Ellerth* affirmative defense when a supervisor’s conduct is the reason for the constructive discharge.


*This case limits the *Ellerth* affirmative defense by providing that a constructive discharge is a tangible employment action that makes the *Ellerth* defense unavailable to employers.*

**Eighth Circuit Holds That Title VII Does Not Allow Employers to be Held Strictly Liable for Single Incidents of Harassment**

An employee for the Arkansas State Police (Police) filed suit alleging a single incident of sexual harassment by her supervisor. The district court granted summary judgment for the Police based on an affirmative defense that the Police had promptly taken remedial action to correct the problem. The Eighth Circuit affirmed the district court’s decision, explaining that Title VII does not hold
employers strictly liable for all incidents of sexual harassment by its supervisors. The court concluded that the defendant was able to establish an affirmative defense because it correctly maintained a harassment policy and implemented that policy at the time of the plaintiff’s complaint. The plaintiff argued that the second prong of the Ellerth affirmative defense, that the employee failed to take advantage of the employer’s harassment policy, could not be proven, and therefore, the affirmative defense was unavailable. The Eighth Circuit disagreed, stating that in this particular case, it was not necessary to strictly adhere to the two-prong affirmative defense rule, as strict adherence to the two-prong rule would hold all employers strictly liable in single incident cases such as this, which was not the intention of the Supreme Court in designing the affirmative defense rule.

**McCurdy v. Arkansas State Police**, 375 F.3d. 762 (8th Cir. 2004).

*This case allows an employer to rely on the Ellerth affirmative defense in single incident cases even though both prongs of the defense were not proven.*

**Fourth Circuit Applies Supreme Court’s Desert Palace Mixed-Motive Jury Instructions Rule**

Plaintiff brought an action against her former employer alleging constructive discharge and sex discrimination in promotion practices. The district court found for the employer, and the plaintiff appealed, arguing that the district court erred in refusing to provide a mixed-motive jury instruction. Mixed-motive instructions allow a jury to find discrimination violations in cases where there are both legitimate and illegitimate reasons for employment decisions. The Supreme Court, in *Desert Palace, Inc. v. Costa*, 539 U.S. 90 (2003), ruled that plaintiffs in mixed-motive cases only have to prove by a preponderance of the evidence that some form of discrimination was a factor in the employment decision. The Court also concluded that plaintiffs could use either direct or circumstantial evidence to support a mixed-motive instruction. In this case, the plaintiff’s evidence of lack of promotions and comments made by other employees was sufficient for the mixed-motive instruction. Accordingly, the Fourth Circuit concluded the district court abused its discretion in not allowing the proper jury instructions.


*Fourth Circuit rules that mixed-motive jury instruction is required in cases where there are both legitimate and illegitimate reasons for employment decisions.*

**Ministerial Exception to Title VII Bars Claims of Harassment and Retaliation Only When a Tangible Employment Action is Taken**

A minister brought claims alleging sexual harassment and retaliation under Title VII against her church and supervisor. The plaintiff alleges the church created a hostile working environment that led to tangible employment actions, including termination. The district court dismissed the claims, stating that the claims fell under the ministerial exception to Title VII. This exception provides churches
freedom from intervention by the courts in the selection process of their ministers.

The Ninth Circuit stated that because the alleged tangible employment actions concern the church’s minister selection process, and because the church cannot be required to justify those decisions, the plaintiff cannot prove these employment actions were related to alleged harassment. However, even without the tangible employment actions, the minister may be able to recover for the harassment itself if the church cannot satisfy the *Ellerth* affirmative defense. Therefore, the ministerial exception does not completely bar the minister’s sexual harassment claim; rather, the case turns on the issue of whether the plaintiff can prove harassment without the tangible employment actions, and whether the church can prove an affirmative defense.

As far as the retaliation claim, the Ninth Circuit concluded that retaliatory harassment claims are not barred by the ministerial exception absent a religious justification for the conduct. The court held that both the harassment and retaliatory claims fall outside the ministerial exception, and that the plaintiff may recover as long as she does not rely on protection ministerial decisions. *Elvig v. Calvin Presbyterian Church*, 375 F.3d 951 (9th Cir. 2004).

*This case is significant because it limits the Title VII ministerial exception and allows claims to proceed if plaintiffs can prove harassment without tangible employment actions.*

“Double-Taxation” of Attorney Fees/Costs in Discrimination Suits Eliminated by Civil Rights Tax Relief Act Of 2004

In a win for plaintiffs in employment–related cases, a section of a corporate tax bill signed on October 22, 2004 enacted the Civil Rights Tax Relief Act of 2004. Prevailing plaintiffs, by way of judgment or settlement, under a broad range of civil rights and employment-related statutes, will no longer be taxed on attorneys’ fees and costs. This tax change takes effect only prospectively. Previously, claimants were taxed under the full amount of any recovery under discrimination claims, including portions assigned to attorneys’ fees. Business, civil rights groups and the ABA supported the change. *Civil Rights Tax Relief Act of 2004* (Oct. 22, 2004).

Deleted Emails Lead to Largest Single-Plaintiff Discrimination Verdict

A federal jury in New York awarded a plaintiff $29.2 million, in what is believed to be the largest, single-plaintiff discrimination verdict to date. The award stems from a claim of gender discrimination and retaliation and included over $20 million in punitive damages (nearly $7 million in front pay and over $2 million in back pay). It is very likely that the large verdict was related to the fact that executives and upper management deleted emails that were alleged to be relevant to the lawsuit during the four years that the case was pending before trial. The deletions resulted in an instruction from the judge that the jury was
entitled to conclude that the destroyed emails contained information adverse to the employer.

The court stated that it is not enough to simply inform persons within the company to suspend whatever regular document destruction policy may exist; affirmative steps must be taken to speak with “key” individuals involved in the litigation (either as witnesses or as persons responsible for working with counsel on the litigation) on a repeated basis to ensure that all potentially relevant email and electronic documents are maintained in a secure manner so as to avoid even accidental elimination.

**Zubulake v. UBS Warburg, LLC**, Case No. 02-1243 (SAS) (S.D.N.Y. jury verdict April 6, 2005).

*Employers must take affirmative steps to ensure that all potentially relevant e-mail and electronic documents are securely maintained in order to avoid even accidental deletion of such materials.*

**USERRA Requires More Protection of Veterans Than Typical Discrimination Analysis**

Steven Duarte was in the Marine Corps reserve and called to active duty. When he returned home, his employer, Agilent Technologies, Inc. (Agilent), put him on a special project rather than his usual job because the cycle for the work he normally did was almost done. As Agilent needed to reduce costs, it decided to layoff Duarte four months after his return to work. Before deciding to lay off Duarte, his boss sought input about his performance and the performance of other design analysts. In addition, Duarte’s manager checked with her superiors and inside counsel, who concurred with the layoff decision.

The decision to select Duarte for layoff may have met the non-discrimination rules: Agilent had a non-discriminatory legitimate reason, there was no discriminatory motivation evidence, and little or no pretext evidence. However, the test under the Uniformed Services Employment and Reemployment Rights Act (USERRA) is more protective of the employee than a non-discrimination test, as USERRA requires the employer to prove it had “cause” for the discharge.

Agilent was ordered to pay Duarte nearly $400,000 and his attorney fees, as the court found that giving Duarte the special assignment rather than his normal duties disadvantaged him because allowing him to perform his regular duties would have improved his contact with the HR managers who were asked to evaluate him; it was not reasonable for his new supervisor to judge his skills in comparison to others if he was not allowed to do the same work; and the need to downsize in this design analyst job was suspect since Agilent transferred someone else in to perform the work and posted for an opening in that job a few months after he was laid off.

The usual discrimination logic and analysis does not apply to USERRA discrimination cases, as employers must prove they had cause in discharging a veteran.

**U.S. Supreme Court Opens New Avenues to Sue for Age Discrimination**

The City of Jackson, Mississippi made revisions to an employee pay plan for police officers that was designed to bring starting salaries up to the regional average. The plan provided for more junior officers to receive raises that were proportionately greater than what more senior officers received. A group of senior officers filed suit under the Age Discrimination in Employment Act (ADEA) and claimed they were adversely affected because of their age. The district and appellate courts ruled in favor of the employer in each instance. The specific issue before the Supreme Court was whether the ADEA allowed a case for age discrimination under the “disparate impact” theory.

While the Supreme Court reversed the lower courts and specifically adopted the use of the “disparate impact” theory, it drew an important distinction between cases arising under the ADEA and those arising under other anti-discrimination statutes. The ADEA specifically allows “otherwise prohibited” actions where “the differentiation is based on reasonable factors other than age” (RFOA). Other anti-discrimination statutes do not have a similar provision. As a result, an employer may avoid liability for age discrimination under the “disparate impact” theory if it can demonstrate that the challenged plan or practice was based on RFOA. Thus, the Court found that the City of Jackson police officers could challenge the pay plan under the disparate impact theory, but the City’s plan withstood scrutiny because it was based on factors other than age.

**Smith v. City of Jackson, Mississippi,** 125 S.Ct 1536 (2005).

In a decision long anticipated (and feared) by employers, the Supreme Court has approved the use of the “disparate impact” theory in cases arising under the ADEA. The impact of this decision is to allow individuals, and more likely a group of individuals, to sue for age discrimination based on the “impact” an employer’s particular plan or practice has rather than showing the employer had a specific intent to discriminate.

**Eighth Circuit Finds IBM Release Ambiguous; Says Engineer May Pursue ADEA Claims**

The Eight Circuit held that an employee who was terminated by International Business Machines Corp. (IBM) was allowed to bring an ADEA case in spite of the fact that he signed a release because the language did not satisfy the strict requirements of the Older Workers Benefits Protection Act (OWBPA). As part of the ADEA, the OWBPA provides that a waiver of ADEA claims must meet “strict and unqualified requirements,” the court noted. The waiver must be written in a manner calculated to be understood by the employee, and if an employer fails to meet any of the statutory requirements, the waiver is ineffective as a matter of law.
The waiver plaintiff signed clearly stated that the employee, in exchange for a certain amount, released IBM from all claims of any kind, including claims under the ADEA. The court noted that "[T]hree paragraphs later, the Agreement then states that ‘[y]ou agree that you will never institute a claim of any kind against IBM . . . including, but not limited to, claims related to your employment with IBM.’" The paragraph continues by stating that "[t]his covenant to sue does not apply to actions based solely under the [ADEA]."

The court held, "without a clear understanding of the legal differences between a release and a covenant not to sue, these provisions would seem to be contradictory; how can an employee bring a suit solely under the ADEA if the employee has waived all claims under the ADEA?" Thus, the court allowed the employee to continue his age discrimination suit.  

**Thomforde v. Inter'l Bus. Machs. Corp.,** 406 F.3d 500 (8th Cir. 2005).

*Employers must ensure that releases comply with the strict requirements of the OWBPA and the ADEA.*

**IV. DISABILITY ISSUES**

**Federal Law Trumps State “Litigation Privilege”**

Plaintiff, a licensed respiratory care practitioner, brought claims under the Americans with Disabilities Act (ADA) against Kaiser Permanente (Kaiser) that were eventually resolved through settlement. Prior to the settlement, plaintiff was terminated by Kaiser, which then reported the termination to the relevant licensing authority, California’s Respiratory Care Board (Board). When the Board investigated plaintiff’s conduct, plaintiff objected to various actions of his employer in responding to the investigation, including the failure to amend his records to show that he was allowed to resign from his position rather than having been terminated. Plaintiff brought additional claims against Kaiser including claims for retaliation and breach of contract.

The Ninth Circuit reversed the grant of summary judgment for Kaiser and concluded that California’s absolute privilege for communications made in the course of litigation, California Civil Code § 47(b), did not override the federal cause of action for retaliation. The court agreed with the reasoning of the Seventh Circuit in *Steffes v. Stepan Co.*, 144 F.3d 1070 (7th Cir. 1998), in which a state litigation privilege did not bar ADA and Title VII claims. Thus, the court held that claims based on conduct prior to the settlement would be barred but post-settlement claims could continue.  

**Pardi v. Kaiser Permanente Hosp.,** 389 F.3d 840 (9th Cir. 2004).

*Litigation privileges under state law do not override otherwise valid federal causes of action for discrimination.*
V. FAMILY AND MEDICAL LEAVE

Employee’s Acceptance of Light Duty Assignment Instead of FMLA Leave Does Not Establish FMLA Claim

Plaintiff, a certified nurse anesthetist at a community hospital, accepted the offer of a paid light duty assignment instead of unpaid leave under the Family and Medical Leave Act (FMLA) after suffering a wrist injury. When she was cleared to return to her regular position, she was unable to find a new nursing position with the employer. Her previous position had been protected during the first twelve weeks of her light duty assignment.

The court, ruling on a motion for summary judgment, found that there was insufficient evidence that the plaintiff had been coerced into accepting the light duty assignment, that she was never denied the right to take FMLA leave, and that she received the same twelve weeks of job protection she was entitled to under FMLA. The court held that FMLA is satisfied as long as acceptance of the light duty assignment is voluntary and the employee gets twelve weeks of job protection, whether that twelve weeks is spent on leave, light duty or a combination of the two. Artis v. Palos Community Hosp., 2004 WL 2125414 (N.D. Ill. 2004).

This case confirms the ability of employers to place injured workers on light duty assignments as long as employees are given protection equal to their rights under FMLA.

Suspicious Timing May be Sufficient to Support FMLA Claim by Terminated Employee

Plaintiff was a hospital administrator. According to his supervisor, he came to a meeting one day with alcohol on his breath. Plaintiff’s supervisors referred him to a rehabilitation program. Plaintiff met with an evaluator, who diagnosed him with “chemical abuse.” Based on the evaluator’s recommendation, plaintiff participated in a five week treatment program at a recovery center. Before participating in the treatment program, plaintiff’s supervisors had documented some performance concerns, and had met with plaintiff to discuss the resolution of these performance problems. While plaintiff was in treatment, additional performance problems came to the attention of his supervisors, including complaints by other employees about plaintiff’s treatment of the staff and plaintiff’s administrative leadership skills. His supervisors decided not to reinstate him. Plaintiff sued his employer, alleging, among other things, that his termination violated the FMLA.

The Sixth Circuit held that plaintiff presented a triable question of fact on his FMLA claim. Although the employer presented some evidence of performance problems justifying plaintiff’s termination, the court found the timing of plaintiff’s
termination suspicious enough to create an issue of fact for the jury. The court emphasized that the employer was aware of many of the same alleged performance deficiencies prior to plaintiff’s FMLA leave, but never intended to terminate him for those deficiencies until after he took his leave. This timing “could lead a fact finder to infer that [plaintiff] would not have been fired absent his actual taking of that FMLA leave.”


*Employers deciding to terminate an employee who has requested or taken FMLA leave must be careful to ensure that the timing alone does not invite a lawsuit. An employer should only terminate the employee if it would have done so regardless of the leave – and can prove it.*

**VI. MISCELLANEOUS**

**California Voters Overturn Mandate for Worker Healthcare Insurance**

In November 2004, California voters narrowly defeated Proposition 72, which would have mandated large and mid-size employers in the state to provide individual and dependent healthcare coverage. Over time, the proposal could have applied to employers with as few as twenty employees. The initiative was narrowly defeated, with an almost equal percentage of votes on each side. Employers would have been required to pay eighty percent of the cost of coverage and either purchase private coverage or participate in a state medical insurance board. The vote overturned a law enacted at the end of the former governor Gray Davis’ administration.

**Ninth Circuit Rules That Employers Must Complete All Non-Medical Aspects Of Application Process Before Conducting Any Medical Exams Or Inquiries**

Three plaintiffs with HIV independently applied for flight attendant positions with American Airlines (Company). Each was interviewed at the Company’s headquarters in Dallas and given conditional offers of employment contingent upon passing both background checks and medical examinations. While the applicants were in Dallas (and before the background checks were completed), American Airlines sent each to the Company’s on-site medical department for medical examinations. Although Company policy obligated them to answer each question truthfully, none of the applicants disclosed his HIV-positive status. Later, when the Company learned through blood tests that each was HIV-positive, the Company rescinded the job offers citing the applicants’ failure to disclose relevant information during their medical examination.

The Ninth Circuit held that the plaintiffs could sustain a claim against the Company under the ADA and FEHA because it required a medical examination before it had made a “real” job offer to the applicants. The court stated that “the ADA and FEHA not only bar intentional discrimination, they also regulate the sequence of employers’ hiring processes” by, among other things, prohibiting
medical examinations and inquiries until after the employer has made a “real” job offer to an applicant. A job offer is “real” only if “the employer has evaluated all relevant non-medical information which it reasonably could have obtained and analyzed prior to giving the offer.” Because the offers to the applicants were subject to both medical and non-medical conditions when they were made, they did not constitute “real” job offers. Thus, the medical examination process was premature and the Company could not penalize the applicants for failing to disclose their HIV-positive status unless it could establish that it could not reasonably have completed the background checks beforehand.

**Leonel v. American Airlines, Inc.**, 400 F.3d 702 (9th Cir. 2005).

*This case is significant because it appears to have effectively removed an employer’s ability to be flexible in its hiring processes. Rather, according to the Ninth Circuit, an employer must complete all non-medical components of its application process before conducting any medical examinations/inquiries. In addition, employers who conduct post-offer, pre-employment medical inquiries should be careful to ensure that (1) all applicants are treated the same; (2) any information gathered is kept in a separate, confidential medical file; (3) the information is not used in a discriminatory or otherwise illegal manner; and (4) if required by state law, medical inquiries/exams are job-related and consistent with business necessity. An employer may also have obligations where a post-offer, pre-employment physical reveals that an employee cannot perform the essential functions of the job.*
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New York Federal Court Dismisses Nursing Home’s Claim That Federal and State Officials Conspired to Violate Its Federal Constitutional Rights

The owners of Beechwood Restorative Care Center (Beechwood) brought an action under 42 U.S.C. § 1983 against several state and federal officials alleging that the government officials deliberately misused their regulatory powers to cause permanent closure of Beechwood in violation of the U.S. Constitution. Beechwood claimed that the officials retaliated against them by finding unwarranted deficiencies and pursuing permanent closure because it exposed problems with the actions and practices of the government officials.

In a hearing before an administrative law judge (ALJ) from the state Department of Health (DOH), the ALJ sustained the DOH’s actions. Based upon this opinion, DOH revoked Beechwood's license and imposed a substantial civil money penalty. Contemporaneously with the state administrative proceeding, Beechwood also filed a federal administrative appeal challenging survey findings that were the basis of the facility's termination of participation in the Medicare and Medicaid programs. Beechwood lost the federal administrative appeal when a federal ALJ held that DOH's findings of noncompliance were proper.

Based on the doctrine of collateral estoppel, the United States District Court for the Western District of New York dismissed Beechwood’s constitutional claims. The court found that the state ALJ had already determined, as a factual matter, that no conspiracy existed between government officials. Further, the court concluded that DOH did not violate Beechwood’s constitutional rights by terminating its license and holding a state regulatory hearing prior to the federal hearing.


The district court’s dismissal of plaintiff’s claims is under appeal to the Second Circuit. Notably, however, one of the district court’s conclusions not appealed – that there exists no prohibition against holding a state administrative hearing regarding a facility’s compliance with federal law prior to a federal administrative hearing – may be helpful to providers defending motions to stay during parallel state and federal administrative appeals.

Sixth Circuit Says Existence of Factual Disputes Regarding Alleged Patient Care Violations Entitles Nursing Home to In-Person Hearing

State surveyors cited Crestview Parke Care Center (Crestview) in Cincinnati, Ohio, for numerous violations of federal regulations, including failing to provide necessary care to residents. The Centers for Medicare and Medicaid Services
(CMS) eventually levied a penalty against Crestview of $27,600 for its noncompliance. Crestview appealed to the Department of Health and Human Services (DHHS) Departmental Appeals Board (DAB). After the parties filed pre-hearing briefs and accompanying declarations, the ALJ opted not to hold an in-person hearing, concluding that the matter could be settled based on the written submissions because “certain material facts . . . are not in dispute.” The ALJ denied Crestview’s objection to the cancellation of the hearing and eventually granted CMS’ motion for summary judgment. After a three-judge panel of the DAB affirmed the ALJ’s decision, Crestview appealed.

The Sixth Circuit vacated the decision, finding that, because genuine issues of material fact did exist as to some of the facility’s alleged acts of noncompliance, the ALJ should have held an in-person hearing. The court concluded that the DAB could decide cases as a matter of law without an oral hearing when it is clear there are no genuine material disputes to be resolved. The court found, however, that the federal regulation governing quality of care, 42 C.F.R. § 483.25, "is not a strict-liability regulation" and that genuine issues of material fact existed concerning the quality of care. Thus, summary judgment was improper. **Crestview Parke Care Ctr. v. Thompson**, 373 F.3d 743 (6th Cir. 2004).

When genuine issues of material fact exist regarding an issue within the DAB’s jurisdiction, the provider has a right to an in-person hearing before an ALJ.

**Florida Appeals Court Says Nursing Home Arbitration Agreement Was Enforceable Even Though It Prevented Residents From Resolving Statutory Claims in Court**

Plaintiff argued that an arbitration clause in a nursing home admission agreement that prevented residents from addressing statutory claims in court should not be enforced because it called for the arbitration to be conducted by the National Health Lawyers Association (NHLA, now the American Health Lawyers Association) whose discovery and evidence rules conflicted with state statutes. The trial court denied arbitration, holding the arbitration clause, by adopting the NHLA rules of procedure, "substantially infringes upon the statutory rights of the resident." The trial court concluded that the provision requiring "binding arbitration" by NHLA was unenforceable as a matter of law.

The Florida District Court of Appeal, Fourth District, reversed, holding the trial court did not have the power "to decline to enforce an arbitration agreement simply because it waives the judicial remedy of access to a court to resolve claims arising under statutory rights." In so holding, the appeals court noted that recent Florida Supreme Court precedent favors the enforcement of arbitration agreements when possible. The appeals court found nothing in the nursing home statutes that addressed the waiver of certain civil remedies in arbitration clauses. **Richmond Healthcare, Inc. v. Digati**, 878 So.2d 388 (Fla. App. 2004).
Like most statutory rights, the right to certain civil remedies, including punitive damages and access to court, may be waived by a nursing home resident if done so knowingly and in a manner that is not unconscionable. For further guidance on drafting arbitration agreements, purchase the “Issues in Drafting and Using Arbitration Clauses in Long Term Care” teleconference recording and materials at http://www.healthlawyers.org/teleconf_materials.cfm.

First Circuit Joins Ninth and D.C. Circuits in Holding That Deduction for Medicare Overpayments During Nursing Home’s Bankruptcy is Permissible Recoupment

During year 2000, the Health Care Financing Administration (HCFA) (now CMS) determined that it overpaid Holyoke Nursing Home (Holyoke), a Medicare provider, $343,639 for years 1997 and 1998. HCFA deducted $177,656.25 from Holyoke’s 2000 request for reimbursement to recover part of the overpayment. Holyoke filed for Chapter 11 bankruptcy. Holyoke then sued HCFA, claiming HCFA’s pre-petition deduction of $99,965.97 was a voidable preferential transfer under bankruptcy law, and the post-petition deduction of $77,690.28 violated the automatic stay provision. The bankruptcy court granted summary judgment to HCFA, stating that the deduction from the reimbursement was a recoupment and did not constitute a preferential transfer or violate the automatic stay provision. Holyoke appealed.

The First Circuit affirmed, stating that the only issue on appeal was whether HCFA’s deduction constituted a permissible “recoupment” or an impermissible “setoff” barred by the automatic stay provision. The court determined that the relevant issue was whether the debt owed to HCFA arose out of the "same transaction" as the debt HCFA owed Holyoke. The court noted that the Medicare law and the bankruptcy code have not addressed the issue, and other federal appeals courts have split over the issue. The First Circuit agreed with the reasoning of the D.C. Circuit and the Ninth Circuit, which held that recoveries of Medicare overpayments relating to previous cost years are permissible recoupments. The court rejected Holyoke’s argument that recoupment is an equitable doctrine and the case should be remanded for equitable balancing because "HCFA has the unqualified right to recoup these overpayments in full." Therefore, the appeals court held equitable balancing was not warranted. Holyoke Nursing Home, Inc. v. Health Care Financing Admin., 372 F.3d 1 (1st Cir. 2004).

Because it is well settled that a post-petition “setoff” violates the bankruptcy automatic stay provision but a “recoupment” does not, the distinction is critical. The split among the federal appeals courts continues to develop, with the D.C., Ninth, and First Circuits applying the “same transaction” test in favor the government, while the Third Circuit uses a different analysis that favors providers.
Class Action Challenges Federal Regulation Allowing Feeding Assistants in Nursing Homes

Patient advocacy groups filed a class action on behalf of the State of Washington’s nursing home residents against DHHS, requesting the court to declare illegal the federal regulations allowing nursing homes to employ trained feeding assistants, 42 C.F.R. §§ 483.35(h) and 483.73(e)(1). According to the plaintiffs, the regulations violate the federal Nursing Home Reform Act by allowing feeding assistants to provide direct care because their training is less than that required of certified nurse aides (CNAs).


Because many states have already adopted their own feeding assistant regulations for nursing homes, resolution of this case will have a significant effect on the long term care profession. To read the plaintiff’s complaint, go to: http://www.nsclc.org/news/04/july/feedasst_finalcomplaint.pdf

HHS ALJ Concedes That Definition of “Good Cause” Standard Applied to Untimely Hearing Requests May be Unsettled

The Heritage Center (Heritage), a nursing home located in Morristown, Tennessee, argued that the deadline to file a hearing request may be extended for “good cause shown” pursuant to 42 C.F.R. § 498.40(c)(2). Heritage believed it demonstrated good cause because: (1) the notice advising Heritage of its right to a hearing from CMS failed to convey explicit notice of the sixty-day deadline; and (2) Heritage’s request for informal dispute resolution tolled the sixty-day deadline. CMS filed a motion to dismiss Heritage’s hearing request as untimely.

The ALJ found that Heritage’s contentions did not rise to the level of good cause. The ALJ determined that the regulations employ, but do not define, the term “good cause.” The ALJ found that attempted showings of good cause have been evaluated by a using the standard enunciated in Hospicio San Martin, Dec. No. 1554 (1996). The Hospicio standard is whether circumstances beyond the provider’s ability to control caused the delay. Citing dicta in three different DAB decisions, however, the ALJ noted that the proper definition of good cause “may not be settled with finality.” But because the ALJ could not find any other standard in prior decisions, he applied the standard from Hospicio.


This decision correctly emphasizes that the definition of “good cause” is not settled with finality. Thus, in appropriate test case circumstances, providers who have not met the sixty-day deadline for filing a hearing request should consider proposing another definition that is supportable under the principles of administrative law.
HHS DAB Further Clarifies Definition of “Immediate Jeopardy”
A survey conducted by the Minnesota Department of Health concluded that Innsbruck HealthCare Center (Innsbruck), a skilled nursing facility in New Brighton, Minnesota, failed to comply substantially with the requirements of 42 C.F.R. § 483.25(i)(2) because it did not provide therapeutic diets to several of its residents who were assessed with nutritional deficits. CMS agreed, and, as a consequence, determined that Innsbruck would lose its authority to conduct a Nurse Aide Training and Competency Evaluation Programs for a period of two years.

Innsbruck sought a hearing before an ALJ. CMS moved for summary judgment, arguing that no genuine issues of material fact existed regarding whether Innsbruck’s noncompliance rose to the level of immediate jeopardy. Innsbruck conceded that it did not substantially comply with § 483.25(i)(2), but contended that its noncompliance did not warrant an immediate jeopardy finding. The ALJ granted CMS’s motion for summary judgment.

The DAB reversed and remanded, holding that “where there is no actual harm, the regulations specify that immediate jeopardy exists only if the noncompliance is ‘likely’ to cause serious harm. A mere ‘risk’ of serious harm is not equivalent to a likelihood of serious harm. Nor is the failure to follow an item in a plan of care sufficient in itself to establish a likelihood of serious harm, and the degree of likely harm is itself a question of fact.”


Considering the increased frequency of motions for summary judgment in DAB cases, this decision may be helpful to providers defending such motions. More importantly, the decision adds to the growing number of recent DAB decisions that clarify the definition of “immediate jeopardy” in cases where there is no actual harm.

HHS ALJ Concludes That a Nursing Home Cannot Appeal From the Loss of Its Prospective Ability to Have a Nurse Aide Training Program
The Texas Department of Human Services conducted a survey at Briarcliff Nursing and Rehabilitation Center (Briarcliff), a nursing home located in McAllen, Texas, and found several instances of substantial noncompliance. As a result of that survey, CMS imposed several sanctions, including withdrawal of approval for Briarcliff’s Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years. Brianwood, which did not have a NATCEP at the time of the sanction, requested a hearing before an ALJ.

CMS filed a motion to dismiss. CMS conceded that 42 C.F.R. § 498.3(b)(16) permits a facility to appeal a citation that leads to the “loss of approval of an existing NATCEP,” but argued that Brianwood could not avail itself of that regulation because it did not then have an existing NATCEP. Briarcliff contended
that, because the sanction ran for a period of two years, it should be permitted to appeal the remedy and thus preserve its ability to create a NATCEP during that two-year period. The ALJ granted CMS’s motion to dismiss, concluding that Briarcliff’s “prospective view of its property right in a future NATCEP . . . must be rejected” because Briarcliff does not have “any interest, plan, or expectation of attempting to gain approval of a NATCEP.”

Briarcliff Nursing and Rehabilitation Center v. CMS, Dec. No. CR1228 (Dep’t Health and Human Servs. Dep’t Appeals Bd. Oct. 6, 2004).

Under the logic of this decision, there is no ability for a provider to appeal the loss of approval of a NATCEP if it does not currently have one, even though the provider may desire to create a NATCEP in the future. The decision does not address the validity of the sanction under such circumstances, nor does the decision indicate whether such a provider has the ability to create and seek approval for NATCEP during the two-year period.

Federal ALJ Concludes That CMS May Not Terminate Home Health Agency’s Medicare Participation for Past Noncompliance

The State of Colorado’s Department of Health (DOH) surveyed ACT of Health (ACT), a home health agency, for compliance with the Medicare requirements of participation. The surveyors concluded that ACT’s noncompliance was so egregious as to constitute immediate jeopardy to beneficiaries under its care; therefore, CMS notified ACT in writing that it concurred with DOH’s findings and determined that, unless the immediate jeopardy level deficiency was corrected by February 28, 2004, it would terminate ACT’s participation in Medicare. DOH did not conduct a revisit survey. On February 28, 2004, CMS terminated ACT’s participation in Medicare. ACT requested an expedited hearing before a federal ALJ to contest CMS’s determination to terminate its Medicare participation.

The ALJ found that, as of February 5, 2004, ACT’s noncompliance rose to an immediate jeopardy level. However, the ALJ also concluded that ACT corrected the immediate jeopardy before February 28, 2004, CMS’s threatened and actual date of termination. The ALJ noted that “CMS was not obligated to offer Petitioner an opportunity to correct its deficiency prior to terminating Petitioner’s participation.” The ALJ concluded that CMS waived its ability to terminate on February 5 and then could not terminate on February 28 for the noncompliance that existed previously. The ALJ, pursuant to the Social Security Act, thus afforded ACT six months from February 5 to attain substantial compliance.


This decision reaffirms the important principle that long term care providers have the ability to prove that they attained substantial compliance with Medicare participation regulations before remedies go into effect, regardless of whether the state health department conducts a revisit survey.
Federal District Court in Arizona Rules That State Medicaid Program Fails to Comply With Equal Access Provision

Medicaid beneficiaries in Arizona brought the class action against the Arizona Health Care Cost Containment System (AHCCCS), which administers the state’s Medicaid program. The plaintiffs receive home-based long term care services including attendant care, personal care, homemaker services, and respite services. They argued that they were unable to receive some or all of the services due to low wages paid by the state's Medicaid system.

The plaintiffs relied on 42 U.S.C. § 1396a(30)(a), the Medicaid Act’s “equal access provision,” which requires state Medicaid programs to assure that payments to providers are “consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area . . . .” The court concluded that AHCCCS' “inadequate payment rates, in addition to the methodologies employed by its Program Coordinators in enlisting sufficient providers, were not consistent with quality of care and access.” Therefore, the court issued an order requiring the state Medicaid program to offer a rate of pay to home healthcare workers that is sufficient to attract enough workers to deliver all of the services for which Medicaid beneficiaries qualify.


Disability advocates nationwide are praising the ruling and believe that it could serve as a blueprint for other states with perceived access and quality of care problems.

U.S. Court in California Finds Subacute Provider Liable Under False Claims Act

In a civil suit against St. Luke’s Subacute Hospital and Nursing Center (St. Luke’s), the U.S. District Court for the Northern District of California granted the government’s motion for partial summary judgment as to the issue of liability under the False Claims Act (FCA). The court also found St. Luke’s liable for violations of 31 U.S.C. § 3729(a)(1)-(3) for submission of false Medicare reimbursement claims for the costs incurred for nursing services. Following an investigation by the Department of Health and Human Services’ Office of the Inspector General (OIG), evidence revealed an allocation of unusually high nursing costs to Medicare patients and the fabrication of nursing schedules. The proceedings to determine the amount of damages, including penalties, are pending but remain stayed under a previous court order. In a related criminal action based on the OIG investigation, a jury found defendants guilty on all counts charged.

This case demonstrates that after a criminal conviction for false claims, a collateral civil action for the same false claims can unfold rapidly.

Florida Supreme Court Holds That Deceased Patient’s Wife Lacks Standing to Claim a Violation of Patient Rights Statute

In answering a question of law certified to it by a state trial court, the Florida Supreme Court held that the wife of a deceased patient cannot sue a nursing home under Florida’s patient rights statute when the patient’s death did not result from the alleged abuse or neglect. Although the patient allegedly suffered from pressure sores, permanently locked limbs, and dehydration while at the nursing home, it was undisputed that the patient died from heart disease rather than as a result of the alleged abuse. After the patient’s death, his wife sued the nursing home on his behalf for abuse and neglect under the state’s nursing home patient rights statute. The Florida Supreme Court held that the patient’s wife did not have a valid claim because the statute, on its face, did not permit survivors to sue for damages when the patient’s death did not result from the abuse or neglect.


It is important to note that this decision only applies to cases filed before May 15, 2001, when Florida’s patient’s rights statute was amended to explicitly permit representatives to sue for damages even if the inadequate patient care did not result in the individual’s death.

U.S. District Court in Pennsylvania Orders Production of Nonparty Patient Records in Employment Discrimination Case

The United States District Court for the Eastern District of Pennsylvania denied a motion for protective order filed by a nursing home in response to discovery requests from the plaintiff in an employment discrimination lawsuit alleging racial discrimination arising from a job interview. As part of the litigation, the plaintiff requested copies of medical records pertaining to a deceased patient. The nursing home requested a protective order on the grounds that disclosure of such records would violate the Health Insurance Portability and Accountability Act Privacy Standards (HIPAA) and a state statute. The nursing home argued that HIPAA protects a deceased patient’s records from disclosure. The court, while agreeing with the nursing home that a deceased patient’s records are governed by HIPAA, declined to issue the protective order because HIPAA permits disclosure of nonparty medical information in the course of any judicial or administrative proceeding under a court order even if no notice can be provided to the nonparty patient.


Federal court in Pennsylvania ruled that HIPAA permits disclosure of nonparty medical information in a judicial or administrative proceeding under a court order even if notice cannot be given to the nonparty patient.
Texas Court of Appeals Reverses Trial Court’s Denial of Motion to Compel Arbitration

The Texas Court of Appeals vacated the trial court’s order denying a motion to compel arbitration, and remanded for further proceedings. The plaintiff argued that the agreement to arbitrate was not enforceable because the agreement: (1) does not involve interstate commerce and, therefore, the Federal Arbitration Act (FAA) does not apply; (2) was signed by the son who is not the legal representative of the patient; and (3) is unconscionable. The court rejected each of the arguments and found the arbitration agreement enforceable, holding that, because the agreement expressly provided for application of the FAA, the nursing home was not required to establish that the transaction at issue involved interstate commerce. The court also held that, although the son was not legally appointed as guardian, there was legal support under Texas law for him to act on his mother’s behalf because she was incapacitated. Finally, the court rejected the plaintiff’s argument that the agreement is procedurally unconscionable because the son did not understand, speak, or read English, finding that incapacity to understand English is not a defense to a contract. Unless the plaintiff can show on remand that he was prevented from reading and understanding the contract by trick or artifice, the court ruled that the agreement is binding.


Specific reference in the arbitration agreement to the FAA may be of use in states where courts have been reluctant to find an impact on interstate commerce. As for the English language issue, it is unclear from this decision whether the patient’s son ever complained about his inability to understand, speak, or read English at the time he signed the agreement. The appellate court’s remand instructions leave the door open for factual arguments regarding “trickery” or “artifice.” Presumably, then, if a non-English speaking plaintiff contended that he asked about the meaning of the agreement and was not told of its material terms, he might still make the case that he was tricked into signing the agreement. Thus, bi-lingual agreements may be the most prudent course in regions where immigrants are common.

Sixth Circuit Affirms Dismissal of Nursing Home’s Challenge to Successor Liability for Civil Monetary Penalties

(CMS imposed civil money penalties (CMPs) against West Chester Management Company d/b/a Barbara Parke Care Center (Barbara Parke) because of alleged inadequate patient care at a nursing home it leased and operated. CMS issued Barbara Parke a notice of its right to a hearing to contest the CMPs. Over the ensuing two years, Barbara Parke: (1) requested a hearing before an ALJ; (2) ceased operating the facility and assigned its Medicare provider agreement to another company; (3) declared bankruptcy; and (4) withdrew its request for a hearing regarding the CMPs. CMS then sought to collect the CMPs from BP Care, Inc. (BP), the new lessee and operator of the nursing home, under a successor liability theory. BP sued CMS in federal district court, alleging that the successor liability scheme violated the Medicare Act’s CMP provisions, denied
BP procedural due process, and constituted arbitrary and capricious agency action under the federal Administrative Procedure Act. The district court found that it lacked subject-matter jurisdiction over most of BP’s claims. The Sixth Circuit affirmed, but held that the district court lacked subject-matter jurisdiction over all of BP’s claims. The court found that BP had actual notice of Barbara Parke’s hearing request withdrawal and could have sought administrative review of the imposed CMPs, but failed to do so. Relying on the Supreme Court’s decision in Shalala v. Illinois Council on Long Term Care, 529 U.S. 1 (2000), the Sixth Circuit concluded that because BP could have sought administrative review, the district court lacked subject matter jurisdiction.

**BP Care, Inc. v. Thompson,** 398 F.3d 503 (6th Cir. 2005).

*Like most courts that have looked at the § 405 subject matter jurisdiction issue since the Supreme Court’s ruling in Illinois Council, the Sixth Circuit looked seriously at the “Michigan Academy” exception stated in Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986), which states that subject matter jurisdiction may exist for direct court challenges to agency action where the administrative appeal process is tantamount to “no review at all.” This case also emphasizes the importance of proper due diligence during any asset purchase, and that CMP notices, hearing requests, and the like should be requested and assessed.*

**New York Supreme Court Blocks Medicaid Recoupment for Lack of Due Process**

Visiting Nurse Service of New York Home Care (VNS) is a not-for-profit certified home health agency that participates in the Medicare and Medicaid programs. During the time period relevant to the case, approximately one-in-six of VNS’s patients were dually eligible, qualifying for both Medicaid and Medicare benefits. For dually eligible patients, Medicaid is the payor of last resort. The New York Department of Health’s (DOH) auditor reviewed all dually eligible claims submitted to DOH, identified those claims that had a high probability of qualifying for Medicare coverage, and then worked with DOH and VNS to ensure those claims were filed with Medicare. Thereafter, DOH not only sought to recoup payments it made to VNS that were covered by Medicare, but also sought to recoup payments it made to VHS for which Medicare refused to reach a coverage determination due to late filing or inadequate documentation. When DOH attempted to recoup amounts exceeding those that VNS had been paid by Medicare, DOH failed to identify the particular cases for which recoupment was sought, and DOH also failed to provide VNS with an opportunity to be heard. The trial court ordered DOH to cease recoupment until after completion of a trial on the merits. On appeal, the New York Supreme Court, Appellate Division, held that: (1) VNS had a vested property interest in Medicaid payments already received and, therefore, was entitled to a pre-deprivation hearing; and (2) DOH failed to follow regulatory requirements of giving notice and scheduling a hearing within prescribed time frames.

Recoupment by states for payments made for dually eligible beneficiaries must follow regulatory requirements and afford providers due process

New Jersey Superior Court Invalidates State Annuity Regulation
After the New Jersey Division of Medical Assistance and Health Services (DMAHS) determined that an institutionalized spouse was ineligible for Medicaid based on an irrevocable and non-assignable annuity purchased for the benefit of the community spouse, the institutionalized spouse appealed. DMAHS adopted a regulation to control allegedly abusive use of annuities to shelter marital assets. The regulation allowed the purchase of an annuity for the benefit of the community spouse, but limits the amount of marital assets that may be used to purchase the annuity. The Superior Court of New Jersey Court cited the general rule that state regulations that are inconsistent with federal law are invalid under the Supremacy Clause. Notably, the court relied on CMS' State Medicaid Manual (Manual) to find that the state regulation was preempted, even though the federal Medicaid Act itself is ambiguous on the subject. Though recognizing the “less than formal” nature of the Manual, the court believed it should grant some deference to the relevant provision in determining the law so long as the provision was not inconsistent with the language of the Medicaid Act and the agency had sufficient expertise in the subject. Addressing the specifics of the annuity, the court reasoned that, since the institutionalized spouse had no ownership interest in the annuity, the irrevocable and non-assignable annuity purchased for the benefit of the community spouse cannot be considered a countable resource.


This case is significant because the New Jersey court relied on CMS’ State Medicaid Manual rather than Medicaid Act to find that a state regulation was preempted.

Sixth Circuit Affirms DAB Decision Denying Evidentiary Hearing for Nursing Home
The Sixth Circuit held that CMS, through its motion for summary judgment, established a prima facie case that Windsor Health Center (Windsor) failed to provide two residents with adequate supervision to prevent accidents pursuant to 42 C.F.R. § 483.25(h)(2). One resident allegedly fell while showering and suffered a laceration requiring stitches, and another allegedly sustained a broken leg when her leg struck the footboard of her bed while being wheeled into her room. To rebut this prima facie showing and defeat CMS’s motion for summary judgment, Windsor should have “acted affirmatively” by presenting some significantly probative evidence to support a reasonable finding that the supervision provided was not inadequate to prevent the accidents. Windsor,
however, indisputably presented no additional evidence. On appeal, Windsor also claimed that the ALJ applied the "Hillman standard," which allegedly resulted in a shift in the burden of proof from CMS to Windsor. The Sixth Circuit concluded, however, that neither the ALJ nor the Departmental Appeals Board (DAB) impermissibly shifted the burden of proof from CMS to Windsor, and that any reference to the standards set forth in "Hillman standard" did not figure into the ultimate decision. Thus, Windsor did not have a right to an evidentiary hearing before an ALJ.


_In order to defeat motion for summary judgment after CMS established prima facie case, provider must present significantly probative rebuttal evidence._

**New York High Court Reverses Appellate Division’s Order Allowing Audit of Nursing Home’s Patient Review Instruments More Than Six Years After They Were Filed**

Blossom View Nursing Home (Blossom) sought to block the New York State Department of Health (DOH) from auditing its Patient Review Instruments (PRIs), which are used to establish the state’s reimbursement rates. DOH attempted to audit PRIs for the years 1994 though 1996, but did not announce its intention to commence audits of Blossom’s PRIs for any of these years until August 2002. Blossom first argued that DOH may never audit PRIs more than six years after filing. Although the New York Court of Appeals found that state statutes and regulations establish six years as the indisputable period for record retention and audit of fiscal and statistical reports and their supporting documentation, as well as for the retention of a resident’s clinical records after discharge or death, the court held that PRIs are neither "fiscal and statistical records and reports" nor clinical records. Thus, the court concluded that DOH may audit PRIs filed more than six years ago. However, the court also decided that "[B]ecause DOH offers no better explanation than ‘administrative oversight’ (meaning inadvertence, not supervision) for the seven-year hiatus in its nearly nine-year long audit of Blossom’s July 1993 PRIs, we hold that any audit of Blossom's PRIs filed in 1995 and 1996 is untimely as a matter of law." The court declined to cite the doctrine of law on which it relied, but the holding appears to rely on the doctrines of latches or waiver.


_This case supports the axiom that, although a statue or regulation may not preclude state action beyond a specific time period, courts will nonetheless impose equitable doctrines such as latches to curtail state action unfair because of the passage of time._

**Ninth Circuit Affirms Lower Court’s Dismissal of Post-Olmstead Home and Community-Based Services “Waiting List” Claim**
The Ninth Circuit held that the U.S. District Court for the Western District of Washington correctly dismissed claims brought under Title II of the Americans with Disabilities Act (ADA) by ARC of Washington, Inc. (ARC). ARC alleged that the Washington State Department of Social and Health Services (DSHS) violated Title II of the ADA by restricting the number of people who could participate in a Medicaid Home and Community-Based Services (HCBS) waiver program for the developmentally disabled. The Ninth Circuit held that states may restrict the number of people who can participate in the special HCBS waiver program pursuant to the Medicaid Act without violating Title II of the ADA because the general ADA injunction against discrimination may not repeal the specific Medicaid provisions for limited waiver programs.

**ARC of Washington State, Inc. v. Braddock,** 403 F.3d 641 (9th Cir. 2005).

*General ADA ban on discrimination does not repeal specific Medicaid provisions regarding limited waiver programs.*

**Tennessee Court of Appeals Rules That Trial Court Cannot Decide Medicaid Cuts**

The Sixth Circuit ruled that a district court that had retained jurisdiction over a Medicaid class action consent decree had no authority over substantive decisions on the disenrollment of beneficiaries because of budget shortfalls. TennCare, Tennessee’s managed care system, had extended eligibility to the uninsurable and other beneficiary groups not covered by traditional Medicaid. Because program costs exceeded available revenues, Governor Phil Bredesen and the agency directors had determined that program reductions were necessary. Last fall, they sought approval from CMS to cut certain categories of beneficiaries from the program and to limit services to some others. After settlement negotiations with beneficiaries failed, the trial court scheduled an evidentiary hearing to resolve that issue and determine whether and how to modify the injunction. The agency filed an expedited appeal. While the appeal was pending, the trial court held its hearing but had not yet ruled when the Sixth Circuit heard and decided the expedited appeal. According to the Sixth Circuit, the trial court had exceeded both its jurisdiction and the parties’ requests for relief. The consent decree required only that the state provide sufficient notice and an opportunity to be heard before disenrolling Medicaid beneficiaries. Therefore, the trial court had no authority to address the substantive policy questions of which groups of beneficiaries or which services should be eliminated.


*Trial court had no authority to address substantive policy questions regarding Medicaid cuts; rather, its authority is limited by a consent decree to procedural issues.*

**State and Federal Legislative Efforts to Circumvent Various Court Rulings Regarding Termination of Life-Prolonging Procedures Fail**
This high profile case involved Theresa Schiavo (Theresa), a woman in a permanent or persistent vegetative state since 1990. As the guardian for Theresa, her husband Michael Schiavo (Michael) obtained an order from the guardianship court authorizing the discontinuance of artificial life support. The guardianship court determined that there was clear and convincing evidence that Theresa was in a persistent vegetative state and that she would elect to cease life-prolonging procedures if she were competent. Theresa’s parents appealed this order and initiated various other actions challenging the guardianship court’s decision. Once all judicial challenges were exhausted, Theresa’s nutrition and hydration tube was removed. Six days later the Florida Legislature enacted a law authorizing the Governor to issue a one-time stay to prevent the withholding of nutrition and hydration (the Act). Subsequently, Theresa’s nutrition and hydration tube was reinserted pursuant to the Governor’s executive order. On the same day, Michael brought a declaratory judgment action arguing that the Act was unconstitutional.

The Florida Supreme Court held that the Act was unconstitutional as applied to Theresa and on its face. The court held the Governor’s executive order effectively reversed a properly rendered final judgment and amounted to an unconstitutional encroachment on the power reserved for the judiciary. The court further held the executive order inappropriately delegated legislative power to the Governor because the Act contained no guidelines or standards to limit the Governor from exercising completely unrestricted discretion with regard to the decision to withhold nutrition and hydration.

Subsequently, Congress enacted “An Act for the relief of the parents of Theresa Marie Schiavo” (Pub. L. No. 109-3), which authorized a Florida court to grant relief in the Schiavo case. Theresa’s parents then filed a petition for a temporary restraining order (TRO), which was denied by the United States District Court for the Middle District of Florida. The district court’s opinion was based upon the standard for granting a TRO. Specifically, the court concluded that the plaintiff’s failed to show a substantial likelihood of success on the merits of any of the five constitutional and statutory claims they raised. On appeal, the Eleventh Circuit Court of Appeals affirmed, concluding that the district court did not abuse its discretion in denying the TRO. The United States Supreme Court declined to review the cases.


*This high profile case illustrates the controversial issues surrounding end of life decisions and the potential for emotions and political agendas to impact such cases.*
Medical Staff, Credentialing, and Peer Review Practice Group

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Ohio Court of Appeals Holds Information Otherwise Obtainable From an Original Source is Not Discoverable From Hospital's Peer Review Records

In a malpractice suit against a hospital and physician, plaintiffs requested documents relating to the credentialing process of the physician to obtain documents that might support the plaintiff's negligent credentialing claim. The hospital objected based on the peer review privilege. The plaintiffs' motion to compel was denied. On a motion for reconsideration, the trial court conducted an in camera review of the documents and ordered that certain portions of the credentialing file be disclosed because the documents were obtainable from original sources. The hospital appealed the discovery order, stating that plaintiffs should be required to obtain the documents from the original sources. Applying a recent amendment to the Ohio peer review statute, the Ohio Court of Appeals held that the portion of a physician's credentialing file that contained such documents was not discoverable by plaintiffs from the hospital.


Under Ohio’s peer review statute, plaintiffs may not obtain physician peer review records from hospitals but must obtain such documents from the original sources.

Ohio Appeals Court Rules That Peer Review Statute Precluded Trial Court From Requiring Hospital to Identify Documents in Its File.

Hospital that was sued over its credentialing of a physician objected to the production of peer review documents. After an in camera review, the trial court sustained the objection but ordered the hospital to produce a list identifying the documents contained within its peer review committee records that could be obtained from the original source. The hospital appealed.

The Ohio Court of Appeals ruled that the order violated the clear intent of the Ohio peer review statute, which statute makes all information considered by a peer review committee privileged and non-discoverable from the hospital. The court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files.


Ohio court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files.
Texas Supreme Court Holds That Claim Against Hospital for Negligent Credentialing is a Claim for Medical Liability

Original plaintiff, Rose, filed a medical malpractice claim against her surgeon, Fowler, for alleged injuries following cosmetic surgery performed at Garland Community Hospital. After learning of similar previous complaints against Fowler, Rose amended her complaint to include a claim for negligent credentialing against Garland. Under Texas law, “healthcare liability” claims require the submission of a supporting expert’s report. At issue for the court was whether the negligent credentialing claim was a healthcare liability claim requiring the mandated submission of such a report.

In answering in the affirmative, the court held that Garland’s credentialing decisions prior to and contemporaneous with her surgery were “an inseparable part of the medical services Rose received” and inextricably intertwined with the patient’s medical treatment and the hospital’s provision of healthcare.” Furthermore, the court noted that "without negligent treatment, a negligent credentialing claim could not exist." Thus, to comply with Texas law, a negligent credentialing claim must be supported by the testimony of an expert.


Other states have adopted the contrary view that hospital credentialing is a process apart from the provision of medical care. See e.g., Browning v. Burt, 613 N.E.2d 993 (Ohio 1993).

Court Says Hospital Peer Review Committee Not Liable for Damages in Suspension Suit

The medical staff bylaws of a non-tertiary hospital required its members to notify the hospital in the event that their clinical privileges at another hospital were subject to corrective action. Surgeon failed to disclose that his privileges had been suspended at an area hospital. When the surgeon sought additional privileges, the hospital learned of the suspension. Thereafter, an in-house review of the applicant’s surgery charts was conducted. The Medical Executive Committee (MEC) sent nine cases for an outside review. Upon learning the outside reviewer’s conclusions, the surgeon was suspended. The suspension was affirmed upon reconsideration. The surgeon requested a hearing to challenge the suspension. At the hearing, the outside reviewer did not testify but his report was admitted into evidence. The hearing officer upheld the suspension.

The trial court granted summary judgment in favor of the defendants based on the Health Care Quality Improvement Act (HCQIA). On appeal, the surgeon argued that the presumption of HCQIA immunity was defeated because hospital personnel had "sinister motives" toward him, and because he presented evidence that the material facts underlying his suspension had been falsified. The appeals court rejected these arguments, reasoning that HCQIA's immunity applies so long as the professional review action was "taken in the reasonable belief that the actions were in the furtherance of quality health care.” The court
further stated that "any purported bad faith or malice on the part of the defendants is immaterial." In addition, the appeals court rejected the challenge to the admission of the expert report, reasoning that hearsay was admissible in these types of proceedings.


*HCQIA’s immunity applies so long as the action taken was in furtherance of quality healthcare; alleged bad faith or malice does not affect the immunity granted.*

**California Court Finds Hospital May Summarily Suspend Physician Who is Imminent Threat to Patients**

Dr. Penny Pancoast is a physician with an internal medicine practice who obtained medical staff privileges at Sharp Memorial Hospital (Sharp). Pancoast’s privileges at Sharp were suspended because she had not completed a number of medical records. In the next few months, various attempts to contact Pancoast failed and her psychiatrist and other associates informed Sharp that Pancoast was stressed and possibly suicidal. Pancoast sued Sharp and its chief of staff, alleging that Sharp acted improperly in suspending her privileges and in failing to provide her with a hearing. The trial court granted Pancoast a writ of mandate directing the hospital to either restore her privileges or provide a hearing.

The California Court of Appeal, Fourth District, directed the trial court to vacate its writ. The court first turned to the issue of whether by allowing suspension where there is likely harm to prospective patients, Sharp’s bylaws go beyond the scope of California Business and Professions Code § 809.5. The court found that, read in light of the public interest in protecting patient safety, the statute protects prospective as well as identified patients. Next, the appeals court found that Sharp had an adequate basis upon which to conclude that Pancoast was an imminent threat to patients. Pancoast argued that she did not intend to begin admitting patients to Sharp as soon as her medical records suspension was over; therefore, she was not an imminent threat to patients. However, the appeals court found that the record contained a “great deal” of proof that Pancoast did intend to begin admitting patients.

**Medical Staff of Sharp Mem’l Hosp. v. Superior Court,** 16 Cal.Rptr.3d 769 (Cal. App. 2004).

*California court held that doctor whose privileges were summarily suspended by hospital could not maintain action because hospital had adequate basis for finding that doctor posed an imminent threat to patients and, as such, was justified in suspending her privileges without a hearing.*
Connecticut Supreme Court Holds State Qualified Immunity Law In Connection With Review of Physician Abrogates Common Law Absolute Immunity
Charlotte Hungerford Hospital (Hospital) contacted the Connecticut State Medical Society’s impaired physician program in March 1997 about Mohinder P. Chadha’s ability to safely practice medicine. In May 1997, the State Department of Public Health (Department) filed a statement of charges against Chadha. Several physicians submitted affidavits to the Department expressing concerns about Chadha. The State Medical Examining Board (Board) summarily suspended Chadha’s license pending a final determination. In November 1997, the Hospital submitted a report about Chadha to the National Practitioner Data Bank (NPDB). The Board subsequently entered a final determination suspending Chadha’s license.

Chadha sued the Hospital and physicians, claiming defamation against the Hospital for submitting a false report to the NPDB and malicious submission of false affidavits to the Department against the physicians. The physicians asserted special defenses, including qualified immunity under state law and common law absolute immunity for statements made in connection with a judicial or quasi-judicial proceeding. The Hospital and physicians moved for summary judgment. The trial court held that the state’s qualified immunity provisions abrogated the common law absolute immunity and that the physicians had failed to counter Chadha’s assertions of malice for purposes of granting summary judgment. The physicians appealed and the Connecticut Appellate Court affirmed the trial court’s judgment, finding that the only reasonable interpretation of the qualified immunity provisions was that they trumped the absolute immunity afforded under common law.

**Chadha v. Hungerford Hosp.,** 865 A.2d 1163 (Conn. 2005).

*Connecticut court ruled that the state’s qualified immunity regarding physician peer review abrogates absolute immunity under common law.*

Eleventh Circuit Upholds Ruling for Georgia Hospital in Challenge to Reappointment Procedures
Physician member of the medical staff resigned during an investigation being conducted by his hospital into whether he had correctly answered two questions on the reappointment application. The MEC appointed an ad hoc committee to investigate the application. An outside consultant reviewed some charts of the reappointment applicant and expressed concern that the member’s surgical complications were outside the range of statistical probability. The MEC scheduled a meeting with the physician. The physician asked if he would be required to attend the meeting if he resigned. After being told that he would not, he requested that a letter be written stating that his privileges at the hospital had not been altered, suspended or revoked. Such a letter was written and the physician then formally resigned. His resignation was accepted, and the MEC ended its investigation. A report was made to the NPDB and the state's medical
board that the physician had resigned while under investigation, the investigation had been discontinued, and no conclusions reached.

Physician appealed the summary judgment in favor of the hospital. The Eleventh Circuit affirmed the judgment for the hospital and held that the physician failed to establish that the hospital did not follow its bylaws. "The undisputed evidence showed that the investigation of the physician’s application for reappointment and of his surgical complications was conducted in a manner consistent with the hospital's bylaws, and there was no evidence to show that the hospital knowingly made a false report to the National Practitioner Data Bank."


U.S. Court in Connecticut Finds PAMII Allows Plaintiff Agency to View Peer Review Records
The State of Connecticut Office of Protection and Advocacy for Persons with Disabilities (OPA) filed suit against Thomas Kirk and other employees of the State of Connecticut Department of Mental Health and Addiction Services (Department) to compel the Department to disclose records relating to the deaths of two former residents of facilities under the Department’s control. OPA based its suit on violation of 42 U.S.C. § 1983 and the Protection and Advocacy for Individuals with Mental Illness Act of 1986, 42 U.S.C. §§ 10801-10827 (PAMII). The Department produced the requested records, except for peer review records related to the incidents in question, citing the State’s peer review statute.

The statutory language at issue states that the Department must produce “reports prepared by . . . staff of a facility . . . that describe incidents of abuse, neglect, and injury occurring at such facility.” According to the Department, this language is ambiguous with respect to disclosure of peer review records; therefore, the court must distinguish between discoverable factual records and nondiscernible records that evaluate facts. The Department argued that peer review records covered “evaluations” of facts and not “description” of facts. The court disagreed with the Department, stating that the plain meaning of PAMII is that any report discussing, recounting, or “describing” the facts of the incident must be produced.


Peer review records may be compelled under PAMII despite state statutory peer review protections.
American Health Lawyers Association

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I. ALTERNATIVE DISPUTE RESOLUTION ISSUES

Arizona Arbitration Act Does Not Apply to Employment Agreements
The Arizona Supreme Court, in a case of first impression, held that the Arizona Uniform Arbitration Act (the Act) does not apply to arbitration agreements between employers and employees. Reversing a lower court ruling holding that only collective bargaining agreements were beyond the Act’s reach, the high court concluded that the legislature intended to exempt all agreements between employers and employees from the provisions of the Act and that the Act has “no application to arbitration agreements between employers and employees or their respective representatives.”


This case is important to physician groups when drafting employment contracts in determining how disputes with employees can be settled. In Arizona, arbitration is not an option for physician employers.

II. ANTITRUST ISSUES

PHO and IPA Settle Price-Fixing Charges With the FTC
The Federal Trade Commission (FTC) issued an administrative complaint in December 2003 against Piedmont Health Alliance, Inc. (Piedmont), a physician-hospital organization (PHO) based in North Carolina, and ten of its physician members, for fixing physician prices. The FTC charged the PHO and the physicians with anticompetitive conduct that harmed consumers in four North Carolina counties, thereby violating § 5 of the FTC Act. Respondents agreed to settle the FTC charges. The consent order prohibits Piedmont and the ten physicians from entering into any kind of negotiations with payors on behalf of any physician. It also prevents the physicians from dealing with any payors. Frye Regional Medical Center, Inc., an acute care hospital that also belonged to the PHO, and its parent company, Tenet Healthcare Corporation, had earlier settled FTC charges against them concerning their role in facilitating the PHO’s price-fixing. Charges were not brought against the other member hospitals, which are non-profit.


The complaint and consent order issued by the FTC indicates the agency’s continued vigilance against anti-competitive activity such as price-fixing.
addition, this action demonstrates that the agency will actively pursue individual physicians.

ALJ Finds Texas IPA Group Guilty of Fixing Prices and Restraining Trade
A September 2003 FTC complaint alleged that physicians participating in North Texas Specialty Physicians (NTSP), an IPA comprising a substantial share of Fort Worth physicians, engaged in horizontal price fixing by collectively bargaining with health insurance plans to obtain higher prices in physician service contracts, thereby violating FTC Act § 5. The ALJ agreed with the FTC’s allegations, finding that the evidence established that NTSP physicians communicated the minimum prices acceptable for their services to NTSP, and the NTSP thereby was able to negotiate higher rates and more favorable terms for non-risk contracts than those initially offered by various health insurance plans. The FTC also provided instances in which NTSP discouraged payors and participating physicians from negotiating directly with payors, resulting in higher prices for physician services. The ALJ concluded that this anticompetitive conduct by NTSP had no plausible or valid efficiency justification and issued an order requiring NTSP to cease and desist from joint negotiation of non-risk contracts or sharing of pricing information with its members. In addition, NTSP must allow termination of all such existing contracts. Finally, for three years, NTSP must notify the FTC before entering into any arrangement with any physician under which it would act as a “messenger,” on behalf of a physician, with a payor regarding contracting issues. Both sides have appealed the ALJ’s decision.


FTC ALJ finds that non-integrated association of physicians engaged in price fixing when it polled its members on acceptable prices, used the data to screen payor agreements on behalf of the members, and prevented its members from individually considering the proposed payor contracts.

III. CONTRACT ISSUES

Court Finds Physician May Sue as Beneficiary of Trauma Services Contract
Baptist Health (Baptist) and Arkansas Trauma Surgeons, PLLC (ATS), entered into a services agreement (Agreement) under which ATS and its physicians provided on-call coverage for Baptist. A surgeon member of ATS sued Baptist for breach of contract when Baptist sought to have ATS remove the surgeon from the on-call schedule. At issue was whether the surgeon was entitled to sue as a third-party beneficiary of the Agreement.

While the Agreement between the parties did not directly speak to whether the individual physicians of ATS were intended third-party beneficiaries, the surgeon specifically alleged that the agreement and the formation of the ATS stemmed
from a discussion between Baptist and the individual physicians and, therefore, that ATS "was formed for the benefit of Baptist and the Services Agreement was entered into for the benefit of the individual physicians." The court noted the terms of the ATS operating agreement were negotiated with and approved by Baptist and included a designation of Baptist as a third-party beneficiary thereto. In addition, the selection of physicians for membership in ATS was subject to Baptist's prior approval, while the Agreement provided that each member of ATS would be compensated based upon the number of times each provided call coverage for Baptist. The court stated that "[h]ere, [the surgeon] not only pled that he benefited from the Services Agreement, but he also pled sufficient facts from which a reasonable inference can be drawn that ATS and Baptist intended to benefit him and other individual physicians."


Court found that physician who was indirect beneficiary under provider agreement for services provided by small practice group was allowed to sue hospital for breach of contract even if he was not specified as a third party beneficiary because he did indeed benefit from the services agreement.

### IV. EMPLOYMENT ISSUES

**Attending Physicians Are Not Exempt, as Managers, From Illinois State Labor Law**

Cook County Hospital (Hospital) claimed the activities of its attending physicians’ committee, the attending physicians participation in department meetings, and their development of individual care plans that involved issuing orders and directing other hospital personnel, were evidence of the physicians’ managerial status. The ALJ found that the attending physicians did not meet the definition of managerial employees because they were not engaged predominantly in executive and management functions. The Illinois Appellate Court noted that for employees to be classified as managerial under the Illinois Public Labor Relations Act, they must be “predominantly engaged in executive and management functions” and they must “exercise responsibility for directing the effectuation of management policies and procedures.” Managerial status requires “sufficient independent authority and discretion to broadly effect a department’s goals or means of achieving its goals,” the court concluded, adding that “[h]ere, the only discretion the attendings exercise is in providing patient care and results from their professional and technical expertise.” The court stated that even if the attending physicians’ work on committees and in department meetings rose to the level of executive and management functions, the doctors “do not engage predominately in such executive and management functions as required for exclusion under the Act.” Rather, the work appeared to comprise approximately ten percent of the attending physicians’ work time.

This case establishes that under Illinois labor relations law, attending physicians may not be considered exempt as “supervisors” because, although they do perform some managerial functions, they do not possess enough administrative responsibility for the state to consider such responsibility to be a major component of their employment.

Competing Physicians Allowed to Maintain Suit Against Hospital
The Idaho District Court stayed several claims involving the possible termination of competing physicians. Four physicians who were threatened with termination of their privileges for referring patients to a competing hospital, Mountain View Hospital, in which they had a financial interest, filed suit against Eastern Idaho Regional Medical Center (EIRMC), an HCA hospital. The physicians alleged that EIRMC acted illegally by using provisions of a medical staff development plan created in 2002 to punish physicians who invested in competing facilities. The doctors claimed that their terminations and the way the hospital adopted its staff development plan were a violation of their contracts and due process rights, that the hospital disparaged their professional reputations in violation of the Idaho Consumer Protection Act and tortuously interfered with their relationships with their patients, and that EIRMC unlawfully monopolized the hospital-services market in Idaho Falls in violation of the Idaho Competition Act. The parties are in settlement discussions.


This case is significant because it shows the tension between hospitals and physicians regarding competing ventures and that hospitals are implementing measures designed to ensure that physicians are not actively engaging in activities that are competitive with the hospitals. Future court proceedings will offer insight into how courts view such measures and the ability of hospitals to terminate physicians in accordance with such measures.

Summary Judgment Deemed Improper in False Claims Act Retaliation Action
Cynthia A. Schuhardt and Nancy M. Becker, coders for Washington University’s Department of Surgery (University), brought a qui tam action alleging that the University violated the FCA; the government declined to intervene in the action. Schuhardt, individually, also made a claim against the University for retaliation under the FCA whistleblower provision. Schuhardt and Becker became concerned that the University was billing for procedures and services as if rendered by a teaching physician when those services were actually rendered by residents, fellows and nurses without the presence of a teaching physician. Schuhardt alleged that as a result of complaining to her supervisor about the billing methods, she was “humiliated, criticized, demoted, harassed and eventually discharged.” The University moved for summary judgment on all claims and the district court granted the University’s motion, finding that
Schuhardt was not engaged in a protected activity and that the University was unaware that she was engaged in the activity.

The Eight Circuit affirmed the dismissal of the qui tam action but reversed the dismissal of Schuhardt’s retaliation claim, holding that because Schuhardt told her supervisors that the University’s billing practices were “illegal” and “fraudulent,” the University had sufficient notice that Schuhardt was engaged in protected activity.

Schuhardt v. Washington Univ., 390 F.3d 563 (8th Cir. 2004).

This case is significant because it illustrates that statements made by employees to supervisors will serve as actual or constructive knowledge to an employer sufficient to prove a key element of a FCA whistleblower retaliation claim.

Restrictive Covenant Not Enforceable With Physicians in Counties Where Healthcare System Did Not Compete

WellSpan, a not-for-profit healthcare system, hired Dr. Philip Bayliss, a perinatologist, as the Medical Director of the Perinatal/Genetic Program at York Hospital (Hospital) and the Associate Residency Program Director for Obstetrics. Shortly before beginning work at the Hospital, Dr. Bayliss signed a professional services agreement that included a post-employment non-competition covenant. By the terms of the covenant, Dr. Bayliss agreed not to engage in the practice of perinatology in York County or its four contiguous counties for two years after termination. Dr. Bayliss announced his resignation from WellSpan and his intention to establish a maternal fetal medicine practice in another county covered by the non-competition covenant, and into which WellSpan and Dr. Bayliss had discussed the possibility of expansion of WellSpan’s maternal fetal medicine services. The trial court upheld the restrictive covenant as to two counties, but concluded that the covenant was unreasonable and unenforceable as to three counties because WellSpan did not compete for perinatology patients in those counties. On appeal, the Pennsylvania Superior Court affirmed the trial court’s judgment, noting that, in the absence of a protectable business interest, WellSpan failed to meet the threshold requirement for an enforceable non-competition contract.


This case demonstrates the importance of narrowly drafting non-compete agreements or risk facing the possibility of a court refusing to enforce the terms of such agreements.

Restrictive Covenant is Not Per Se Unenforceable or Unreasonable

Community Hospital Group (Hospital) entered into an employment agreement with a neurosurgeon that included a provision restricting the neurosurgeon from practicing within thirty miles of the Hospital for a period of two years after termination of the employment agreement. The New Jersey Supreme Court employed a three-part test to determine the reasonableness of the restrictive
covenant: whether the covenant (i) protects the legitimate interests of the hospital, (ii) imposes no undue hardship on the physician, and (iii) does not injure the public. The court determined that the covenant was within the Hospital’s legitimate interests, as it had a large role in developing the physician’s skills as a neurosurgeon, and did not impose undue hardship on the physician, as he voluntarily terminated the employment agreement. However, the court found that the public interest was harmed by the restrictive covenant because of the shortage of neurosurgeons in the area where the physician was restricted in practice, and in particular those patients presenting to the emergency room in one of the other hospitals within the restricted area would suffer harm due to the lack of neurosurgical services available to them. The court ruled that the thirty-mile practice area should be reduced to allow the neurosurgeon to provide services in these underserved areas.


This case illustrates that although a restrictive covenant may appear reasonable on its face, public interest must be served (and not harmed) by the restriction in order for courts to uphold the covenant.

V. FRAUD AND ABUSE ISSUES

DHHS OIG Approves Arrangement Whereby Pharmaceutical Companies Survey Physician Preferences

The Office of Inspector General (OIG) determined that it would not impose administrative sanctions under the Anti-kickback Statute against an independent marketing firm, specializing in direct mailings, that designs, develops, and implements physician surveys on behalf of pharmaceutical companies. Under the arrangement, the marketing firm prepares and distributes surveys containing product-specific questions designed to gather information regarding physician preferences on drug labeling and product information. The survey responses are printed on the back of a one-dollar check made out to the physician, which can either be endorsed and paid to the physician, or the physician can elect to donate the dollar to one of several non-profit organizations listed on the check. The marketing firm is paid based on the price establish in the one-year contract entered into with the pharmaceutical company.

Although the arrangement implicated the Anti-kickback Statute, the OIG concluded that the arrangement reflected a number of safeguards that mitigated the risk of fraud or abuse. First, the OIG notes that the amount of compensation paid to a physician in a twelve-month period is limited to a maximum of twelve dollars, thus reducing the risk that the survey response checks are intended to induce referrals. Second, the OIG determined that the nature and limited scope of the surveys reduced the likelihood that the survey is intended to influence physicians’ prescribing practices. Third, the OIG concluded that the marketing firm had no discernible ability to influence referrals of business for its
pharmaceutical company clients. Fourth, because the survey responses are contained on the back of a standard check that must be endorsed by a physician for deposit, the OIG determined that this feature enhanced the integrity of the survey program by safeguarding against individuals other than physician completing the survey. 


*This Advisory Opinion is significant because it offers more guidance from the OIG regarding arrangements between pharmaceutical companies and physicians.*

**DHHS OIG Allows Pathology Lab to Receive Referrals for Volunteering in Medical Assistance Program**

The OIG has determined that a proposed arrangement whereby a pathology lab would provide services on a voluntary basis to low-income, uninsured patients through a charitable foundation’s medical assistance program would not generate prohibited remuneration under the Anti-kickback Statute. As a volunteer, the pathology lab would agree to provide laboratory services at no charge for patients referred by the foundation’s volunteer physicians. The lab certified that no remuneration would be provided directly or indirectly to any volunteer physician, the volunteer pathology laboratory, the pathologists performing the laboratory services, or the foundation. In determining that the proposed arrangement poses no apparent risk of fraud and abuse under the Anti-kickback Statute, the OIG concluded that the lab’s voluntary participation did not result in any economic value to any party in a position to refer Federal healthcare program business to the lab. 


*This Advisory Opinion demonstrates that arrangements that do not result in any economic value to parties who make referrals to Federal healthcare programs do not violate the Anti-kickback Statute.*

**DHHS OIG Determines That Proposed Physician-Owned Physical Therapy Center Cannot Lease Its Space, Equipment, and Personnel to Physicians**

The OIG has determined that a proposed arrangement involving a physician group’s intention to develop and own a comprehensive physical therapy center that leases its space, equipment, and personnel to physicians requiring physical therapy services would implicate the Anti-kickback Statute. Under the arrangement, the center would be open on an unlimited first-come, first served basis in which each lessee would bill Medicare, Medicaid, and other third-party payors for services provided at the center. Each lessee would enter into a one-year lease with the physician group and pay a monthly rental fee for unlimited use of the center. The OIG declined to rule out administrative sanctions because
the physician group and lessees “are potential sources of referrals of Federal healthcare program business for one another.”


*This Advisory Opinion is significant because it provides insight into what kind of structure implicates the Anti-Kickback Statute.*

**DHHS OIG Approves Arrangement Between Geriatric Group Practice and Consulting Physicians**

The OIG has determined that a geriatric group’s proposal to employ primary care physicians who treat residents before their admission to a nursing home as consultants would not generate prohibited remuneration under the Anti-kickback Statute. Under the arrangement, the consulting physicians would be available to respond to questions from the group about a particular patient’s medical history. The consulting physician would receive fifty dollars per hour for a maximum number of hours per month based on the number of patients for which they consult. The group provided the OIG with a private letter ruling issued by the Internal Revenue Service (IRS) indicating that the consulting physicians qualify as bona fide employees of the group. Considering the IRS definition of bona fide employees, the OIG concluded that the Anti-kickback Statute’s employment arrangement safe harbor would apply. The OIG reasoned that where such payments are made through an employment relationship specifically deemed bona fide by the IRS, such an arrangement is protected despite the risk it otherwise presents of fraud and abuse.


*This Advisory Opinion shows that bona fide employment arrangements may be the safest way to structure physician relationships.*

**DHHS OIG Permits Rural Medical Center to Subsidize Malpractice Insurance Premiums for Obstetricians**

The OIG approved a rural medical center's two-year partial subsidization of malpractice insurance for the only four obstetricians on its medical staff. Although the arrangement failed to meet the Anti-kickback Statute's safe harbor for obstetrical malpractice subsidies, the OIG approved the subsidy because it posed no greater risk of fraud and abuse, and it furthered the purpose of the safe harbor – the delivery of adequate obstetrical care in areas in which such services are not sufficiently available.

The OIG relied not only on the fact that the medical center satisfied the remaining requirements of the safe harbor, but also on the existence of other factors favoring the approval of the subsidy: (i) the subsidy would be provided in response to sharply escalating premiums and only on a temporary, interim basis; (ii) the subsidy would not create a windfall to the obstetricians because it would
cover only part of the malpractice premium, leaving each obstetrician to pay at least as much for insurance as he paid in the year before the subsidy; (iii) the subsidized insurance would cover the obstetricians while they perform services at places other than the medical center; and (iv) the subsidy would permit the obstetricians to benefit many underserved patients in the geographic area, including persons who are the patients of a migrant workers’ clinic that is not affiliated with the medical center.


*Additional safeguards which further the purpose of the obstetrical malpractice premium subsidy safe harbor, coupled with only a minor deviation from the safe harbor's enumerated requirements, support the OIG's approval of a malpractice premium subsidy.*

**Physician Participating in Internet Pharmacy Guilty of Conspiracy to Distribute Controlled Prescription Drugs**

A physician and others created a website through which customers could order hydrocodone, a powerful and addictive painkiller. The evidence at trial showed that after customers completed a brief online questionnaire, the defendant physician signed thousands of prescriptions without ever seeing a customer. The prescriptions were then transmitted to and filled by a pharmacy operated by the physician’s co-conspirators. The pharmacy billed the customer an inflated price for the drugs and paid the physician a fee for each of the prescriptions. The physician was paid nearly $200,000 wired to a bank in Antigua.

The physician appealed his conviction, asserting that the standard for conviction under 21 U.S.C. § 846 required that he have been found to have distributed the drugs both outside the usual course of his professional practice and without a legitimate medical purpose. He argued that the trial court erred by charging the jury disjunctively rather than conjunctively. The Tenth Circuit held that it is sufficient that the physician conspired either to have distributed the drugs outside his professional practice or to have distributed the drugs without a legitimate medical purpose.

**United States v. Nelson,** 338 F.3d 1227 (10th Cir. 2004).

*Physician was guilty of conspiracy to distribute prescription drugs as the Tenth Circuit held that it is sufficient that the physician conspired either to have distributed the drugs outside his professional practice or to have distributed the drugs without a legitimate medical purpose.*

**DHHS OIG Says Pathology Lab Joint Venture Violates Anti-Kickback Statute as Suspect Contractual Joint Venture**

The OIG reviewed a request from a pathology laboratory company to enter into a series of contracts with various physician groups to operate a pathology lab for each group at an off-site location. The OIG determined that all of the entities
involved in the proposed arrangement were sufficiently related as evidenced by overlapping officers and directors, common control by a parent company and the ability to assign the contracts for the arrangement to other affiliated entities. Therefore, the OIG treated the entities as a single legal entity for purposes of its analysis of the proposed arrangement. The OIG further determined that the arrangement had many characteristics of a suspect contractual joint venture because the physician groups would contract out substantially all of the operations of the lab services, including the professional services component needed to provide the pathology services, and would bear little financial risk in the venture. As a result, the OIG found that the possibility existed that the pathology lab was offering the physician groups impermissible remuneration by giving the groups the opportunity to generate a fee and profit (to which the group would not otherwise have been entitled) and to obtain the difference between the reimbursement the physician groups received from Federal healthcare programs and the fees the physician groups paid the pathology lab. The OIG further stated that there was a “significant risk” that the proposed arrangement was an impermissible contractual joint venture that would serve to reward the physicians for their referrals to the pathology lab.


This Advisory Opinion is significant because it articulates the OIG’s longstanding position that impermissible remuneration may occur where there is the opportunity given to generate a fee and a profit (to which a party would not otherwise have had the right to bill and receive). Additionally, the OIG demonstrated its concern about “marketing the spread” by discussing this issue for the first time in a context other than pharmaceutical relationships. This Advisory Opinion also expands on the OIG’s analysis of a joint venture under the Special Advisory Bulletin on Contractual Joint Ventures. See 68 Fed. Reg. 23148 (April 30, 2003).

DHHS OIG Approves Hospital Subsidy of Physicians’ Medical Malpractice Insurance
The OIG determined that it would not impose administrative sanctions in connection with a malpractice insurance subsidy arrangement between a hospital and two neurosurgeons. Although the OIG concluded that the arrangement could potentially generate prohibited remuneration under the Anti-kickback Statute, the OIG found that the facts and circumstances of the proposed arrangement adequately reduced the risk that the arrangement would be improper under the Anti-kickback Statute. First, the facts indicated that the arrangement would be implemented as a temporary and urgent measure to prevent a gap in the local availability of neurosurgical services in the area. Moreover, the arrangement would be limited to a period of two years. Second, the OIG determined that the arrangement would be structured to prevent a significant windfall for the physician. Third, the risk of an undue benefit to the physicians would be reduced because the physicians would be required to provide call coverage, maintain a
full-time practice, serve on hospital committees, and furnish Medicaid and indigent care services. Finally, the fact that the subsidized malpractice insurance covers services furnished at sites other than the hospital minimized the risk that the arrangement would be connected to referrals.


*This Advisory Opinion is significant because it signals the OIG’s willingness to give physicians and hospitals relief on the malpractice front.*

**Doctor and Wife Found Guilty in Defrauding Government and Healthcare Plans**

Dr. Abdorasool Janati and his wife, Forouzandeh Janati, were indicted for a conspiracy in Northern Virginia to defraud the United States and private insurance plans of funds for medical reimbursement by submitting to Medicare and the private plans false claims for services allegedly performed by Dr. Janati and others in his neurology practice from 1996 to 2003. In addition to the conspiracy count, Dr. and Mrs. Janati were indicted on sixty-one additional counts alleging overt acts, representing some of the criminal conduct allegedly undertaken in furtherance of the conspiracy. Dr. Janati was the primary physician at the Neurological Institute of Northern Virginia and his wife was the Institute’s office manager. The Janatis face a maximum penalty of 615 years imprisonment, a $15.5 million fine, and full restitution to their victims.


*This case serves as a clear warning that defrauding the government and private health plans will not be tolerated. It also illustrates that not only doctors will face criminal prosecution, but also their family members and other individuals who are involved with the physician practice and are part of the illegal conduct.*

**Pharmaceutical Executives Indicted for Providing Kickbacks to Physicians**

Two former Serono vice presidents and two former regional sales managers were indicted on charges of paying kickbacks to physicians in exchange for prescribing the company’s treatment for AIDS. According to prosecutors, in an effort to boost sales of Serono’s AIDS drug Serostim, the Serono sales executives offered physicians paid trips to a 1999 AIDS conference in France in exchange for prescribing Serostim. The vice presidents were charged with conspiracy and seven counts of offering to pay illegal remuneration, while the regional sales managers were charged with conspiracy and two counts each of offering to pay illegal remuneration. The government’s investigation is continuing.

This case illustrates the government’s continued interest in the relationship between physicians and pharmaceutical manufacturers.

DHHS OIG Issues Six Concurrent Advisory Opinions Approving Similarly-Structured Gainsharing Arrangements Between Physicians and Hospitals. The OIG, through six separate Advisory Opinions, approved gainsharing arrangements between hospitals and physicians, which examined a similar fact pattern. In each opinion, the OIG stated that it would not prosecute the participants under either the Anti-kickback Statute or the civil monetary penalties statute.

The OIG concluded that it would not pursue sanctions under the civil monetary penalties statute, although technical violations of the statute were likely. The safety mechanisms inherent in the arrangements were key to this result. The most important safety mechanism in the arrangements appeared to be the "transparency" of the arrangements created by distinct and separate measures producing the gainsharing. The OIG also noted that there was "credible medical support" for the proposition that none of the arrangements would adversely affect patient care. In addition, the OIG recognized that the cost savings generated by the arrangements would not disproportionately derive from procedures financed by government programs; that excessive decreases in services would be prevented by the historically-based utilization "floor" below which no savings may be accrued; that disclosure to patients of the arrangements would permit them to scrutinize the effect of the cost saving measures; that the amount and duration of the savings to be distributed to the physicians would be limited; and that the savings to participating physicians would be distributed on a basis that did not take into account individual utilization.

The OIG also concluded that it would not pursue sanctions under the Anti-kickback Statute, although technical violations of the statute were likely. The OIG noted that none of the arrangements would likely attract additional physicians, increase referrals, or provide a means to reward referrals because participation in the arrangements was limited to existing staff members, there is a cap on the number of procedures eligible for inclusion in each of the arrangements, and each arrangement lasts for only one year. In addition, the OIG conceded that the shared gain resulting from the savings properly compensates the participating physicians for their effort in producing the savings and the added liability risk they will assume by implementing the changes to produce the savings. Advisory Op. No. 05-01 (January 28, 2005), Nos. 05-02, 05-03, and 05-04 (February 10, 2005), and Nos. 05-05, 05-06 (February 18, 2005) (Dep’t Health and Human Servs. Office of Inspector Gen.).

Specific linkage between cost savings and particular cost reduction measures, safety to patients, and unlikelihood of payments for referrals prevented OIG from imposing sanctions for gainsharing arrangements.
VI. MEDICAL MALPRACTICE ISSUES

Damages Caps Upheld in Medical Malpractice Action
The Colorado Supreme Court has ruled that a damages cap statute, which caps total and noneconomic damages in medical malpractice actions, is constitutional. The court determined that such caps did not violate any constitutional principles raised by the plaintiffs, such as the right to a jury trial, separation of powers, and equal protection. The court explained that the right to a jury trial only applies in criminal cases and that the damages cap statute is a substantive law that did not violate separation of powers by infringing on the judiciary’s constitutional rule making authority. The court further stated that the statute did not violate equal protection because the plaintiffs could not establish that they were treated differently from other persons whose cause of action accrued at the same time as theirs.

Garhart v. Columbia/HealthONE, LLC, 95 P.3d 571 (Col. 2004).

This case gives additional protection to Colorado physicians facing medical malpractice claims by upholding damages caps.

Texas Court of Appeals Holds That No Ongoing Physician-Patient Relationship Existed to Support Malpractice Claim When Minor Patients’ Parent Failed to Keep or Reschedule Clinical Appointment
A pediatric ophthalmologist examined newborn twins in a hospital neonatal intensive care unit shortly after their premature birth. The ophthalmologist noted the possibility that at least one of the twins suffered a malady called retinopathy of prematurity and scheduled an appointment for the mother to bring the twins to his office for a further examination two weeks later. The twins’ neonatologist gave the mother a letter urging her to follow up with the twins’ care with the ophthalmologist and others. The mother neither kept the appointment nor did she ever reschedule another appointment. Eventually, both twins developed further complications which led to their blindness. The mother sued the ophthalmologist, the hospital, and others for causing her children's blindness, and received a verdict on behalf of the twins against the ophthalmologist and others.

The ophthalmologist appealed, arguing that he had no continuing physician-patient relationship with the twins once the mother failed to keep or reschedule the follow-up appointment. Therefore, he argued that he had no duty to the twins and was not liable for their injury. The mother countered with the contention that, in spite of her failure to keep the twin's appointment, the neonatologist's letter created an ongoing relationship with the ophthalmologist.

The court of appeals held that the letter from the neonatologist, who was unrelated to the ophthalmologist, could not bind the ophthalmologist into an ongoing relationship with the plaintiff. Thus, the court held that the mother's failure to keep or reschedule the appointment with the ophthalmologist severed
any relationship that existed with him and absolved him of a continuing duty to the twins. 


*No continuing physician-patient relationship existed when patient failed to keep or reschedule follow-up appointment.*

**Patient Only Seeking Referral Establishes Doctor-Patient Relationship**

The Georgia Court of Appeals has ruled that a doctor-patient relationship existed where a patient admitted she only sought a referral and not treatment from a physician. The court found that on plaintiff Vivian Harris’ first visit, Dr. Alvin Griffin gave her a referral, but that he also examined her and required her to sign a consent form for treatment. Harris sued Griffin, two other doctors, and a hospital, contending that they committed medical malpractice when they failed to diagnose her herniated thoracic disk, which led to permanent neurological motor deficits. 


*This case demonstrates how easily a doctor-patient relationship is established even when it is not the intent of the parties involved.*

**VII. INSURANCE ISSUES**

**Indiana Appeals Court Holds Liability Extends to Each Act of Malpractice in a Single Surgery**

An Indiana Appeals Court has held that a malpractice insurer was liable for payment for two separate acts of malpractice where the physician breached the duty of care twice during the same surgery and in each instance caused a significant injury to the patient. The Indiana Medical Malpractice Act (the Act) provides for a cap on damages, creation of the Indiana’s Compensation Fund (the Fund), and a splitting of damages between an insurer and the Fund. The court determined that the Act was ambiguous because, when addressing how much a patient may recover, it refers to recovery for “an act of malpractice”; however, when addressing how much an insurer must pay, the Act refers to “an occurrence of malpractice”. The court determined that the Act contained no language that excuses a healthcare provider for multiple, separate acts of malpractice during a single surgery and because the physician was liable for two acts of malpractice, the insurer is liable for each act of malpractice.

**Medical Assurance of Indiana v. McCarty,** 808 N.E.2d 737 (Ind. App 2004).

*This case puts Indiana physicians and insurers on notice that there is unlimited liability where a physician causes multiple injuries to a patient even if they occur during the same procedure.*
New York Court Rules That No Payments From Insurers Required for Illegally Structured Medical Enterprises

As a result of a certified question from the United States Court of Appeals for the Second Circuit as to whether New York’s “no-fault” insurance laws would permit insurers to withhold payment for medical services provided by fraudulently incorporated enterprises, the New York Court of Appeals ruled that insurance carriers may withhold payment for services provided by fraudulently incorporated medical enterprises even if the care received by the patient was appropriate and within the scope of the licenses of the persons providing the treatment. The court further held that non-physician medical professionals who had evaded state law prohibiting non-physicians from sharing ownership in medical service corporations could not obtain payments from carriers under the state’s no-fault insurance statute.


This decision is important because it illustrates that the professional service corporation laws will be vigorously enforced in New York, and that failure to comply will result in the denial of payment for services rendered, even if the care was necessary and appropriate.

VIII. PROFESSIONAL RIGHTS

West Virginia Supreme Court Holds That Public or Quasi-Public Hospitals Barred From Excluding Physicians on Staff

Three physicians with staff privileges at Monongalia County General Hospital (Hospital) who also were employees and shareholders of Monongalia Anesthesia Associates Inc., which previously provided anesthesia services to the Hospital, challenged the Hospital’s exclusive contract with another provider that covered virtually all general anesthesia services.

The West Virginia Supreme Court rejected the physicians’ position that they had a property interest in their staff privileges and also held that the hospital’s medical staff bylaws did not constitute a contract with the physicians. It distinguished the scope of judicial review in cases involving public and private hospitals, saying that, in public hospitals, physicians do not practice at the will of the hospitals’ governing authorities, but are “entitled to practice,” so long as they stay within the law and conform to all “reasonable” rules and regulations. The court then examined whether the hospital’s decision to enter into the exclusive contract was reasonable, concluding that “the total exclusion of physicians from their hospital practices, and the concomitant complete deprivation of patient choice, simply cannot be justified “by the ends the hospital sought to achieve.

Although the court acknowledged that its decision was contrary to prevailing authority upholding exclusive contracts, it disagreed with those precedents. It found that a preferential contract would have allowed the lead plaintiff access to
hospital facilities to treat patients when he was requested, allowed the hospital management the discretion to contract to secure a primary provider of medical services to solve scheduling and staffing problems, and also would have preserved patient choice.


*West Virginia Supreme Court* set a new precedent disallowing exclusive provider agreements because such agreements unfairly excluded other physicians, hindered a patient’s right to choose his or her physician and were aimed at solving a problem that could have been addressed by less restrictive means.

**Missouri Appeals Court Finds Hospital Protected by HCQIA in Suspension of Anesthesiologist**

Keshav Joshi, M.D., worked for St. Luke’s Episcopal Presbyterian Hospital (Hospital) as an anesthesiologist from 1989 to 1996. The peer review committee at the Hospital reviewed multiple incidents in which Joshi allegedly rendered poor patient care. In addition, several nurses complained about Joshi’s care.

The Hospital’s Chief of Anesthesiology reviewed all of the complaints against Joshi and recommended a summary suspension because he believed that Joshi posed an imminent threat to patients. Joshi’s attorney requested a preliminary hearing at which a decision was rendered to continue the suspension pending a full hearing. Before the hearing took place, Joshi resigned. Joshi then sued the Hospital, the Chief of Anesthesiology, and others (Defendants) seeking damages and injunctive relief. Defendants moved for summary judgment, claiming that they were entitled to immunity under the Health Care Quality Improvement Act (HCQIA). The trial court granted defendants summary judgment, but denied their request for attorneys' fees.

Rejecting Joshi’s argument that Defendants did not make a reasonable effort to find the facts of the matter, the appeals court found that the totality of the evidence showed that Defendants’ efforts to obtain the facts were more than reasonable. The appeals court further found that adequate notice and a full and fair hearing were provided to Joshi. Lastly, the appeals court held that the numerous complaints about Joshi, along with various reports, demonstrated a reasonable belief that the action was warranted. Accordingly, the appeals court affirmed the trial court’s judgment.


*This case is important because it recognized the continued viability and necessity of HCQIA immunity.*
California Court Finds Hospital May Summarily Suspend Physician Who is Imminent Threat to Patients

Dr. Penny Pancoast is a physician with an internal medicine practice who obtained medical staff privileges at Sharp Memorial Hospital (Sharp). Pancoast’s privileges at Sharp were suspended because she had not completed a number of medical records. In the next few months, various attempts to contact Pancoast failed and her psychiatrist and other associates informed Sharp that Pancoast was stressed and possibly suicidal. Pancoast sued Sharp and its chief of staff, alleging that Sharp acted improperly in suspending her privileges and in failing to provide her with a hearing. The trial court granted Pancoast a writ of mandate directing the hospital to either restore her privileges or provide a hearing.

The California Court of Appeal, Fourth District, directed the trial court to vacate its writ. The court first turned to the issue of whether by allowing suspension where there is likely harm to prospective patients, Sharp’s bylaws go beyond the scope of California Business and Professions Code § 809.5. The court found that, read in light of the public interest in protecting patient safety, the statute protects prospective as well as identified patients. Next, the appeals court found that Sharp had an adequate basis upon which to conclude that Pancoast was an imminent threat to patients. Pancoast argued that she did not intend to begin admitting patients to Sharp as soon as her medical records suspension was over; therefore, she was not an imminent threat to patients. However, the appeals court found that the record contained a “great deal” of proof that Pancoast did intend to begin admitting patients.

Medical Staff of Sharp Mem’l Hosp. v. Superior Court, 16 Cal.Rptr.3d 769 (Cal. App. 2004).

California court held that doctor whose privileges were summarily suspended by hospital could not maintain action because hospital had adequate basis for finding that doctor posed an imminent threat to patients and, as such, was justified in suspending her privileges without a hearing.

Texas Court Found Employer Did Not Waive Contractual Automatic Termination and There Was No Defamation Based on Employer's Post-Termination Comments to Patients

Physician's employment automatically terminated according to the terms of her employment agreement after she had been disabled for three months. Nevertheless, after the termination date passed, the clinic-employer wrote to her stating that her employment was considered in "inactive status," thus allowing her to continue to receive insurance and other benefits during her disability. The letters advised her, however, that there was no assurance that she would be reinstated to her former position.

Eventually, the physician recovered from her disability and requested her former position, asserting that the letters advising her that she had been retained on "inactive status" constituted a waiver of the automatic termination provision of the
employment agreement. The court denied the "waiver" claim, observing that a right must currently exist in order for it to be waived. Because the employment agreement had already automatically terminated before the purported waiver occurred, the right was extinguished with the termination of the agreement.

The physician further claimed that the employer's answers to patient inquiries about the physician were defamatory. The court observed that the statements, though not entirely accurate, were "substantially" true and, therefore, as a matter of law, not defamatory. Further, the court found that Texas law provides a qualified privilege for non-malicious statements "made by employees of a medical employer to the patients of a former employee-physician for the purpose of explaining the whereabouts of [a] former [physician] employee." In this case, the court found no showing of actual malice on the former employer's part; accordingly, the court affirmed the dismissal of the defamation claim. 


*Under Texas law, waiver of employment termination is not possible after such termination became effective; also, defamation cannot be based on substantial truth or non-malicious statements to patients about former physician's whereabouts.*

**Court Rules DHHS Bound by HIPAA When Reviewing NPDB Reports But Physician’s Action Challenging Record Was Time-Barred**

St. John’s Mercy Medical Center (St. John’s) in St. Louis, Missouri filed an adverse action report with the National Practitioner Data Bank (NPDB) after it summarily suspended an unidentified physician (plaintiff) for an indefinite period of time as required by the HCQIA. Plaintiff objected to the reference to a “positive” psychiatric evaluation in the revised report and asked DHHS to amend the records pursuant to HIPAA. DHHS informed plaintiff that his only administrative remedy was through the procedures for disputing information contained in the NPDB under 45 C.F.R. § 60.14. Applying the regulation, the DHHS Secretary concluded that the revised report was inaccurate and amended it to indicate that plaintiff “was not suffering from any type of psychiatric disorder.” However, plaintiff still objected, arguing that pursuant to HIPAA, the NPDB records should make no reference whatsoever to a psychiatric evaluation.

The U.S. District Court for the District of Columbia held that HIPAA, which requires an agency to “make reasonable efforts” to assure the accuracy, completeness, relevance, and timeliness of records disseminated about an individual, provides more protection than the DHHS regulations for challenging a record submitted to the NPDB. However, the court found that plaintiff’s HIPAA claims were time-barred under the applicable two-year statute of limitations. The court rejected plaintiff’s contention that a new cause of action was initiated every time DHHS disseminated the report after he notified the agency of the problem. The critical time period, said the court, is when plaintiff knew or should have
known of the alleged inaccuracy in the NPDB report. Accordingly, the court granted summary judgment in the Secretary’s favor on the ground that the action was time-barred.


*This case is significant because it explains when HIPAA’s statute of limitation begins – when the plaintiff become aware of the privacy violation. Furthermore, it explains that the government must adhere to HIPAA’s requirements in processing disputes regarding disputed National Practitioner Data Bank reports because HIPAA is more protective.*

**California Appeals Court Holds Physician Alleging Tort Claims Against Medical Group Bound by Arbitration Clause in Employment Agreement**

Physician Carl Buckhorn entered into an employment agreement with St. Jude Heritage Medical Group (Group). The employment contract included an arbitration clause. The St. Jude Heritage Health Foundation (Foundation), which provides healthcare facilities and administrative support in exchange for medical services rendered by the Group through a professional services agreement (PSA), was named as a third-party beneficiary of the employment contract. The PSA was subsequently amended to include a mandatory arbitration provision. Buckhorn sued the Group and the Foundation (collectively, Defendants) after he was terminated. In addition to his wrongful termination claims, Buckhorn also claimed defendants committed various torts after he was discharged, including defamation and interference with prospective economic advantage. Defendants moved to compel arbitration under the employment contract and the PSA. The trial court denied the motion. In its final order, the trial court found that Buckhorn was not bound by the arbitration clause in the PSA but did not refer to the arbitration clause in the employment agreement. Defendants appealed.

The California Court of Appeal, Fourth Appellate District, reversed, holding that the arbitration clause in the employment agreement applied to all of Buckhorn’s claims including those alleging Defendants engaged in tortious conduct against him after his termination. Buckhorn failed to show that his tort claims were “wholly independent” of the employment agreement; therefore, the appeals court held that they should have been submitted to arbitration.


*Arbitration clause in employment agreement applied to all of plaintiff physician’s claims, including those claims that arose after termination, as such claims were rooted in the contractual relationship.*

**Minnesota Law Does Not Prohibit the Corporate Employment of Chiropractic, Physical Therapy, or Massage Therapy Practitioners**

Jeannette Couf, a layperson not licensed as a healthcare provider, is the sole shareholder of three clinics that provide chiropractic, physical therapy, and
massage services. The clinics are not organized under the Minnesota Professional Firms Act, but instead are organized under the Minnesota Business Corporation Act. The clinics provided treatment to various individuals involved in car accidents who had no-fault insurance through defendant, Progressive Northern Insurance Company (Progressive). The clinics employed various people, including licensed chiropractors, to perform these treatments. While Progressive initially covered these treatments, it stopped paying for them in the spring of 2002. Couf brought five suits against Progressive, alleging breach of contract and a violation of the Minnesota Fair Claims Practices Act. Progressive brought a counterclaim in each case alleging violations of the corporate practice of medicine doctrine and the Minnesota Professional Firms Act. On appeal from summary judgment, Couf argued that Minnesota law allows regular business corporations to provide chiropractic, physical therapy, and massage therapy, as long as duly licensed professionals are responsible for directly and independently providing the healthcare services. The Minnesota Court of Appeals found that neither statutes nor case law barred the corporate employment of chiropractic, physical therapy, or massage therapy practitioners. 


*Minnesota does not prohibit the corporate practice of chiropractic, physical therapy, and massage services*

**Consumer Protection Law Does NotAuthorize Suit Against Physician**

Clair Henderson brought actions against Dr. Winston Gandy, Jr., and the Atlanta Cardiology Group alleging malpractice in causing her husband’s injury and death from a pressure ulcer following by-pass surgery. After discovery commenced, Ms. Henderson filed an amended complaint alleging that her husband’s medical records were altered in violation of Georgia’s Fair Business Practices Act (FBPA), which forbids and declares unlawful any unfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce. The trial court dismissed the plaintiff’s claims on the FBPA issue. The Georgia Court of Appeals affirmed the trial court’s dismissal and ruled that the FBPA does not authorize a lawsuit against a physician who allegedly altered medical records. The court held that the medical group’s policy of allowing nurses to perform treatment on patients following heart by-pass surgery and notations that the physician authorized the treatment when, in fact, he did not had no effect on the general consuming public. The court noted that the medical groups’ policy and physician’s notations did not constitute “consumer acts or practices” within the meaning of the FBPA. 


*This case is interesting in that the plaintiff used a novel theory in trying to hold the physician and his group accountable for their conduct; however, the Georgia courts dismissed the action.*
IX. HIPAA

Covered Entity May Disclose PHI in Lawsuits if Adequate Safeguards are Maintained
DHHS Office of Civil Rights (OCR), through answers to frequently asked questions (FAQs) published on its web site, has restated and clarified that protected health information (PHI) may be disclosed during legal proceedings under certain circumstances, provided that certain safeguards are maintained. Providers will not have to account to an individual when disclosing that individual's PHI in a legal proceeding when the disclosure is made with the individual's authorization, or if the covered entity is a part of the litigation and such disclosures are part of the covered entity's healthcare operations. As a necessary safeguard, however, only the minimum necessary PHI may be disclosed. This extends to the attorney in the matter, when the attorney is part of the covered entity’s workforce or a business associate. If the covered entity is not a party to a legal proceeding, the covered entity may disclose PHI as set forth in the HIPAA Privacy Rule at 45 C.F.R. § 164.512(e). The FAQs are available at http://www.hhs.gov/ocr/hipaa/

These FAQs represent continuing efforts by OCR to give the industry guidance on the use and disclosure of PHI during litigation and other administrative proceedings.

First Criminal Conviction Under HIPAA
On August 19, 2004, a former cancer clinic employee, Richard W. Gibson, pleaded guilty in federal court in Seattle to wrongful disclosure of individually identifiable health information for economic gain. Under the plea agreement, Gibson admitted to obtaining demographic information about a cancer patient and disclosing that information, including the patient's name, date of birth and social security number, in order to obtain four credit cards in the patient’s name.

Significantly, although the defendant was not a “covered entity” under HIPAA, the Department of Justice (DOJ) chose the HIPAA felony law to prosecute the defendant even though there are numerous other laws that could have been used to prosecute the identity theft.


Many see this first HIPAA guilty plea as a statement by the DOJ that HIPAA’s felony provision will reach well beyond covered entities.
X.  HOSPITAL ISSUES

Advisory Group to Deal With On-Call Issue in EMTALA Rule
As required by § 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS has formed a Technical Advisory Group (TAG) to advise and make recommendations concerning the Emergency Medical Treatment and Labor Act (EMTALA) and regulations. At the inaugural meeting, the American Hospital Association (AHA) and physicians sought broad changes to on-call provisions in the EMTALA rules, stating that the refusal by specialty physicians to take emergency call limits patient access to specialty care. The AHA asked that CMS address the issue, perhaps by revising the Medicare Conditions of Participation for physicians, to require emergency call participation. TAG responded by requesting that the groups provide it with more data regarding the barriers faced so that it can formulate an appropriate response. Information about EMTALA TAG is available at http://www.cms.hhs.gov/providers/emtala/default.asp

The first meeting of EMTALA TAG illustrates that the on-call provisions of EMTALA continue to create significant issues for hospitals and physicians.

New Texas Senate Bill to Study Effect of Transfers to Physician-Owned Hospitals
The Texas Senate approved Senate Bill 872 requiring the state to study the potential economic harm to community hospitals of physicians sending patients to specialty healthcare facilities or “niche” hospitals in which doctors are investors. The Texas Senate sent the bill to the Texas House for consideration, where it is progressing. The bill will also require physicians to disclose any financial interests they have in these facilities and to inform patients that they may use other healthcare facilities. Niche hospitals are doctor-owned, limited healthcare businesses. According to the Texas Hospital Association, of the 100 or so niche hospitals in the country, about half are located in Texas. Information on the bill is available at http://www.capitol.state.tx.us. If approved, the bill would take effect September 1, 2005.

This bill is important because it demonstrates the ongoing debate regarding the effect of specialty hospitals on community hospitals. Furthermore, this bill is indicative of how states are willing to get involved to ensure that community hospitals have the ability to sustain and provide necessary services. For federal action and recommendations regarding specialty hospitals, see the Medicare Payment Advisory Commission (MedPAC) report issued in March 2005 in which MedPAC recommended that Congress extend through January 2007 the current moratorium on the development of new specialty hospitals. The MedPAC report is available at www.medpac.gov/publications/congressional_reports/Mar05_SpecHospitals.pdf.
EMTALA Statute of Limitation Bars Patient Dumping Claim

In June 2002, plaintiff Adam Merce was discharged from emergency room treatment by Drs. David Pope and Mark Greenwood. Shortly after his discharge, he suffered serious injuries that he alleged should have been discovered in his emergency room visit. In July 2004, Merce filed suit against Drs. Pope and Greenwood, claiming violations of EMTALA’s anti-dumping provisions. The physicians moved to dismiss the EMTALA claims, citing EMTALA’s two-year statute of limitations. Merce argued that the two-year statute had not run because of various state law tolling provisions, including tolling provisions for pre-litigation screening procedures and delayed discovery of an injury. The U.S. District Court for the District of Utah, rejecting Merce’s argument, found that EMTALA does not incorporate state law pre-litigation claim screening requirements and that its two year limitation period begins to run from the date of the alleged violation. Because Merce filed his claims more than two years after the alleged violation, the Court held that the EMTALA claims were untimely filed and granted the physicians’ motions to dismiss.


This case demonstrates that EMTALA does not incorporate state law pre-litigation requirements and that its statute of limitations begins on the date of the alleged violation.

XI. PAYMENT ISSUES

Nephrology Group Names DHHS and CMS in Complaint Based on Stark II Regulations

The Renal Physicians Association (RPA) filed a complaint against DHHS and CMS alleging that the Stark II interim final rule safe harbor provision regarding fair market value compensation for medical directors would result in drastically reduced compensation for nephrologists who act as medical directors for dialysis centers. The safe harbor provision provides two methodologies for calculating compensation for physicians providing personal services: (i) the average hourly rate of area emergency room doctors, or (ii) data pulled from national physician salary surveys. Medicare requires that dialysis centers employ medical directors, while other healthcare facilities can choose not to. Therefore, as alleged by RPA, nephrologists acting as medical directors of dialysis centers would necessarily be under-compensated by the compensation methodologies proposed in the rule, which would lead to difficulty in recruiting the highest skilled and experienced individuals to serve as medical directors of dialysis centers. In September 2004, however, CMS stated that healthcare facilities, including dialysis centers, could use any appropriate methodology to calculate medical director compensation. Nevertheless, the RPA alleges that healthcare facilities will be more inclined to use the methodologies set forth in the Stark II interim final rule. The complaint also alleges that CMS’s failure to truly review and consider public comments to
the rule means that the safe harbor is in violation of the Administrative Procedures Act.


This case is significant because it illustrates the impact of the Stark II rules on physician groups, the unintended consequences of those rules, and that physician groups are willing to fight to change such unintended consequences.
AMERICAN HEALTH LAWYERS ASSOCIATION

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I. CASE SUMMARIES

CMNs Adequately Document Medical Necessity
Durable medical equipment (DME) supplier sought judicial review of a final administrative decision made by the Medicare Appeals Council (MAC) of the Department of Health and Human Services (DHHS) affirming an overpayment assessment made by its Medicare carrier. The carrier contended that the supplier had insufficiently documented the medical necessity of the wheelchairs that it billed to the Medicare program. The supplier appealed the MAC’s decision, claiming that the certificates of medical necessity (CMNs) furnished by physicians were sufficient to document the medical necessity of the equipment being provided. The United States District Court for the Eastern District of California found that the plain language of 42 U.S.C. § 1395m(j)(2)(A)(i) supported the supplier’s positions that it may rely on a CMN to provide the required information for determining medical necessity and reasonableness, and that DHHS cannot require DME suppliers to obtain medical records and make independent judgments with regard to medical necessity and reasonableness. Consequently, the court granted the plaintiff’s motion for summary judgment and permanent injunction prohibiting DHHS from recouping, offsetting or otherwise collecting any alleged overpayments. 


DME suppliers may rely on CMNs to document medical necessity and cannot be required to obtain additional information.

Medicare Law Does Not Preclude False Claims Action
Federal government claims of Part A upcoding by twenty-six hospitals then owned and operated by AMI were defended by a jurisdictional challenge that common law claims were barred by the Medicare Act and related regulations. Tenet Healthcare Corp. (Tenet), which currently owns and operates the hospitals, argued that § 405(h) of the Social Security Act (the Act) expressly precludes judicial review of reimbursement determinations, except as provided by the Act, which permits only providers and beneficiaries to appeal a reimbursement or benefits determination via suit in federal district court. Moreover, Tenet argued that the comprehensive nature of the Medicare Act and related regulations preempted any "outside the system" common law recoupment actions. The government countered that the Act and regulations did not repeal or limit the district court's jurisdiction under § 1345 of the Act. The court found that it had jurisdiction to hear the case, and dismissed the Tenet's motion to dismiss. 

District court has jurisdiction over FCA action, as Social Security Act does not preclude judicial review.

**Fifth Circuit Finds Disputed M+C Subcontracted ESRD Services Are Not Medicare Claims, as Risk Was Transferred to M+C Plan**

Humana, a Texas HMO, contracted with the Centers for Medicare and Medicaid Services (CMS) to provide health services to Medicare+Choice (M+C) beneficiaries under Part C of the Medicare program. Humana subcontracted with RenCare for end-stage renal disease (ESRD) services for both M+C beneficiaries and other HMO enrollees. The amount of reimbursement paid by Humana to RenCare was disputed, and RenCare sued Humana in Texas state court. Humana moved for removal, arguing that the claims were preempted by the Medicare Act and thus belonged in federal court. The district court retained jurisdiction over the case as it related to M+C beneficiaries only and later dismissed the case for RenCare’s failure to exhaust administrative remedies. RenCare appealed. The Fifth Circuit found that RenCare’s claims were not Medicare claims, as the federal government had transferred its risk of loss under Medicare Part C to Humana. Accordingly, RenCare’s claims were not subject to the M+C administrative appeals process and the claims were remanded to state court.

**RenCare, Ltd. v. Humana Health Plan of Texas, Inc.,** 395 F.3d 555 (5th Cir. 2004).

M+C claims are not subject to the M+C administrative appeals process, as the government transferred its risk of loss to the M+C plan; therefore, such claims belong in state court.

**ALJ Denies Attorneys Fees Pursuant to Equal Access to Justice Act**

As a result of a nursing facility compliance survey, CMS imposed CMPs against Park Manor of $150 per day from March 22 through June 10, 2001, totaling $12,150. however, the ALJ’s decision was overturned by the DAB. Thereafter, Park Manor sought attorneys fees, costs and expenses totaling $253,837.90 under the Equal Access to Justice Act (EAJA). CMS objected, contending that its remedy determination and litigation of the case were substantially justified. The ALJ denied Park Manor’s petition, finding that the EAJA was not intended to make the government liable for fees and costs whenever it lost an administrative proceeding.


**DAB Finds ASC Certified by AAAHC Not Automatically Medicare Certified**

The DAB held that an ambulatory surgical center (ASC) that was certified by the Accreditation Association for Ambulatory Health Care (AAAHC) under regular accreditation standards but not Medicare certification standards, is not automatically certified as a Medicare-accredited supplier. The DAB found that there were two types of AAAHC standards: regular and regular plus Medicare,
which include all Medicare Conditions of Participation for ASCs (including life safety code requirements). The DAB found that the ASC did not meet the life safety code requirements; therefore, CMS properly denied it Medicare certification until the day the ASC met the life safety code requirements.  


**Sixth Circuit Affirms Dismissal of Nursing Home’s Challenge to Successor Liability for Civil Monetary Penalties**

(CMS imposed civil money penalties (CMPs) against West Chester Management Company d/b/a Barbara Parke Care Center (Barbara Parke) because of alleged inadequate patient care at a nursing home it leased and operated. CMS issued Barbara Parke a notice of its right to a hearing to contest the CMPs. Over the ensuing two years, Barbara Parke: (1) requested a hearing before an ALJ; (2) ceased operating the facility and assigned its Medicare provider agreement to another company; (3) declared bankruptcy; and (4) withdrew its request for a hearing regarding the CMPs. CMS then sought to collect the CMPs from BP Care, Inc. (BP), the new lessee and operator of the nursing home, under a successor liability theory. BP sued CMS in federal district court, alleging that the successor liability scheme violated the Medicare Act’s CMP provisions, denied BP procedural due process, and constituted arbitrary and capricious agency action under the federal Administrative Procedure Act. The district court found that it lacked subject-matter jurisdiction over most of BP’s claims. The Sixth Circuit affirmed, but held that the district court lacked subject-matter jurisdiction over all of BP’s claims. The court found that BP had actual notice of Barbara Parke’s hearing request withdrawal and could have sought administrative review of the imposed CMPs, but failed to do so. Relying on the Supreme Court’s decision in **Shalala v. Illinois Council on Long Term Care**, 529 U.S. 1 (2000), the Sixth Circuit concluded that because BP could have sought administrative review, the district court lacked subject matter jurisdiction.

**BP Care, Inc. v. Thompson**, 398 F.3d 503 (6th Cir. 2005).

*Like most courts that have looked at the § 405 subject matter jurisdiction issue since the Supreme Court’s ruling in Illinois Council, the Sixth Circuit looked seriously at the “Michigan Academy” exception stated in Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986), which states that subject matter jurisdiction may exist for direct court challenges to agency action where the administrative appeal process is tantamount to “no review at all.” This case also emphasizes the importance of proper due diligence during any asset purchase, and that CMP notices, hearing requests, and the like should be requested and assessed.*
II. JCAHO UPDATE

GAO Faults Hospital Accreditations
A recent study by the General Accounting Office (GAO) reviewed the Joint Commission on Accreditation of Health Care Organizations (JCAHO) accreditation process. The GAO determined that JCAHO did not identify most of the hospitals that were found to have deficiencies in Medicare requirements when they were surveyed by state survey agencies. Of the hospitals that were accredited by JCAHO, thirty-one percent were cited for non-compliance with Medicare requirements by state agency validation surveys. The GAO recommends that Congress give CMS authority over JCAHO’s hospital accreditation program and further recommends that CMS modify its current methods for accessing JCAHO’s performance.


JCAHO Proposes Collection of Race, Ethnicity, and Language Data
JCAHO proposed a new standard to require the managed care organizations and integrated delivery systems that it accredits to collect information on patients’ race, ethnicity and primary language. JCAHO believes that collecting this information will allow managed care plans to better understand the characteristics of the populations they serve and to provide safer and higher quality healthcare.

JCAHO Proposes Reform of Medical Liability System
JCAHO is urging reform of the medical liability system in a public policy white paper entitled *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury* (the Report). The Report emphasizes patient safety and medical injury prevention by healthcare providers and practitioners along with open communication between patients and practitioners. JCAHO is also proposing the creation of an injury compensation system that is “patient-centered.” JCAHO believes the current liability system fails “because it does not effectively deter negligence, truly offer corrective justice, or provide for compensation to those who have been injured through the care process.” An executive summary of the Report may be found at [http://www.jcaho.org/news+room/press+kits/tort+reform/medical_liability_exec_summary.pdf](http://www.jcaho.org/news+room/press+kits/tort+reform/medical_liability_exec_summary.pdf).

JCAHO Unveils Principles Guiding Pay-For-Performance Program Development
JCAHO released a set of principles to guide the development of “healthcare pay-for-performance programs” (the Principles). The Principles are designed to be used by policymakers, third-party payers, health plans, purchasers and others involved in programs that provide incentives for achieving performance benchmarks. JCAHO estimates that over 100 pay-for-performance programs exist nationally but that only a few of these are guided by explicit principles. Pay-for-performance programs are generally programs that offer structured incentives.
for practitioners and providers to achieve certain benchmarks. The hope is that by offering financial incentives, higher quality healthcare will be delivered on a more consistent basis. The Principles require programs to ensure that the measurements upon which incentives are based are credible, valid and reliable; furthermore, programs should include timely feedback and opportunities for appropriate dialogue, among others. The Principles are available at www.jcaho.org/news+room/news+release+archives/jcaho_112204_principles.htm.

**JCAHO and CMS Commit to Make Common Performance Principles Identical**

JCAHO and CMS announced the signing of an agreement to work together to align current and future common hospital quality measures in their condition-specific performance measure sets. The measures currently address heart attack, heart failure, pneumonia, and surgical infection prevention. Both CMS and JCAHO have made available on their websites a common measures specification manual. The goal is to make it easier and less expensive for hospitals to comply with the CMS and JCAHO requirements for data collection and reporting.

**Rights Groups Petition JCAHO for Standard Governing Notification of Institutional Ethical or Religious Restrictions.**

On October 12, 2004, the National Women’s Law Center asked JCAHO to modify its standards for hospitals and other healthcare institutions to include a standard governing ethical or religious restrictions on healthcare services. The letter was joined by numerous other organizations interested in individual’s rights. The proposed standard would require hospitals to inform patients and prospective patients prior to admission and before transfer, when possible, concerning any institutional religious or ethical restrictions on providing or foregoing healthcare services with a clear and precise statement of the medical conditions and procedures affected by the restriction. The letter can be found at www.aclu.org/religiousliberty/religiousliberty.cfm?ID=16826&c=29.

**CMS Renews JCAHO for Home Health Agency Accreditation**

CMS announced recently the renewal of JCAHO as a national accreditation program for home health agencies seeking participation in Medicare or Medicaid programs. CMS noted two inconsistencies between its conditions of participation and survey requirements and JCAHO’s accreditation standards. Thus, JCAHO agreed that it would not schedule unannounced home health surveys absent a written confirmation of a successful Outcomes and Assessment Information Set (OASIS). Additionally, JCAHO amended its policies and procedures so that surveyors are permitted to serve as witnesses in CMS actions based on accreditation findings.

**Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Joint Commission on Accreditation of Healthcare Organizations**
(JCAHO) for Home Health Agencies, 70 Fed. Reg. 15331 (Dep’t Health and Human Servs. Final Notice March 25, 2005).

JCAHO Establishes Patient Safety Webite
JCAHO and Joint Commission Resources (JCR) jointly sponsor the Joint Commission International Center for Patient Safety (the Center) which advocates safety in healthcare by promoting solutions which are established through scientific research, consensus of expert opinions, and multi-disciplinary educational principles. The Center is implementing a new website, www.jcipatientssafety.org, to function as a repository that provides a wide array of information and resources relating to patient safety through practical safety solutions that can be utilized by healthcare practitioners, organizations and patients. The Center’s announced goal is to have the site serve as a central source of highly accessible and relevant patient safety information.

III. REGULATORY UPDATE

CMS Issues FY 2005 Update of IPPS
CMS published a final rule revising the Medicare inpatient prospective payment system (IPPS). The revision implements statutory requirements and changes arising from experience with the system and related provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Addendum to the final rule describes the changes to the amounts and factors that determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. The changes would be applied to discharges occurring on or after October 1, 2004. Also, the rule sets forth rate-of-increase limits and policy changes for hospitals and hospital units excluded from IPPS that are paid in full or in part on a reasonable cost basis.


CMS Establishes Prospective Payment System for Inpatient Psychiatric Facilities
CMS published a final rule establishing a prospective payment system (PPS) for Medicare payment of inpatient hospital services furnished in psychiatric hospitals and psychiatric units of acute care hospitals and critical access hospitals. The final rule implements § 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA). The final rule responds to comments based on the November 2003 proposed rule, in which CMS proposed to establish a federal payment for each patient day in an inpatient psychiatry facility (IPF) derived from the national average daily routine operating, ancillary, and capital costs in IPFs. The federal per diem payment would comprise a federal per diem base rate adjusted by factors for patient and facility characteristics that account for variation in patient resource use.
CMS corrected certain errors and supplemented the final rule by clarifying its policy on payment for the costs of operating an approved allied healthcare teaching program (i.e. pastoral training, nursing). Such covered costs include trainee stipends and teacher compensation. Under 42 CFR § 413.85, hospitals that operate approved nursing or allied health education programs may receive Medicare payment on a reasonable cost basis for costs of these programs. The payment is a “pass-through” (that is, it is paid separately and distinctly from the IPF PPS); payment is made to both freestanding IPFs and IPPS hospitals with psychiatric units.


**Medicare Program; Prospective Payment System for Inpatient Psychiatric Facilities**, 70 Fed. Reg. 16724 (Dep’t Health and Human Servs. Final Rule; Correction April 1, 2005).

**CMS Issues FY 2005 OPPS Update**
CMS published a final rule revising the Medicare outpatient prospective payment system (OPPS) to implement applicable statutory requirements, operating changes, and certain related provisions of the MMA. In addition, the final rule describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services applicable to services furnished on or after January 1, 2005. In this final rule with comment period, CMS responds to public comments received on the January 6, 2004 interim final rule relating to MMA provisions that were effective January 1, 2004, and finalizing those policies, and to public comments received on the November 7, 2003 final rule pertaining to the ambulatory payment classification assignment.

**Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates**, 69 Fed. Reg. 65682 (Dep’t Health and Human Servs. Final Rule Nov. 15, 2004).

**CMS Publishes Final Rule on Recordkeeping Requirements for Drug Manufacturers**
CMS implemented a ten-year recordkeeping requirement for drug manufacturers under the Medicaid drug rebate program. Manufacturers must retain records for ten years from the date the manufacturer reports data to CMS for a rebate period. This final rule also finalizes the requirement that manufacturers must retain records beyond the ten-year period if the records are known by the manufacturer to be the subject of an audit or a government investigation.

CMS Issues Final Rule Regarding Expedited Procedures for Provider Service Terminations

CMS issued a final rule implementing the requirement under § 1869(b)(1)(F) of the Social Security Act that a beneficiary has a right to an expedited determination upon notification by a provider of the provider’s decision to discharge the beneficiary or to terminate services. This rule specifies that certain providers (SNFs, HHAs, CORFs and hospices) must issue a standardized termination notice before all discharges or service terminations to inform beneficiaries of these new appeal rights. The rule sets forth the expedited determination process and the beneficiary’s rights. CMS believes that these changes will enhance the rights of Medicare beneficiaries, and will significantly reduce a beneficiary’s potential liability in situations where disputed provider services are denied on appeal. This rule is effective on July 1, 2005.


CMS Publishes Medicare Prescription Drug Benefit Final Rule and Interpretation

CMS issued a final rule implementing the Medicare voluntary Prescription Drug Benefit Program, which was enacted with § 101 of Title I of the MMA, and is slated to become available to beneficiaries beginning on January 1, 2006. Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which will offer prescription drug coverage that is integrated with the healthcare coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. MA-PDs or PDPs may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available, and the ability to have a cost-sharing structure other than the statutorily defined structure, subject to certain actuarial tests.

In addition, the final rule provides for subsidy payments to sponsors of qualified retiree prescription drug plans to encourage retention of employer-sponsored benefits. It also provides for options for facilitating additional coverage through employer plans, MA-PD plans and high-option PDPs, and through charity organizations and State pharmaceutical assistance programs. CMS is issuing separate guidance on many operational details, such as formulary review criteria, risk plan and fallback plan solicitations, bid instructions, solvency standards and pricing tools, and plan benefit packages.
In response to comments received in response to the final rule, CMS issued an Interpretation clarifying certain explanations set forth in the final rule.


**CMS Issues Final Rule and Interpretation Regarding Medicare Advantage**

CMS published a final rule implementing Title II of the MMA by establishing and regulating the Medicare Advantage (MA) program. The MA program replaces the M+C program. While retaining most key features of the M+C program, the MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries. According to CMS, the MA program is designed to provide for regional plans that may make private plan options available to many more beneficiaries, especially those in rural areas; and expand the number and type of plans provided for, so that beneficiaries can choose from several different types of plans.

Beginning in 2006, payments for local and regional MA plans will be based on competitive bids rather than administered pricing. MA organizations will submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon the MA organization’s determination of expected costs in the plan’s service area for the national average beneficiary for providing non-drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits, if any, (including reductions in cost sharing).

In response to comments received in response to the final rule, CMS issued an Interpretation clarifying certain explanations set forth in the final rule.


**CMS Issues Proposed Rule Regarding Medicare Approval for Transplant Centers**

CMS published a proposed rule setting forth the requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. These proposed requirements focus on an organ transplant center’s ability to perform successful transplants and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. CMS proposes that approval, as determined by a center’s compliance with the proposed data submission, outcome, and process requirements, would be granted for three years and renewable every three years for centers that continue to meet these requirements. CMS later extended the comment period for sixty days, until June 6, 2005.

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants, 70 Fed. Reg. 15264 (Dep’t Health and Human Servs. Extension of Comment Period March 25, 2005).

CMS Issues Proposed Rule Regarding Competitive Acquisition of Outpatient Drugs and Biologicals

CMS issued a proposed rule that would execute provisions of the MMA that require the implementation of a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or PPS basis. Beginning January 1, 2006, physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price system. CMS seeks comments on which of the proposed approaches it should use to implement the competitive acquisition program as well as the criteria and standards that should be applied in the selection and enrollment of vendors.

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I. BANKRUPTCY

First Circuit Holds Deduction for Medicare Overpayments is Recoupment Not Subject to Bankruptcy Law

During year 2000, the Health Care Financing Administration (HCFA) (now CMS) determined that it overpaid Holyoke Nursing Home (Holyoke), a Medicare provider, $343,639 for years 1997 and 1998. HCFA deducted $177,656.25 from Holyoke's 2000 request for reimbursement to recover part of the overpayment. Holyoke filed for Chapter 11 bankruptcy. Holyoke then sued HCFA, claiming HCFA's pre-petition deduction of $99,965.97 was a voidable preferential transfer under bankruptcy law, and the post-petition deduction of $77,690.28 violated the automatic stay provision. The bankruptcy court granted summary judgment to HCFA, stating that the deduction from the reimbursement was a recoupment and did not constitute a preferential transfer or violate the automatic stay provision. Holyoke appealed.

The First Circuit affirmed, stating that the only issue on appeal was whether HCFA's deduction constituted a permissible “recoupment” or an impermissible “setoff” barred by the automatic stay provision. The court determined that the relevant issue was whether the debt owed to HCFA arose out of the "same transaction" as the debt HCFA owed Holyoke. The court noted that the Medicare law and the bankruptcy code have not addressed the issue, and other federal appeals courts have split over the issue. The First Circuit agreed with the reasoning of the D.C. Circuit and the Ninth Circuit, which held that recoveries of Medicare overpayments relating to previous cost years are permissible recoupments. The court rejected Holyoke's argument that recoupment is an equitable doctrine and the case should be remanded for equitable balancing because "HCFA has the unqualified right to recoup these overpayments in full." Therefore, the appeals court held equitable balancing was not warranted.

**Holyoke Nursing Home, Inc. v. Health Care Financing Admin.,** 372 F.3d 1 (1st Cir. 2004).

Because it is well settled that a post-petition “setoff” violates the bankruptcy automatic stay provision but a “recoupment” does not, this distinction is critical. The split among the federal appeals courts continues to develop, with the D.C., Ninth, and First Circuits applying the “same transaction” test in favor the government, while the Third Circuit uses a different analysis that favors providers.
Reimbursement Dispute Arose Under Medicare Act, Not Bankruptcy Code; Therefore, Exhaustion of Administrative Remedies Required
Excel Home Care, Inc. (Excel), is a home healthcare organization and a provider under Medicare Part A that filed for Chapter 11 bankruptcy in 2001. The Department of Health and Human Services (DHHS) was a creditor to whom Excel owed approximately $438,000 due to overpayments for services. Under Excel’s plan of reorganization (the Plan), confirmed by the Bankruptcy Court, Excel was to repay DHHS $7,000 per month for seven years. In 2003, Excel’s fiscal intermediary revealed that DHHS underpaid Excel approximately $127,000 for services in 2000. Instead of paying the $127,000 to Excel, DHHS deducted the amount from Excel’s outstanding balance. Excel filed suit, alleging that DHHS violated the Plan by breaching its repayment terms.

The U.S. District Court for the District of Massachusetts dismissed Excel’s suit for failure to exhaust administrative remedies as required by 42 U.S.C. § 405(h). Generally, with respect to disputes that arise under the Medicare Act, the decision of the Secretary of DHHS is final and is not subject to judicial review until all administrative remedies are exhausted. Excel asserted that the courts had jurisdiction because the dispute was a bankruptcy matter, i.e., whether DHHS had violated the terms of the Plan, by which DHHS was bound under federal bankruptcy statutes. The court disagreed, characterizing the matter as a reimbursement dispute arising under the Medicare Act. According to the court, the legislative history and the caselaw under the Medicare Act indicate the intent of Congress to place broad limits on judicial review of reimbursement disputes, even on providers in bankruptcy. Excel Home Care, Inc. v. U.S. Dep’t of Health and Human Services, 316 B.R. 565, 2004 WL 2441212 (D. Mass. 2004).

This case shows that courts will dismiss for lack of subject matter jurisdiction a provider’s claim that withholding Medicare payments violated a Chapter 11 plan of reorganization because the dispute arose under the Medicare Act and required the provider to exhaust administrative remedies before seeking judicial review.

First Circuit Approves Recoupment of Medicare Overpayments From Bankrupt Nursing Home
A Rhode Island nursing home (Nursing Home) accepted Medicare funds to pay unrelated parties for services, but failed to pay the unrelated parties as agreed. Nursing Home then filed for Chapter 11 bankruptcy, and was unable to pay the unrelated parties. The fiscal intermediary notified Nursing Home that Nursing Home had received overpayments of approximately $400,000, most of which were in connection with the amounts that were owed by Nursing Home to the unrelated parties. Nursing Home sought injunctive and declaratory relief to prevent the government from recouping the overpayments. The bankruptcy court agreed that the government’s claim was one of recoupment (rather than setoff), but applied equitable principles to grant the injunction. A district court agreed with the characterization of the government’s claim as one of recoupment, but reversed the bankruptcy court’s conclusion on equitable principles. On appeal,
the First Circuit affirmed the district court, agreeing with the lower court’s conclusion that, but for the recoupment, Nursing Home would experience a windfall profit. 

**In re Slater Health Center, Inc.,** 398 F.3d 98 (1st Cir. 2005).

*The First Circuit ruled that the government’s attempts to recover an overpayment were a recoupment (rather than an offset) and, therefore, not subject to the automatic stay provisions of the federal bankruptcy code.*

**II. TAXATION**

**Ohio Supreme Court Says Fitness Center Did Not Have Charitable Purpose and Thus Was Not Exempt From Real Property Tax**

Plaintiff Bethesda Healthcare, Inc., a non-profit corporation, owns the TriHealth Fitness and Health Pavilion, which it leases in part to itself for a fitness center and also to physician practice groups. Plaintiff owns Bethesda Hospital, Inc. and uses part of the pavilion for hospital departments. Plaintiff applied for a real property tax exemption for the space it used. The Tax Commissioner (Commissioner) granted an exemption in part for the space used for the hospital’s departments, but not for the fitness center. Plaintiff appealed the determination, and the Board of Tax Appeals held the fitness center was not exempt because it was a private facility with paying members and had no charitable purpose that would qualify it for an exemption. Plaintiff appealed.

The Ohio Supreme Court affirmed the Commissioner’s determination. The high court determined that the charging of a fee did not necessarily negate consideration of the fitness center as having a charitable purpose; rather, it was the overall purpose of the fitness center that determined whether it was operated for a charitable purpose. Of 5,400 members, the fitness center only provided a small number of free or reduced price memberships, supporting a finding that the services rendered by the fitness center did not have a substantial charitable purpose.

**Bethesda Healthcare v. Wilkins,** 806 N.E.2d 142 (Ohio 2004).

*Fitness center that was located in a tax-exempt hospital location was not a tax-exempt entity because it was operated separate from the hospital and did not share the hospital’s charitable purpose.*

**New Jersey Court Rules That Property Owned by Nonprofit Health Organization Is Exempt From Property Taxes**

The New Jersey Superior Court, Appellate Division, ruled that a lower level tax court did not err in determining that property owned by Disabilities Resource Center/Atlantic and Cape May, Inc., was exempt from property taxes pursuant to N.J. Stat. Ann. § 54:4-3.6. The tax court correctly reasoned that, because the property was owned by a qualified nonprofit organization and was exclusively
utilized for the purposes of the training of the “feeble minded,” it was entitled to a tax exemption.  

**Disabilities Resource Ctr./Altantic and Cape May, Inc. v. City of Somers Point, 851 A.2d 792 (N.J. Super.A.D. 2004).**

*This case shows that property owned by a qualified nonprofit organization that is exclusively used to train the “feeble minded” is exempt from property taxes under New Jersey law.*

**Government and St. David’s Agree to Settle Texas Hospital Joint Venture Litigation**

Less than a month after the federal government signaled its intent to appeal a jury verdict that had allowed a Texas nonprofit healthcare system to keep its tax exemption, the system announced the litigation will soon come to an end. Carol C. Clark, interim president of St. David’s Health Care System (St. David’s), said that the Department of Justice (DOJ) had withdrawn its appeal of a March jury verdict that rejected the Internal Revenue Service’s (IRS’s) position that the nonprofit system’s whole hospital joint venture with for-profit HCA Inc. compromised its charitable mission and required it to forfeit its tax exemption under I.R.C. §501(c)(3).

The government withdrew its appeal of the jury’s verdict in exchange for the system’s agreement not to seek attorneys’ fees in the case. On March 4, 2004, a jury in the U.S. District Court for the Western District of Texas decided that Austin, Texas-based St. David’s should retain its nonprofit status, even though the IRS claimed the system forfeited its exemption when it entered into a whole-hospital joint venture in 1996.

The government’s decision not to follow through with an appeal ends a long dispute. The IRS revoked St. David’s tax exemption in 2000, arguing that it no longer operated exclusively for charitable purposes because of the then four-year-old partnership with HCA; the case has been in the courts since. Had St. David’s lost, it could have owed nearly $40 million in back taxes, interest and penalties, Clark said. The DOJ declined to comment on the matter.

*The ongoing litigation regarding St. David’s Hospital’s disputed tax exempt status was brought to an end when the hospital and the government agreed to a confidential settlement, thus ending the federal government’s appeal of an earlier jury verdict in favor of St. David’s. Nevertheless, tax-exempt hospitals must be careful when structuring whole-hospital joint ventures not to cede operational control to a non-exempt party concerning certain charitable and clinical matters.*

**IRS Announces Major Enforcement Initiative in Exempt Organization Area.**

The Internal Revenue Service (IRS) announced a new enforcement effort to identify and halt abuses by tax-exempt organizations that pay excessive compensation and benefits to their officers and other insiders. As part of the Tax Exempt Compensation Enforcement Project, the IRS stated that it will contact
approximately 2,000 charities and foundations to seek more information about their compensation practices and procedures. The IRS will utilize intermediate sanctions penalties as its principal enforcement tool where compliance problems are identified.

According to the IRS, the purposes of the project are to: (i) address the compensation of specific individuals or instances of questionable compensation practices; (ii) increase awareness of tax issues as organizations set compensation in the future, and (iii) learn more about the practices organizations are following as they set compensation and report it to the IRS and the public on their annual Form 990 returns.

The initiative will focus on particular areas, including the compensation of specific officers and various kinds of insider transactions, such as loans and the sale, exchange or leasing of property to officers and others. The IRS will also focus on Form 990 reporting, including how organizations answered question 89(b) on the Form 990 regarding excess benefit transactions, and other compensation information. The IRS began this enforcement project at the end of July 2004 and says it will continue into 2005.


_The IRS has undertaken a significant enforcement initiative in the area of compensation practices conducted by exempt organizations, with more than 2000 exempt organizations planned for contact and possible examination._

**IRS Approves Proposed Hospital-Controlled Physician-Hospital Imaging Center Joint Venture to Own and Operate IDTF**

A nonprofit, tax-exempt hospital proposed to form a new joint venture structured as a limited partnership to own and operate a freestanding diagnostic imaging center. Units in the limited partnership will be offered to physician investors and related physician groups. If the offering becomes fully subscribed, the joint venture will be structured so that a LLC wholly owned by the nonprofit hospital will serve as general partner and own one percent, the nonprofit hospital as a limited partner will own fifty-four percent, the physician investors will own forty percent, and an independent management company will own five percent of the limited partnership.

The IRS essentially followed its guidance in Revenue Ruling 98-15, concluding that the joint venture was permissible due to certain factors. First, the hospital's wholly owned LLC, acting as general partner, will have effective control over major decisions of the joint venture which will ensure that the imaging center will be operated in a charitable manner (i.e., promoting health for a broad cross section of the community) regardless of ability to pay. The partnership agreement specifically provides that the duty of the general partner is to operate the partnership in a manner that furthers charitable purposes and overrides any duty to operate the partnership for the financial benefit of anyone else. The general
partner can only be removed by the limited partners holding more than eighty percent of the sharing ratios of all partners. Second, the imaging center will have an open medical staff and utilize the charity care policy of the hospital. Physician privileges were not dependent on owning an interest in the joint venture. The charity care policy will be advertised to patients and the center's radiologists are required to treat all members of the community, including Medicare, Medicaid and indigent patients. The management agreement will require the manager to operate the center for charitable purposes, with charitable purposes taking precedence over any profit motive. Third, contributions to the partnership and allocations of profits, losses, and distributions from it will be in proportion to the interests of the partners. Finally, all fees paid are subject to a ceiling amount that will not exceed fair market value.

In addition, the IRS did not object to the management fee, which was based on a percentage of net revenue collected. **IRS Priv. Ltr. Rul. 200436002** (June 6, 2004).

*The IRS affirmed its position set forth in Rev. Rul. 98-15 that governance control is the most important factor in healthcare nonprofit, for profit joint venture transactions.*

**Class Actions Filed Against Some of the Largest Nonprofit Hospitals in the U.S. by Consortium of Plaintiff's Firms Representing Uninsured Patients.** Class action lawsuits were filed in federal court against numerous nonprofit hospital systems across the country. The suits allege that nonprofit hospitals retain hundreds of millions of dollars annually as a result of their tax-exempt status, in exchange for which the hospitals should be providing charity care. The suits allege that the hospitals improperly charge uninsured patients the "sticker" prices for healthcare, an amount higher than any other patient group, and then administer aggressive collection efforts. The cases have sought monetary damages for the cost of medical care charged, injunctive relief and the imposition of constructive trusts to be imposed on the defendants and from these trusts medical care will be paid for to the plaintiffs and class in each case. More than seventy-five suits have since been filed in, or removed to, federal courts, implicating over 500 hospitals and systems across the country.

In August 2004, Richard Scruggs, former big tobacco plaintiff's counsel, announced a settlement with North Mississippi Health Services (NMHS). The settlement was announced prior to the filing of a lawsuit and prescribes sliding-scale discounts for the uninsured up to 400% of the federal poverty level, and based on that scale, requires NMHS to forgive debt or refund payments to uninsured it treated over the last three years. To date, NMHS is the only hospital to have settled.

The federal Judicial Panel on Multidistrict Litigation rejected a motion to consolidate the individual lawsuits into a single class action. *In re Not-for-Profit*
Hospitals/Uninsured Patients Litigation, 341 F.Supp.2d 1354 (Jud.Pan.Multi.Lit. 2004). Subsequently, many of the federal cases have been voluntarily dismissed or dismissed on the merits for lack of standing, absence of a private right of action or failure to state a claim. Uniformly, the courts have rejected the legal theory that a patient can be the third-party beneficiary of the tax-exempt status granted by the government to a hospital, or that the granting of such status creates a charitable trust in favor of a patient. Courts generally have ruled that requiring a patient to agree to repay a hospital before the provision of healthcare services does not set out a violation of EMTALA.

Scruggs has announced that his group will re-file many of these cases in state courts.

A consortium of plaintiff's law firms, led by tobacco lawyer Richard Scruggs, filed class action litigation in federal courts against numerous nonprofit hospital systems, alleging impropriety in the application and administration of charity care and collections policies by the hospital systems vis-à-vis uninsured patients. Most courts have dismissed all federal claims and have refused to exercise supplemental jurisdiction over the state claims. In one case, the court dismissed the non-EMTALA federal claims, but permitted the plaintiffs leave to amend to properly plead an EMTALA claim, see Burton v. William Beaumont Hosp., 2004 WL 2790624 (E.D. Mich. 2004).

Michigan Court of Appeals Upholds Denial of Tax Exemption to Medical Center, Physician Practice Groups
The Michigan Court of Appeals concluded a medical center and two independent physician practice groups did not qualify as hospitals serving public health needs that would be eligible for exemption from ad valorem property tax assessments imposed by two cities. The court found that mere acceptance of Medicare and Medicaid patients was insufficient to justify treatment as a charitable institution. The court further stated that the center and practice groups’ provision of a negligible amount of free care undermined their contention that they were charitable institutions that served a public health purpose.

The original tribunal and the appeals court said their decisions were governed by ProMed Healthcare v. Kalamazoo, 644 N.W.2d 47 (Mich. App. 2002), which found that the charitable activities of an entity claiming tax exemption must be more than an incidental part of its operations. One of the practice groups in the instant case argued that it was exempt because its healthcare services at the subject property were “available to the general public without restriction, regardless of the ability to pay, and lessen[ed] the burdens of government.” The court found that argument insufficient, holding that the center “failed to present evidence that its ‘provision of charitable medical care constituted anything more than an incidental part of its operations.’” The court further stated that the center and practice groups needed to show that their activities, taken as a whole,
constituted either a charitable gift for the benefit of the general public without restriction or were undertaken for the benefit of an indefinite number of persons. **McLaren Regional Medical Center v. Owosso**, 2004 WL 1882645 (Mich. App. 2004).

*This case sets a high standard for what can be considered charitable care by a hospital for tax exemption purposes and declares that simple acceptance of Medicare and Medicaid patients alone is not sufficient to justify a hospital’s assertion of charitable purpose.*

**Qui Tam Award is Not Excludable From Taxable Income as Compensation for Personal Injury**

Dr. Hilton Brooks was a physician on the medical staff of Pineville Community Hospital (Hospital) in Pineville, Kentucky. While serving on the Hospital’s quality assurance committee, Dr. Brooks uncovered numerous billing improprieties by the Hospital and two physicians. The Hospital retaliated against Dr. Brooks with pressure to stop the investigation and move his practice elsewhere, threatened loss of clinical privileges, unfavorable reviews, and public criticism. Dr. Brooks filed a qui tam suit on the government’s behalf, which the Hospital and physicians settled for $2.5 million. The district court awarded Dr. Brooks twenty-five percent of the settlement amount, net of fees and costs, for an award of $210,067. After paying $78,607 in federal income taxes, Dr. Brooks sought a refund on the basis that the qui tam award was compensation for personal injuries excludable from taxable income under Internal Revenue Code (IRC) § 104(a)(2). The IRS denied his refund claim, Dr. Brooks filed suit, and the U.S. District Court for the Eastern District of Kentucky granted summary judgment to the government.

The Sixth Circuit, affirming the district court, concluded that Dr. Brooks met neither of the two requirements for excluding taxable income under IRC § 104(a)(2). First, Dr. Brooks did not show that the underlying cause of action is based in tort or tort-type rights. Although relators like Dr. Brooks may suffer injury as a result of their allegations, that tort is redressed under a separate “whistleblower” provision of the False Claims Act, not by the qui tam award. Second, Dr. Brooks did not show that the qui tam award was received on account of personal injury or sickness. **Brooks v. United States**, 383 F.3d 521 (6th Cir. 2004).

*The Sixth Circuit held that a qui tam award is neither derived from tort or tort-type rights nor received on account of personal injury or sickness and is therefore not excludable from taxable income under Internal Revenue Code § 104(a)(2).*

**Joint Committee on Taxation Issues Proposals for Exempt Organizations**

The Joint Committee on Taxation issued “Options to Improve Tax Compliance and Reform Tax Expenditures.” Part VIII of this publication includes twelve recommendations for changes to the taxation and compliance rules applicable to tax-exempt entities, including not-for-profit healthcare providers. Part IX of the
publication includes six recommendations for changes in the tax-exempt bond rules, an area of particular interest to not-for-profit healthcare facilities. It is believed that these recommendations were prompted by the Senate Finance Committee’s hearings last summer on alleged abuses by exempt organizations. *Options To Improve Tax Compliance And Reform Tax Expenditures*, Joint Committee on Taxation (JCS-2-05) (January 27, 2005).

*The Joint Committee on Taxation issued a new set of tax reform proposals, including significant changes to the tax and compliance rules governing exempt organizations and tax-exempt bonds.*

**IRS Issues Regulations Amending Treasury Department Circular 230**
The IRS issues final regulations amending Treasury Department Circular 230, which governs the conduct of attorneys, accountants and other tax professionals before the IRS. The final regulations, which generally follow the proposed regulations issued in December 2003, set forth best practices for tax advisors, impose strict due diligence and disclosure standards for certain tax opinions (termed “covered opinions”), and establish minimum ethical standards for other written tax advice.

Segregating the issue of tax-exempt bonds for special consideration, the Treasury Department simultaneously issued proposed regulations with standards for tax-exempt bond opinions. These proposed regulations include a requirement that the bond offering materials include a detailed, reasoned opinion for the bond issuer’s use in addition to the traditional, unqualified opinion used in marketing the bonds.


*The IRS issued final rules governing conduct before the IRS that will have a significant impact on best practices, due diligence, written tax advice, and ethical standards. The IRS has also issue proposed rules that would govern certain tax opinions issued in connection with tax-exempt bonds.*
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I. PAYMENT ISSUES

A. Medicare Provider Issues

Ninth Circuit Says Plaintiffs Waived Arguments About Outlier Payments by Failing to Raise Them During Rulemaking

Plaintiffs, seventy-nine hospitals and two healthcare corporations, alleged that the Department of Health and Human Services (DHHS) had failed to make the correct adjustments to the calculation of outlier payments under Medicare and sought reimbursement for alleged shortfalls in the outlier payments they received for fiscal years 1991 and 1996. Plaintiffs argued the DHHS’ outlier thresholds for 1991 to 1996 were arbitrary and capricious because DHHS did not make the correct calculations of the thresholds. The district court granted DHHS' motion for summary judgment and held plaintiffs failed to raise any arguments during the comment period.

The Ninth Circuit affirmed the district court’s ruling that the arguments were waived because they were not raised during the administrative rulemaking procedure. The appeals court noted that in Exxon Mobil v. EPA, 217 F.3d 1246 (9th Cir. 2000), it held that plaintiffs’ arguments were waived because they did not raise them during the administrative rulemaking procedure. Plaintiffs argued that Exxon was on point, but that it lacked discussion or analysis of the issue and was inconsistent with the appeals court’s authority and should not be followed. Rejecting plaintiffs’ arguments, the appeals court said it was bound by its holding in Exxon and the terseness of the opinion was irrelevant. Universal Health Services, Inc. v. Thompson, 363 F.3d 1013 (9th Cir. 2004).

Ninth Circuit found that health systems had waived arguments regarding DHHS’ improper use of an outlier formula because they failed to assert such arguments when provided the opportunity to do so during the administrative rulemaking procedure.

Fourth Circuit States That DHHS Secretary’s Interpretation of DSH Adjustment Was Reasonable and Should Be Given Deference

District Memorial Hospital (Hospital) is a small, rural hospital with a “swing bed” agreement with DHHS where the Hospital’s beds are licensed for acute care, but if necessary, can be used for skilled nursing care. The Hospital’s Medicare cost reports for 1991 to 1997 contained a disproportionate share hospital (DSH) adjustment for providing inpatient acute care to a significantly disproportionate number of low-income patients. The Hospital requested an adjustment in its calculation days for patients who received skilled nursing care in the swing beds
located in the acute care section of the hospital. After DHHS reversed the Provider Reimbursement Board’s (PRRB’s) determination in favor of the Hospital, the Hospital sought judicial review before the district court, which held that the Hospital was entitled to the adjustment, reasoning that geographic location of the beds was the basis for determining whether the beds were for skilled nursing or acute care. The Fourth Circuit reversed, stating that the DHHS’ interpretation of its own regulations should be given deference. Although the court found the specific language of 42 C.F.R. § 412.106 to be ambiguous, DHHS’ interpretation of the rule was reasonable: that “areas” of the hospital refer to the scope of the activity and not to a geographic location in a hospital. Dist. Mem’l Hosp. of Southwestern North Carolina v. Thompson, 364 F.3d 513 (4th Cir. 2004).

The Fourth Circuit held that a federal agency’s interpretation of its own rules should be given deference, and specifically that DHHS’ interpretation of the DSH adjustment rule was reasonable: “areas” of a hospital refer to the scope of the activity and not to a geographic location in a hospital.

Eleventh Circuit Rules That Ambulance Companies Must Exhaust Administrative Remedies Before Seeking Mandamus Relief Regarding Fee Schedule

Ambulance companies providing services to Medicare beneficiaries sought injunctive relief in the form of a writ of mandamus to compel the Centers for Medicare and Medicaid Services (CMS) to establish a national fee schedule for ambulance services. CMS failed to establish a national fee schedule by the statutory deadline required by the Balanced Budget Act of 1997 and the Benefits Improvement and Protection Act of 2000. The district court granted summary judgment in favor of plaintiffs on the ground that plaintiffs did not need to exhaust their administrative remedies and that mandamus relief was available. The Eleventh Circuit reversed the judgment because plaintiffs had remedial administrative relief available to them under the Medicare statute. The court further stated that the Medicare statute’s exhaustion requirement is not subject to judicially created exceptions despite plaintiffs’ claims that any efforts to exhaust such remedies would be futile. To reach its holding, the court relied on Heckler v. Ringer, 466 U.S. 602 (1984), which stated that mandamus jurisdiction is not appropriate where a plaintiff does not exhaust all administrative avenues because it appears that such efforts would be futile. It also stated that according to Shalala v. Illinois Council on Long Term Care, 529 U.S. 1 (2000), a plaintiff must exhaust all administrative remedies even if plaintiff’s statutory challenge cannot be resolved administratively. Here, plaintiffs merely established that they were unlikely to obtain the relief sought and not that they had no alternate means of relief.

Lifestar Ambulance Serv., Inc. v. United States, 365 F.3d 1293 (11th Cir. 2004).
**Plaintiffs must exhaust all CMS administrative remedies, despite futility in doing so, before they can seek judicial mandamus relief to compel CMS to act.**

**Ninth Circuit Holds Local Coverage Determination Guidelines Were Not Subject to APA Rulemaking**

In 2001, a class of Medicare beneficiaries (plaintiffs) sued the Secretary of DHHS, claiming that Local Coverage Determinations (LCDs) were substantive rules that required notice and comment rulemaking under the Administrative Procedure Act (APA). CMS contracts with private insurance companies to process Medicare claims who rely on National Coverage Determinations (NCDs) and LCDs in determining coverage. The NCDs were developed to exclude certain items and services not covered by Medicare; when no NCD applies, a contractor must make a reasonable determination of coverage based on the LCDs. Upon challenge by plaintiffs, the district court held the LCDs were interpretive rules that were not subject to APA rulemaking. Plaintiffs appealed.

The Ninth Circuit affirmed the district court’s judgment regarding whether the LCDs were interpretive rules or legislative rules. The appeals court applied the three-part test in *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993), for determining the difference between a legislative rule and an interpretive rule, and determined that in the absence of the LCDs, a standard still existed for Medicare contractors to use because they would still be under obligation to pay only for items and services that were “reasonable and necessary;” that there was no separate agency authority apart from the mandate of the statute, and therefore the agency’s rule had no general legislative authority; and finally, that plaintiffs failed to allege the LCDs amended a prior legislative rule. Therefore, the appeals court held the LCDs guidelines were interpretive and not legislative rules subject to APA rulemaking. *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004).

Local coverage determination guidelines are not subject to APA rulemaking requirements because they are interpretive rather than legislative rules.

**First Circuit Joins Ninth and D.C. Circuits in Holding That Deduction for Medicare Overpayments During Nursing Home’s Bankruptcy is Permissible Recoupment**

During year 2000, the Health Care Financing Administration (HCFA) (now CMS) determined that it overpaid Holyoke Nursing Home (Holyoke), a Medicare provider, $343,639 for years 1997 and 1998. HCFA deducted $177,656.25 from Holyoke’s 2000 request for reimbursement to recover part of the overpayment. Holyoke filed for Chapter 11 bankruptcy. Holyoke then sued HCFA, claiming HCFA’s pre-petition deduction of $99,965.97 was a voidable preferential transfer under bankruptcy law, and the post-petition deduction of $77,690.28 violated the automatic stay provision. The bankruptcy court granted summary judgment to HCFA, stating that the deduction from the reimbursement was a recoupment and
did not constitute a preferential transfer or violate the automatic stay provision. Holyoke appealed.

The First Circuit affirmed, stating that the only issue on appeal was whether HCFA's deduction constituted a permissible “recoupment” or an impermissible “setoff” barred by the automatic stay provision. The court determined that the relevant issue was whether the debt owed to HCFA arose out of the "same transaction" as the debt HCFA owed to Holyoke. The court noted that the Medicare law and the bankruptcy code have not addressed the issue, and other federal appeals courts have split over the issue. The First Circuit agreed with the reasoning of the D.C. Circuit and the Ninth Circuit, which held that recoveries of Medicare overpayments relating to previous cost years are permissible recoupments. The court rejected Holyoke's argument that recoupment is an equitable doctrine and the case should be remanded for equitable balancing because "HCFA has the unqualified right to recoup these overpayments in full." Therefore, the appeals court held equitable balancing was not warranted. Holyoke Nursing Home, Inc. v. Health Care Financing Admin., 372 F.3d 1 (1st Cir. 2004).

Because it is well settled that a post-petition “setoff” violates the bankruptcy automatic stay provision but a “recoupment” does not, the distinction is critical. The split among the federal appeals courts continues to develop, with the D.C., Ninth, and First Circuits applying the “same transaction” test in favor the government, while the Third Circuit uses a different analysis that favors providers.

U.S. Court in Rhode Island Holds Plaintiff Was Not Entitled to Discovery on Claims Stemming From Change to Cost Apportionment Method
Plaintiff HMO and Medicare provider sued DHHS and CMS seeking review of the agency’s decision that it had to obtain prior approval before changing its cost apportionment methods. Plaintiff made a discovery request for documents related to CMS' procedures for responding to requests for changes to cost apportionment methods in 1994, and the criteria for reviewing the requests. Defendants moved for a protective order and at a hearing, the magistrate judge concluded that discovery on the due process claim was unnecessary because the administrative record was complete on defendants' reasons for determining the change notice was deficient.

On appeal, the court noted that under the APA, it is limited to review based solely on the administrative record. The court determined that plaintiff did not waive its equal protection argument because waivers only occur when there has been an intentional waiver of a known right, and plaintiff did not know it was required to raise its constitutional claims before the agency before it could seek judicial review. The court suggested plaintiff should pursue its equal protection claim first through the administrative process. Therefore, the trial court correctly determined
that discovery was not warranted on the equal protection claim, but erred in holding the claim had been waived.


*Discovery request was denied on the basis the administrative record was complete, but plaintiff could bring an equal protection claim because the waiver had not been "knowing."*

**U.S. Court in California Holds That DHHS Secretary Cannot Require DME Suppliers to Prove Medical Necessity Through Medical Records**

Plaintiff Maximum Comfort, Inc., supplies durable medical equipment (DME), including motorized wheelchairs. To receive payment, plaintiff submits invoices to Cigna Healthcare, a Medicare claims processor (Cigna), which approves the claims. After an audit, Cigna reversed its approval of the claims and began recouping the overpayment by offsetting plaintiff's Medicare account. Plaintiff challenged administratively, and the DHHS Medicare Appeals Council determined that the wheelchairs were not reimbursable because plaintiff had not sufficiently documented the medical necessity. Plaintiff sought a preliminary injunction prohibiting DHHS from collecting on the alleged overpayments. The U.S. District Court for the Eastern District of California held that the Secretary of DHHS may not require a DME supplier to obtain and submit medical documentation in addition to the certificate of medical necessity (CMN). Congress had addressed medical necessity documentation for DME in 42 U.S.C. § 1395m(j), and although the Secretary had broad authority to determine what criteria must be met for an item to be medically necessary, it did not follow that the Secretary could require additional documentation to establish medical necessity. The court did not believe that Congress intended DME suppliers to be required to review medical records and second-guess physician orders for DME. The court also noted that requiring review of medical records as proposed would result in serious privacy concerns.


*Where Congress has specified the documentation required to establish medical necessity, DHHS is not authorized to require DME suppliers to submit additional documentation of medical necessity.*

**Ninth Circuit Finds Hospital Is Not Entitled to Additional Payments Under Medicare Because it Could Not Show DSH Status**

The PRRB ruled that the Medicare intermediary properly adjusted the cost reports of University Medical Center of Southern Nevada (Hospital) after finding the Hospital was not eligible for Medicare disproportionate share reimbursement, reducing the Hospital’s total reimbursement by $6.8 million. To determine disproportionate share qualification, the PRRB used the “Pickle Amendment” test, which is based on the relationship of net inpatient care revenues from state
and local government sources to total inpatient care revenues. Such proportionate amount must exceed thirty percent for eligibility.

The Ninth Circuit concluded that the hospital’s argument that the word “such” referred to “net inpatient care revenue,” was not supported by the statutory language. By ignoring the noun “total,” it violated “the principle that every word in a statute must be given effect whenever possible.” Although the original statute clearly supported the Secretary’s interpretation that the relevant state and local funding must exceed thirty percent of total net inpatient care revenue without any deduction for Medicare and Medicaid, the legislative history surrounding the 1987 amendment was more equivocal. The conference report’s exclusion of Medicare and Medicaid supported the hospital’s position, but it was not the deciding factor. The court said that subsequent legislative history was an unreliable guide to legislative intent, particularly where the discussion of existing law did not accompany a related amendment to the pertinent statutory provision. It wrote that “[b]ecause the Secretary’s interpretation reflects a permissible construction of the statutory language, it is entitled to deference,” affirming the district court’s judgment in favor of the Secretary.  

University Medical Center of Southern Nevada v. Thompson, 380 F.3d 1197 (9th Cir. 2004).

The Ninth Circuit deferred to the interpretation of the DSH qualification statute put forth by DHHS and found that the hospital did not provide sufficient evidence to maintain its DSH status.

U.S. Court in Louisiana Holds PHP Claims Were Properly Denied as Not Medically Necessary

Lady of the Sea General Hospital (plaintiff) filed claims for Medicare reimbursement for psychiatric partial hospitalization services provided to eight Medicaid beneficiaries through a partial hospitalization program (PHP). After the Medicare intermediary denied those claims, and an administrative law judge (ALJ) agreed with that denial, the plaintiff appealed to the DHHS Departmental Appeals Board, which also denied the claims. Plaintiff then sought judicial review. The U.S. District Court for the Eastern District of Louisiana granted the DHHS Secretary’s motion for summary judgment, stating that a prerequisite for approval of reimbursement for PHP services is physician certification that the beneficiary would require inpatient psychiatric care if partial hospitalization was not provided. The ALJ had determined that seven of the eight beneficiaries lacked such physician certification, thus supporting a technical denial of the claims. Further, the ALJ evaluated medical evidence and concluded that the claims were also properly denied because of a lack of medical necessity.  

A prerequisite for approval of reimbursement for psychiatric partial hospitalization services is a physician’s certification that the beneficiary would require psychiatric care if partial hospitalization was not provided.

Third Circuit Reverses Decision Denying Reclassification of GME Costs
Mercy Catholic Medical Center (Mercy) appealed the re-audit results of its Medicare intermediary’s downward adjustments to graduate medical education (GME) costs and refusal to reclassify certain of Mercy’s operating costs as GME costs. The PRRB declined to re-adjust the intermediary’s results and Mercy sought judicial review. Many of Mercy’s files documenting GME costs were lost or had been destroyed. Therefore, the trial court found that Mercy had failed to provide sufficient documentation to verify those costs. The Third Circuit disagreed, reversing and remanding the case. The Third Circuit cited a special rule by the Secretary of DHHS that discusses re-auditing of GME costs when contemporaneous records do not exist. That rule allows for later time studies to be used to verify any originally claimed GME costs in a year, but not to support the addition of costs not originally claimed as GME costs. The Secretary of DHHS argued this exception can only be used to verify GME costs and cannot be used as a basis for reclassifying operating costs. The court concluded the DHHS Secretary’s interpretation contradicts the express language of the regulation because the regulation does not limit the use of re-audit corrections to reclassify operating costs; rather, the regulation clearly provides that re-audit corrections may be used not only for misclassified GME costs but also for all misclassified costs. The Third Circuit also pointed out that CMS had inconsistently applied the Secretary’s instructions and its changing positions affected the amount of deference due to the Secretary’s interpretation. The Third Circuit reversed the trial court’s decision on the ground that Mercy had produced sufficient contemporaneous evidence of teaching programs to support re-classification of costs.


A special rule issued by the Secretary of DHHS permits the use of later time studies to verify originally claimed GME costs, but not to support the addition of costs. However, the re-audit corrections may be used to reclassify all misclassified costs, including operating costs.

Texas Appeals Court Says Trial Court Lacked Jurisdiction Because Plaintiffs Failed to Exhaust Administrative Remedies
Aetna, Inc. owns an HMO that became a Medicare+Choice (M+C) organization. Aetna entered into a contract with North American Medical Management (NAMM) for the administration of the M+C plan. Pursuant to that contract, Aetna paid NAMM a monthly capitation payment and NAMM paid claims for M+C patients. NAMM then contracted with a number of hospitals, including Christus Health Gulf Coast, Christus Health Southeast Texas, Gulf Coast Division, Inc., Memorial Hermann Hospital System and Baptist Hospitals of Southeast Texas (collectively, the Hospitals) to provide healthcare services. However, NAMM became insolvent.
and failed to pay claims worth over $13 million to the Hospitals. When Aetna refused the Hospitals’ demand for payment, the Hospitals sued Aetna. The trial court agreed with Aetna that it did not have subject matter jurisdiction because the Hospitals failed to exhaust their administrative remedies under Medicare. Therefore, the trial court granted Aetna’s motion to dismiss. The Hospitals appealed.

The Texas Court of Appeals affirmed, stating that providers that have an interest in the outcome are parties to the proceedings and are provided for in the administrative process. The court concluded that Aetna clearly made an organizational determination when it refused to pay the claims that NAMM had failed to pay. Thus, the administrative process applied to the dispute. The court declined to follow RenCare, Ltd. v. Humana Health Plan of Texas, Inc., 395 F.3d 555 (5th Cir. 2004), which the court said was distinguishable because it dealt with “a pure payment dispute with no mention of any potential coverage issues.” Christus Health Gulf Coast v. Aetna, Inc., 2005 WL 851187 (Tx. App. 2005).

A claim arises under the Medicare Act if the claim is either based on the Medicare Act or the claim is “inextricably intertwined” with a claim for benefits.

D.C. Circuit Says New Provider Exemption Applied to Medical Center That Purchased Operational Rights From Nursing Home

St. Elizabeth’s Medical Center of Boston (St. Elizabeth’s) purchased operational rights from Friel Nursing Home and opened a transitional care unit (TCU). State law required facilities to have operating rights in order to obtain a determination of need for operating a new nursing facility. TCUs qualify as skilled nursing facilities (SNFs) under Medicare. The following year, St. Elizabeth’s applied for a new provider exemption for the TCU, but CMS denied the request on the ground that the TCU was operated previously under Friel and, therefore, was not a new provider. St. Elizabeth’s appealed the decision and the PRRB reversed CMS’ decision, holding that St. Elizabeth’s was entitled to the new provider exemption. The Secretary of DHHS reversed the PRRB’s decision and in 2003, St. Elizabeth’s filed suit in federal district court challenging that decision as arbitrary and capricious. St. Elizabeth’s argued that Friel’s operating rights were never transferred, and even if they were, the transfer of operating rights was not a transfer of ownership. The district court ruled in favor of the government. The D.C. Circuit found that because Friel was primarily engaged as a nursing facility and not a SNF, the new provider exemption was available to St. Elizabeth’s. St. Elizabeth’s Med. Ctr. of Boston, Inc. v. Thompson, 396 F.3d 1228 (D.C. Cir. 2005).

Where an entity purchases operational rights from a nursing facility (as opposed to a SNF), the new provider exemption is available to a purchaser opening a transitional care unit.
First Circuit Finds Subject Matter Jurisdiction Over Government’s Action to Recover Medicare Overpayments

The federal government brought an action in district court against Lahey Clinic Hospitals (Lahey) in connection with laboratory tests and other diagnostic procedures billed to and paid for by Medicare. The government alleged Lahey submitted claims for individual blood chemistry tests that could have been performed more economically as a single panel test. Further, the government alleged that Lahey submitted claims for hematology tests that were performed but were medically unnecessary. The government did not allege fraud but sought restitution for the overpayment under the common law theories of unjust enrichment and payment under mistake of fact. Lahey moved to dismiss, claiming the court lacked subject matter jurisdiction because the government had failed to pursue administrative remedies before initiating the action. The district court denied the motion, holding that the Medicare Act’s jurisdictional provisions, 42 U.S.C. §§ 405(h) and (g), only apply to claims brought against the federal government, not to claims initiated by the government. The First Circuit affirmed, holding that 28 U.S.C. § 1345 grants federal courts broad jurisdictional powers over actions in which the United States is plaintiff and was not repealed by the Medicare Act. The appeals court rejected Lahey’s arguments that the Medicare Act expressly or implicitly repealed § 1345 with respect to Medicare payment decisions. Further, the court rejected Lahey’s contention that the Medicare Act displaced the government’s common law causes of action by directly addressing the government’s remedy for collecting overpayments. The court found no inconsistency between allowing the Secretary to collect overpayments and the government’s ability to pursue an independent collection action. Accordingly, the appeals court affirmed the lower court’s ruling.

U.S. v. Lahey Clinic Hosp., Inc., 399 F.3d 1 (1st Cir. 2005).

The Medicare Act’s jurisdictional provisions do not bar actions by the federal government in federal district court seeking restitution of Medicare overpayments.

U.S. Court in Arkansas Says High Dose Chemotherapy Services Covered by Medicare Even Though Followed by Non-Covered Stem Cell Transplantation

The University of Arkansas sought review of the DHHS Secretary’s decision denying Medicare coverage of high dose chemotherapy and autologous stem cell transplantation provided by the University of Arkansas Medical Center (UAMC) in 1999. At that time, autologous stem cell transplants were not considered reasonable and necessary for treating multiple myeloma and therefore not covered. In May 2000, multiple myeloma became a covered condition for autologous stem cell transplantation. UAMC sought payment from Medicare, arguing that the procedures it performed in 1999 on twelve patients were covered by the revised Medicare Coverage Issues Manual § 35.30.1. In the alternative, UAMC sought payment of a lesser amount, contending that the NCD in effect at
the time covered high dose chemotherapy provided to patients with multiple myeloma.

The ALJ upheld the intermediary’s denial of coverage, finding that all of the services were connected with the non-covered stem cell transplants. The U.S. District Court for the Eastern District of Arkansas agreed in part, finding that stem cell transplantations were not covered, but that high dose chemotherapy was covered for multiple myeloma. The court disagreed with the ALJ’s conclusion that the main purpose of the patients’ hospital admissions was stem cell transplantation. As support for its conclusion, the court cited Medicare Intermediary Manual § 3101, which provides that a covered service can be severed from a non-covered service so long as the covered service is medically necessary and appropriate. Therefore, the high dose chemotherapy was covered by Medicare.

Board of Trustees of the Univ. of Arkansas v. Thompson, 354 F.Supp.2d 924 (E.D. Ark. 2005).

DHHS should not have denied Medicare coverage for high dose chemotherapy provided to patients with multiple myeloma based on the fact that those services were followed by non-covered stem cell transplantations.

U.S. Court in Pennsylvania Finds Secretary’s Retroactive Action Regarding Medicare Allocation Methodology Supported by Substantial Evidence

Mercy Home Health (Mercy) is the only subsidiary of Mercy Home Health Services (Home Office), a Medicare provider. The Home Office requested its intermediary, Independence Blue Cross (IBC), to allow it to use an alternate allocation method for its costs, stating that most of its business is service oriented so the “costs of the Home Office should be largely allocated to those subsidiaries with high personnel costs, [such as Mercy].” IBC eventually agreed, and the Home Office used the alternate methodology from 1993 through 1996; however, IBC informed the Home Office that it would need to use the original cost allocation method beginning in 1997. Wellmark Blue Cross Blue Shield of Iowa and Cahaba Government Benefit Association (Wellmark) later took over the intermediary contract and disallowed the Home Office’s allocation methodology for the Home Office’s 1995 and 1996 cost reports.

The Home Office appealed and the PRRB found in its favor, but CMS reversed the determination. On appeal to the U.S. District Court for the Eastern District of Pennsylvania, the court found that the Secretary of the DHHS has the ability to take retroactive actions to remedy incorrect Medicare reimbursements, and that substantial deference should be given to those decisions. Wellmark reversed IBC’s decision to allow the alternate methodology within the three-year time period allowed under 42 C.F.R. § 405.1885(b)(1). Moreover, the Home Office presented inadequate evidence of why the alternate methodology should be used. The court noted that substantial deference should be accorded to the Secretary’s determinations because the statutes involved pertain to a “complex
and highly technical regulatory program” and “require significant expertise and entail the exercise of judgment grounded in policy concerns.”


*Medicare intermediary may retroactively remedy incorrect Medicare reimbursement by making institution change its cost allocation method.*

**U.S. Court in New York Upholds Hospital MSA Groupings but Finds DHHS Secretary Could Not Partially Implement Occupational Mix Adjustment**

Seventy-six hospitals in and around New York City (the Hospitals) sued the Secretary of DHHS to challenge the new rules affecting their reimbursement under the Inpatient Prospective Payment System (IPPS) beginning October 1, 2004. The first challenge involved how the Secretary grouped the Hospitals in a metropolitan statistical area (MSA) that included three New Jersey counties previously grouped in another MSA; the Hospitals claimed their wage indices were diluted because suburban hospitals have lower wage levels. The U.S. District Court for the Southern District of New York granted the Secretary summary judgment on this claim, noting that inaccuracies will be inherent to some extent in any averages; to make the MSAs completely accurate, DHHS would have to treat each individual hospital as its own separate MSA, which is in contravention of Congressional policies underlying the development of IPPS. The court also noted that the Hospitals did not offer any alternate MSAs and did not show any material inaccuracies in the newly adopted MSAs.

The Hospitals also charged that Congress did not give the Secretary the discretion to partially implement the occupational mix adjustment, and therefore, his actions were arbitrary and capricious. In the final rule, the Secretary based the wage index on a blend of ten percent of an average hourly wage that takes into account occupational mix, and ninety percent of an average hourly wage that does not. The court ruled in the Hospitals’ favor, finding that the Medicare statute did not provide the Secretary with the leeway to implement the occupational mix on a partial basis; rather, it must be implemented in full.


*Any changes to the occupational mix by the Secretary of the DHHS must be made in full, as the Medicare statute does not support partial implementation.*

**Florida Appeals Court Says Lower Court Erred in Ordering Tortfeasor to Pay Medicare Beneficiary Settlement Proceeds Directly**

Plaintiff Edna Tripp reached a settlement agreement with Pollo Operations for $55,000 following a slip and fall incident, $37,000 of which had been already paid by Medicare to cover her medical bills. The settlement agreement provided that all medical liens would be satisfied from the settlement funds. However, the trial court granted plaintiff’s request to order Pollo Operations to deliver the settlement check directly to her, which would enable the plaintiff to avoid paying back Medicare as required under the Medicare Secondary Payer (MSP) statute. The
appeals court reversed, stating that the MSP statute makes Medicare the secondary payer and subrogates Medicare to recoup any sums it has paid out from the rightful primary payer. Moreover, the court stated that Florida courts have found that the MSP statute applies whenever a liability insurer pays a Medicare beneficiary for a tortfeasor’s legal liability. Thus, plaintiff could not receive the tort settlement check directly.


A Medicare beneficiary cannot have a tort settlement paid directly to her to avoid reimbursing Medicare under the Medicare Secondary Payer statute.

B. Medicaid Provider Issues

Delegation of Audit Authority to State Controller's Office Upheld.

A 1999 audit conducted by the California State Controller’s Office (SCO) of medical services provided by plaintiff physician and billed to Medi-Cal found that over a three-year period, the physician billed for 46,802 needle electromyographic studies of the sphincter and 43,131 intra-abdominal voiding pressure tests, which amounted to ninety-nine percent of all Medi-Cal’s payments for those procedures. An audit concluded that plaintiff had billed for procedures he had not performed. Plaintiff appealed, and following a hearing on the issues, an ALJ issued a proposed decision upholding the findings, which was adopted by the Director of the Department of Health Services (Department) as the final decision. Plaintiff petitioned the trial court for a writ of mandate, which the trial court denied. Plaintiff appealed to the California Court of Appeal, Second District, which reversed in part and affirmed in part. Because the Department’s final decision was issued more than 180 days after the close of the record, it was untimely; thus, plaintiff’s overpayment should be reduced by ten percent under state law. However, the court rejected plaintiff’s argument that the Department violated the single agency rule under 42 U.S.C § 1396a by allowing the SCO to perform and take action on the audit. The delegation was permissible under RCJ Medical Services, Inc. v. Bonta, 111 Cal.Rptr.2d 223 (Cal. App. 2001), because the federal agency that administered the Medicaid program had approved the delegation, based on a reasonable construction of the statute.


California appeals court ruled that the Department of Health Services acted appropriately in its delegation of authority to the state Controller’s Office to conduct and take action on the audit of a physician.

U.S. Court in New York Holds Plaintiffs Have No Enforcement Rights Under Medicaid Act

Plaintiff New York Association of Homes and Services for the Aging, Inc., a non-profit organization of Medicaid provider members, sued the state of New York and various state agencies (defendants) claiming that cost control measures enacted by New York as part of the state’s annual budget violated healthcare
providers’ rights under the Medicaid Act. The U.S. District Court held that under §1983 that plaintiff’s claims against defendants were unenforceable. Plaintiff first argued that defendants failed to comply with the requirements of the Boren Amendment, which was enacted in 1980 and gave healthcare providers a right to reasonable and adequate reimbursement rates under Medicaid. Although the Boren Amendment was repealed in 1997, there is still a statutory requirement that states provide a public process for Medicaid reimbursement rate determinations.

The court observed that it is well established that a state cannot be sued under §1983 unless it is for injunctive relief to prevent an ongoing violation of federal law, and does not extend to retrospective relief. The court held that Eleventh Amendment immunity applied to plaintiff’s claims because they sought a declaration that the Boren Amendment was violated in the past.

The further court determined that §1396a(a)(13) establishes that the states must provide certain public processes for the determination of rates, but that §1396a(a)(13) does not create any rights plaintiff could enforce. Thus, plaintiff had no enforceable rights under §1396a(a)(13), and the court dismissed the Medicaid statutory claims.


Section 1983 does not itself create an enforceable federal right; rather, a §1983 cause of action must be based on an enforceable right in another statute. The Medicaid Act did not create any such enforceable right.

Texas Appeals Court Says No Controversy Existed Between Parties After Summary Judgment

The Texas Department of Health and Human Services (Department) contracted with HMO Blue, Inc. (Blue), to provide health services for Medicaid beneficiaries under the state’s STAR program. Blue contracted with Vista Health Plan, Inc. (Vista), to provide the services, and Vista was to be paid capitated payments instead of fee-for-service payments. In 2001, Vista disputed the payments made by Blue for premature infants, arguing the claims were for ineligible Medicaid recipients and the infants were covered under Medicare or a Medicaid fee-for-service plan.

Vista sought a judgment under the Uniform Declaratory Judgments Act (UDJA) that the Department exceeded its authority in interpreting the Medicaid regulations, misinterpreted certain statutes, and impaired Vista’s constitutional rights.

The court explained that a party may seek an interpretation of an agency’s statutory authority under the UDJA; however, in this case, there was no justiciable controversy between Vista and the Department, as Vista only had a dispute with the Department because of its dispute with Blue. Therefore, without
the dispute with Blue, Vista would have no claims against the Department. Accordingly, as the trial court had correctly granted Blue summary judgment, the appeals court held that there was no controversy for which Vista could seek relief.


No controversy existed between plaintiff and state agency for which a declaratory judgment could be granted under UDJA, as plaintiff’s dispute was with state agency’s contractor, which had already been granted summary judgment.

Massachusetts High Court Permits Recovery of Cost of Care From Medicaid Beneficiaries Despite Tobacco Settlement.
Plaintiffs sought to prevent the state from recovering costs of decedents’ care for tobacco-related illnesses under its estate recovery program, arguing that since the state had received funds from the tobacco settlement, recovery from beneficiaries' estates would constitute double recovery. The Massachusetts Supreme Judicial Court disagreed, holding that sovereign immunity barred most of the claims alleging double recovery and unjust enrichment, because the state had pursued its claims directly rather than through a subrogation action. Although, under state law, plaintiffs might have a setoff right against a claim brought against them by the state, that state claim was prohibited because of the Congressional amendment of the Medicaid act that precluded Medicaid beneficiaries from claiming any portion of the settlement funds.


A state may recoup from Medicaid beneficiaries and their estates payments for tobacco-related illnesses, even though the state received funds for such care through the tobacco litigation settlement. Any right to setoff under state law was trumped by the federal law prohibiting any claim to a portion of the tobacco settlement by Medicaid beneficiaries.

Eighth Circuit Says Hospital Appeal Regarding Inclusion of State-Only Days in DSH Calculation Was Not Timely
On October 15, 1999, CMS issued Program Memorandum A-99-62, clarifying the methodology hospitals must use in calculating their DSH payments. Some states provide health insurance for indigent residents who do not qualify for Medicaid—these are known as “state only” days and should not be used in calculating a hospital’s DSH payment calculation. The Program Memorandum provided for DSH calculation appeals and set a cut-off date of October 15, 1999 for appeals. Hospitals that had included state-only days in their DSH calculations and had been reimbursed for doing so prior to the cut-off date would not be subject to a recoupment action; but hospitals that did not include state-only days in their calculations could be reimbursed for those days if they filed an appeal by the cut-off date. Any hospital that had not raised the issue of reimbursement for state-only days until after the cut-off date was barred from receiving reimbursement.
United Hospital (Hospital) appealed its cost reports, including its DSH calculation for 1991 and 1992, but did not specifically raise the issue of state-only days. The Eighth Circuit held that the appeal for state-only days reimbursement was not timely filed. The Hospital had already raised the issue of DSH payments before the PRRB and was denied; thus, there was no rational basis to allow the Hospital to bring up new DSH issues and backdate them to be timely. The Eighth Circuit also held that CMS’ actions in setting a cut-off date for state-only days reimbursement was not arbitrary and capricious. 

*United Hosp. v. Thompson,* 383 F.3d 728 (8th Cir. 2004).

Providers must ensure that they raise all cost report issues in a timely manner, as courts do not hesitate to declare appeals untimely.

**Ninth Circuit Holds DSH Calculations Should Include Patient Days of Expanded Populations Under § 1115**

Plaintiffs were hospitals that had excluded patient days of expansion populations from the Medicaid fraction in determining their DSH calculation. They sued the Secretary of the DHHS, claiming that he erroneously interpreted the § 1115 waiver provisions, which govern the calculation of DSH payments, to exclude expansion populations. The district court held, and the Ninth Circuit affirmed, that patient days of low-income individuals who are covered by Medicare under a § 1115 waiver but who would not otherwise be eligible for the program should be accounted for in the Medicaid fraction used in the DSH calculation.

The Ninth Circuit stated that the DSH statute provides that the Medicaid fraction includes those days attributable to patients who “were eligible for medical assistance under a State plan approved under [Title] XIX . . . .” The court reasoned that the statutory scheme unambiguously supported the conclusion that § 1115 expansion populations receive medical assistance under a State plan by tying § 1115 waivers to approved State Medicaid plans, which provides that their costs be treated as expenditures under a State plan. “[B]ecause expansion population patients are capable of receiving Title XIX assistance, they must be regarded as ‘eligible’ for it.”

*Portland Adventist Med. Ctr. v. Thompson,* 399 F.3d 1091 (9th Cir. 2005).

Hospitals may include patient days of expanded populations in the calculations for their DSH payments.

**Eighth Circuit Holds Federal Medicaid Statute Allows States to Recover Funds From Third-Party Payments Made for Medical Expenses Only**

The State of Arkansas Department of Human Services (ADHS) paid to Medicaid beneficiary Heidi Ahlborn $215,645 in medical bills for injuries she sustained in a car accident that left her permanently disabled. When applying for the benefits, Ahlborn assigned her right to any settlement, judgment or award she might receive from third parties “to the full extent of any amount which may be paid by
Medicaid for the benefit of the applicant.” Alhborn eventually received a $550,000 lump sum settlement payment from her insurance company and the party responsible for her injuries.

ADHS placed a lien for $215,645 on Ahlborn’s settlement, and she sought a declaratory judgment that ADHS should only be allowed reimbursement for $35,581, the amount of medical services paid by ADHS. The trial court granted summary judgment in favor of ADHS, holding that the State was entitled to recover for the total amount of benefits provided. The Eighth Circuit reversed, finding the “straight-forward interpretation of the text of [the Medicaid] statutes demonstrates that . . . [the State may only] recover payment from third parties to the extent of their legal liability to compensate the beneficiary for medical care and services incurred by the beneficiary.”

_Ahlborn v. Arkansas Dep't Human Servs._, 397 F.3d 620 (8th Cir. 2005).

_State Medicaid programs may only recover amounts paid for medical services on behalf of a beneficiary when the beneficiary later receives a third-party settlement._

C. _Beneficiary Actions_

_Ninth Circuit Upholds Preliminary Injunction Enjoining County From Closing a Hospital and Reducing Services at Another Hospital_

In January 2003, the Los Angeles County Board of Supervisors (Board) voted to close one hospital and reduce the services offered at another. Plaintiffs, a group of chronically ill, indigent patients who rely on county health services, sought injunctive relief against this action. The district court granted a preliminary injunction and the Board appealed. The Ninth Circuit held that the district court judge’s issuance of the preliminary injunction was not an abuse of discretion. Plaintiffs had standing to sue because they demonstrated that they are chronically ill and rely on the county healthcare system, including the two hospitals in question. Plaintiffs also showed that following closure and reduction of services, the county would have greater difficulty in providing them with timely and appropriate care as required by law. The Ninth Circuit stated that the plaintiffs did not have to wait until the hospitals actually closed or reduced services to establish a potential injury to each plaintiff. Plaintiffs also established the necessary causation by showing that their health was linked to the services provided by both hospitals. Finally, plaintiffs demonstrated that the injunction would remedy their potential injury. The Ninth Circuit concluded that the county’s budget crisis was not a valid defense to plaintiffs’ state law claims because the county is statutorily required to provide appropriate health services to the State’s needy population.

_Harris v. Bd. of Supervisors, L.A. County_, 366 F.3d 754 (9th Cir. 2004).
The Ninth Circuit Court held that closure of hospitals as a result of a budget crisis was properly enjoined because state law required the county to provide care to the needy.

Ninth Circuit Rules That District Court Had Jurisdiction to Enforce Consent Decrees Against State Officials to Provide Services to Mentally Disabled Children

Plaintiffs, a class of indigent children suffering from severe emotional and mental disabilities, sued a number of state officials seeking declaratory and injunctive relief to prevent defendants from placing plaintiffs in hospital facilities which housed known sexual predators and child molesters. An agreement was negotiated; however, two consent decrees were entered into after defendants failed to perform under the agreement. A third consent decree was later entered into that obligated defendants to supply additional needs assessments for the children and draft a compliance plan. Plaintiffs disagreed with the compliance plan and moved for a finding of contempt against defendants. Defendants claimed that the district court no longer had jurisdiction over the consent decrees and moved to dismiss the case and vacate the consent decrees. The court denied the motions and defendants appealed.

The Ninth Circuit affirmed the district court’s judgment, stating that the district court had continuing jurisdiction over the consent decrees, and that the Ninth Circuit had jurisdiction because a denial of a motion to vacate a judgment is a final appealable order. It rejected defendant’s argument that plaintiffs failed to show a continuing violation of federal law that would give the district court subject matter jurisdiction. Under Rufo v. Inmates of the Suffolk County Jail, 504 U.S. 367 (1992), “a party seeking to enforce a consent decree does not need to show a continuing violation of federal law. To hold otherwise would completely eviscerate the central purpose of consent decrees.” Defendants failed to show “that circumstances in law or fact had changed so significantly that relief from the judgment was warranted.”

Jeff D. v. Kempthorne, 365 F.3d 844 (9th Cir. 2004).

A federal district court has continuing jurisdiction to enforce a consent decree where federal rights are involved, and claimants need not show a continuing violation of law on the part of the other party to seek judicial enforcement.

Nevada High Court Rules That Government’s Filing of Lien on Deceased Medicaid Recipient’s Interest in Property Is Not Impermissible Recovery

The Nevada Department of Human Resources, Welfare Division (NSWD), recorded a notice of lis pendens and filed a lien on deceased Medicaid recipient Harold Ullmer’s interest in the home he owned in joint tenancy with his wife Agnes to recover Medicaid benefits that had been paid on Harold’s behalf before his death. The notice and lien did not state that NSWD would release the lien if Agnes wished to sell the property, although NSWD had an unwritten policy to do so. Agnes sought to enjoin NSWD from placing liens on the homes of deceased
Medicaid recipients. The district court certified a class of surviving spouses and granted the motion for injunctive relief. NSWD appealed. The Nevada Supreme Court held that the liens were overly broad, but reversed the grant of injunctive relief for the class members as a whole on the ground that the district court had prematurely considered the matter before the end of the class notification period.

The court looked at the plain language of the Nevada estate recovery statute, and finding that “recovery” was not defined, relied on its plain, everyday meaning. The court concluded that a lien was not a “recovery” because repayment of the Medicaid funds does not occur until the surviving spouse dies. However, the court determined that the State’s ability to impose a lien under these circumstances is not absolute, as the lien must contain a notice that it will be released for a bona fide transfer, but not for a gift transfer. Because Agnes’ lien did not contain this limiting language, the court held that the lien was overly broad and affirmed the district court’s injunction.


State may place a lien on deceased Medicaid beneficiary’s home to recover benefits paid so long as the lien contains certain limiting language.

**Third Circuit Says Plaintiffs May Sue State for Failing to Provide Services Under Medicaid Act**

Plaintiffs, a class of mentally retarded adults who qualify for intermediate care facility services for persons with mental retardation (ICF/MR), sued the Secretary of the Pennsylvania Department of Public Welfare (DPW) under § 1983 to force the state to provide them with the services. Plaintiffs argued they had a right to the services but had been on a waiting list, and DPW argued it did not have funds to provide the services and that the only remedy for its noncompliance was a suspension of funding by Congress. The district court dismissed the case and held that plaintiffs could not vindicate their right to the services through a § 1983 action and plaintiffs appealed. The Third Circuit reversed the district court’s judgment.

The court concluded that for a statute to confer individual enforceable rights, there must be the intent to confer the rights, the statute could not be vague, and the statute must impose an obligation on the state. Additionally, a plaintiff’s rights must be more than just in “the general zone of interest that the statute is intended to protect” and the statute must contain “rights creating language” that provides for an individual entitlement while also benefiting a class. The court further found that the Medicaid statute creates binding obligations on the states that accept Medicaid funding.

Finally, the court considered whether Congress has precluded individual enforcement either expressly or by providing a remedial scheme and found there was no express preclusion of individual actions and no apparent remedial
scheme in the statute. Accordingly, the court held that plaintiffs had provided sufficient evidence that they were the intended recipients of the ICF/MR services, and that Congress intended them to have those services and did not preclude enforcement of their individual rights to the services.


*Plaintiffs, if they can show that they are the intended recipients of services under the Medicaid act, have the right to sue states through a § 1983 action for failing to provide services under the Medicaid Act.*

**U.S. Court in Oregon Enjoins Government From Charging Non-Nominal Co-Payments for New Medical Program, but Refuses to Certify Plaintiffs as a Class**

In 2001, the state of Oregon adopted a New Medicaid program in which the old program, the Oregon Health Plan (OHP), was designated the Oregon Health Plan Plus (OHP Plus). OHP Plus continued with the same level of Medicaid benefits including nominal copayments for drugs and outpatient service. An expansion plan was also enacted called the Oregon Health Plan Standard (OHP Standard), which expanded coverage to certain uninsured adults that otherwise would not be eligible for coverage without a waiver. The OHP Standard plan reduced benefits and imposed monthly premiums and co-payments regardless of an individual’s ability to pay and allowed healthcare providers to refuse service to a recipient who failed to make the co-payments.

Plaintiff brought suit challenging the imposition of the premiums and co-payments for OHP Standard. The district court held that the OHP Standard plan violated federal law by imposing co-payments without meeting certain requirements. The court granted an injunction that would bar all co-payments because defendants failed to meet the federal requirements for imposing such co-payments on expansion populations for Medicaid benefits. However, the court denied the motion for class certification on the grounds that plaintiffs cannot adequately represent the interests of the putative class and the relief plaintiffs have obtained will benefit all putative class members.


*Due to the state of Oregon’s failure to meet the federal requirements for imposing co-payments on expansion populations for Medicaid benefits, charging for such co-payments was enjoined. However, the court did not grant the plaintiffs class certification request.*

**Federal Court Rejects Doctors’ Attempt to Block Publication of Settlements**

The U.S. District Court for the District of New Jersey found that neither federal law nor the U.S. Constitution bars the release of information on medical malpractice payments submitted to the state by malpractice insurers to comply with a 1989 state law, rejecting arguments by physicians that publication of
medical malpractice claim settlements would void the confidentiality provisions of existing settlement contracts.

The ruling clears the way for the state to enforce a disputed provision of the New Jersey Health Care Consumer Information Act, which was enacted in 2003. At issue is the requirement for the New Jersey Division of Consumer Affairs, in consultation with the State Board of Medical Examiners, to develop and make available to the public over the Internet and through a toll-free telephone number profiles of all the state’s licensed physicians and podiatrists.

The court stated that the legislation serves a significant and legitimate consumer protection interest that overrides any disservice to existing contracts. In light of the legitimate public purpose behind the statute and the fact that the state is not a party to the medical malpractice agreements, “this Court must respect the New Jersey Legislature’s policy-making authority with regard to the necessity and the reasonableness behind disclosure of statutorily mandated medical malpractice information.”

**Medical Soc. of New Jersey v. Mottola, 320 F.Supp.2d 254 (D.N.J. 2004).**

*Information about medical malpractice settlements required under New Jersey’s Health Care Consumer Information Act was not protected by state or federal law and the State Board of Medical Examiners, which was required to provide the information, was not bound by the confidentiality provisions found in the settlement agreements themselves.*

**Sixth Circuit Holds Date Government Announces Coverage for Procedure Triggers Entitlement**

In 1997, DHHS issued an NCD prohibiting reimbursement for cryosurgery on the basis of inadequate evidence of effectiveness. On February 1, 1999, DHHS issued a decision memorandum approving reimbursement for cryosurgery, finding that efficacy had been established. The decision memorandum set forth various administrative actions necessary to effect the coverage for cryosurgery. Cryosurgery became reimbursable on July 1, 1999.

Plaintiff, a Medicare beneficiary, underwent cryosurgery to treat prostate cancer on March 30, 1999. Reimbursement was denied on the basis of the earlier NCD. The case was appealed to the Sixth Circuit, which held that because the DHHS Secretary had declared cryosurgery to be a reasonable and necessary treatment for prostate cancer two months prior to plaintiff's surgery, plaintiff was entitled to reimbursement. The court stated that the fact that certain administrative steps had not been completed at the time of plaintiff's procedure did not preclude reimbursement. The court further granted attorneys’ fees and costs to plaintiff.

**Guzzo v. Thompson, 2004 WL 1532254 (6th Cir. 2004).**
Entitlement to reimbursement under Medicare begins when DHHS declares a given procedure to be medically necessary, without regard to completion of administrative steps related to claims processing.

Fourth Circuit Says Medicare Was Entitled to Reimbursement From Malpractice Settlement as Secondary Payor
Plaintiff brought a malpractice claim against Kaiser Health Plan for the Mid-Atlantic States after developing a perforated colon and sepsis that was not promptly treated and received a $285,000 settlement. Medicare sought reimbursement for amounts expended in treating the condition. Plaintiff filed suit seeking a declaratory judgment that the Secretary of DHHS was not entitled to reimbursement out of the malpractice settlement. The district court held that DHHS was entitled to reimbursement under the MSP statute even though there was no expectation at the time the payments were made that a settlement would be made promptly. The court further held that Kaiser's self-insurance plan constituted a "primary plan" for purposes of the MSP statute.

The Fourth Circuit affirmed, noting that a split of opinion had existed among courts on each of these issues, but that provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) had clarified the law. The prompt payment provision was clarified to provide that Medicare is entitled to reimbursement whenever a primary plan is responsible for the payment of medical services. The Fourth Circuit held that application of this provision to plaintiff would not be unfair, since it merely clarified, rather than changed, the law. Similarly, the MMA amendments clarified that a self-insurance plan, where an entity carries its own risk in whole or in part, can be a primary plan under the MSP statute.
Brown v. Thompson, 374 F.3d 253 (4th Cir. 2004).

Given the MMA amendments clarifying the "prompt payment" and "primary plan" provisions of the MSP statute, Medicare payments may be recovered from the proceeds of self-insured malpractice settlements.

New Jersey Supreme Court Says Child Beneficiary’s Transfer of Parent’s Assets for Medicaid Spend Down Was Proper
Petitioner filed a petition seeking guardianship of his mother who had been certified by her physician as suffering from irreversible dementia. Petitioner requested court approval of his Medicaid “spend-down” plan. The trial court approved the guardianship and sale of the home but denied petitioner the authority to transfer the assets under the spend-down plan. The appellate division remanded the case for a determination of whether Petitioner’s mother had expressed a preference, before her incompetency, about the spend-down plan and for a determination of whether Petitioner should be allowed to sell his mother’s house. Petitioner appealed.
The New Jersey Supreme Court reversed the appellate division’s judgment. The high court stated it was adopting the \textit{Trott} criteria, \textit{In re Trott}, 288 A.2d 436 (N.J.Super.Ch. 1972), which requires a court to consider the best interests of the ward in determining if the ward would have approved the plan if the ward had been competent. The court determined that the \textit{Trott} criteria implies a presumption in favor of the beneficiaries of the ward’s estate.

The high court further determined that the \textit{Trott} criteria had been met in this case because Petitioner’s mother was incompetent, the spend-down plan was designed to adequately fund her care, and her placement in a nursing home was necessary. There was also substantial evidence that Petitioner’s mother would not have disapproved the spend-down plan. Accordingly, the high court revered the appellate division’s judgment and remanded the case. \textit{In the Matter of Mildred Keri}, 853 A.2d 50 (N.J. 2004).

\textit{New Jersey courts will apply the Trott criteria to determine if a child beneficiary’s transfer of a parent’s assets for Medicaid spend down is proper.}

\textbf{U.S. Court in Arizona Orders State Medicaid Agency to Provide Adequate Services for Disabled and Elderly}

A group of Arizona Medicaid beneficiaries sued the Arizona Health Care Cost Containment System (AHCCCS) for not providing adequate home- and community-based services to the elderly and disabled through the State’s Long Term Care System (LTCS). The U.S. District Court for the District of Arizona determined that the LTCS could not provide adequate care because of low wages paid and because the AHCCCS did not have a contingency plan in place to cover care gaps where no workers were available or failed to show up as scheduled; further, no data is kept on whether the beneficiaries actually received authorized care or continuity of care. The court held that once an agency elects to participate in Medicaid, it must comply with all provisions of the Medicaid Act, and that all beneficiaries have a property right in the benefits for which they qualify. As such, AHCCCS must provide equal services by providing high-enough pay to ensure that it can employ sufficient numbers of home health providers so that all beneficiaries receive service. \textit{Ball v. Biedess}, 2004 WL 2566262 (D. Ariz. 2004).

\textit{U.S. District Court in Arizona held that a state agency must pay its home health providers a sufficient wage in order to ensure that there are enough providers to care for all beneficiaries entitled to home health services.}

\textbf{U.S. Court in Connecticut Holds Elderly Resident of Assisted Living Facility Was Not Entitled to Medicaid Coverage}

Plaintiff, a resident of an assisted living facility (ALF), sued the Commissioner of the Department of Social Services of the State of Connecticut and the DHHS Secretary (Defendants), claiming the Medicaid program violated her equal
protection rights because Medicaid would pay for her SNF stay, but would not pay for her stay in an ALF.

The U.S. District Court for the District of Connecticut first addressed the plaintiff’s standing to pursue a claim. The court held that because the plaintiff would be forced to move from the ALF because of the Medicaid requirements, and the situation could be remedied if Medicaid covered her expenses for living at the ALF, she had standing to assert her claim.

In evaluating the equal protection claim, the court considered whether the statute disadvantaged a suspect class or abridged a fundamental right. The court held that age and disability were not suspect classifications, and further, the statute did not affect any fundamental rights. In addition, the court held that plaintiff may have a liberty interest under the Due Process Clause in remaining at the ALF; however, the federal government does not have an affirmative obligation to fund plaintiff’s expenses so she could exercise such liberty interest. Finally, the court held that because benefits were available to all qualified individuals on an equal basis, there was not an Americans with Disabilities Act (ADA) violation. _Leocata ex rel. Gilbride v. Wilson-Coker_, 343 F.Supp.2d 144 (D.Conn. 2004)

_Plaintiffs may not use the Equal Protection Clause, Due Process Clause or ADA to force Medicaid to fund their stays at assisted living facilities._

**Sixth Circuit Rules That Beneficiary Entitled to Reimbursement From Michigan Medicaid for Out-Of-Pocket Medical Expenses**

Plaintiff Levy sued the Michigan Medicaid program for failure to reimburse her out-of-pocket expenses incurred during the statutory three-month retroactive coverage period. Plaintiff applied for Medicaid coverage, was initially denied, then was approved on appeal, where it was determined that plaintiff was eligible at the time of the initial application. After submitting her initial application, plaintiff paid some expenses incurred during the three-month period immediately prior to her application.

The trial court ordered the state to reimburse plaintiff for the out-of-pocket expenses, but imposed several limitations on the requirement. The state appealed the ruling requiring reimbursement of out-of-pocket expenses, and plaintiff appealed the imposition of limitations on the reimbursements.

The Sixth Circuit affirmed the district court’s ruling requiring direct reimbursement, stating that a failure to reimburse would violate 42 U.S.C. § 1396a(a)(10). The state argued that although permitted by the Medicaid statute (§1396d(a)), Michigan’s program is a vendor-payment system that does not permit making direct payments to recipients. Citing _Blanchard v. Forrest_, 71 F.3d 1163 (5th Cir. 1996), however, the court stated that recipients who made a good-faith effort to pay would not receive coverage except where the providers chose to provide a refund and bill Medicaid, whereas those individuals who did not pay
would receive full coverage. Such a result would violate the equitable standards set out in § 1396a(a)(10). The court noted that its holding was limited to situations in which the Medicaid recipients were first rejected and then were successful on appeal.

With regard to the limitations imposed on the direct reimbursement, the circuit court held that payments made on behalf of a recipient by third parties who have no legal obligation to pay should also be reimbursed. Additionally, the circuit court reversed the district court’s decision that the reimbursements be limited to the Medicaid rate because it “shifts the burden of spiraling healthcare costs onto those who can least afford it.” Finally, citing equitable concerns, the court affirmed the district court’s decision to require that reimbursements be reduced by the amount that allowed the recipient to become eligible for Medicaid. Schott v. Olszewski, 401 F.3d 682 (6th Cir. 2005).

In cases where Medicaid recipients are initially denied coverage, the state must reimburse them for out-of-pocket expenses paid for covered services during the retroactive-coverage period.

II. PROFESSIONAL RIGHTS

Ninth Circuit Rules That Medical Disciplinary Entities Are Entitled to Absolute Immunity for Actions in Connection With Denial of Plaintiff’s Claim for Reinstatement

Loren Olsen, a physician assistant who overdosed on drugs, was denied reinstatement by the Idaho State Board of Professional Discipline (BOPD). Olsen filed an action against the Idaho State Medical Board, BOPD, and others (collectively, Defendants), claiming that Defendants’ actions in denying her application were motivated by religious discrimination. The case was removed to federal court, which dismissed Olsen’s claims because Defendants were entitled to absolute immunity. The Ninth Circuit affirmed the district court’s holding, using the Supreme Court’s analysis in Butz v. Economou, 438 U.S. 478 (1978), to determine whether Defendants functions are sufficiently similar to judicial process to qualify for absolute immunity. Factors considered include the need to assure that the agency representative can perform his functions without harassment or intimidation; the presence of safeguards that reduce the need for private damages actions to control unconstitutional conduct; and whether agency representatives are adequately insulated from political pressure. The court concluded that the public interest in ensuring that only qualified individuals engage in medical practice mandates action without fear of harassment or intimidation; safeguards were available and whether those safeguards were properly exercised is irrelevant to the absolute immunity inquiry; and the agency was sufficiently insulated from political influence. Olsen v. Idaho State Bd. of Med., 363 F.3d 916 (9th Cir. 2004).
Members of the Idaho State Board of Medicine were entitled to absolute immunity for their actions in regard to a plaintiff’s loss and attempted reinstatement of her license to practice as a physician assistant.

Massachusetts High Court Rules That Reciprocal Discipline for Physician Was Appropriate
Plaintiff Dr. Randolph Ramirez entered into a consent order with the Connecticut Department of Public Health in which he agreed not to contest allegations of wrongdoing regarding his conduct toward female patients during office visits that constituted incompetent or negligent conduct in the practice of medicine. Ramirez was also licensed to practice medicine in Massachusetts, and shortly thereafter, the Massachusetts Board of Registration in Medicine (Board) commenced reciprocal discipline proceedings against Ramirez. An administrative magistrate concluded that the Connecticut consent order could not be the basis for reciprocal discipline in Massachusetts because Ramirez did not admit to any wrongdoing and there was no final adjudication of the matter. The Board rejected the administrative magistrate’s findings. Ramirez sought judicial review and the Massachusetts Supreme Judicial Court affirmed the Board’s determination, noting that although the state’s statute regulating reciprocal discipline had never been applied to a consensual discipline order, there was nothing in the statute that would limit its application to contested disciplinary proceedings. The court adopted the holding in *Marek v. Board of Podiatric Medicine*, 20 Cal.Rptr.2d 474 (Cal. App. 1993), where the California Court of Appeals held that reciprocal discipline of physicians should not be limited to circumstances where a physician has admitted to misconduct or where such misconduct has been proven because that would allow a physician faced with disciplinary action to seek a “safe haven” in another state.


*Massachusetts Supreme Judicial Court concluded that the state statute governing reciprocal discipline of physicians can be applied in circumstances where the physician has entered voluntarily into a consent order in another state, and that its application is not limited to circumstances where a physician has admitted to misconduct or where such misconduct has been proven.*

Texas Court Rules Res Judicata, Collateral Estoppel and “Law of the Case” Do Not Apply on Remand to State Court
Due to an incident during surgery, the Texas State Board of Medical Examiners (the Board) filed a formal complaint against Robert Berezoski, M.D., seeking to revoke his license. After a hearing before an ALJ, the Board entered an order imposing a two-year suspension of Berezoski’s medical license, eight years probation, and a $5,000 fine. Berezoski appealed to the district court, which remanded and reversed the Board’s decision. On remand, the Board entered a second order suspending Berezoski’s license "until he can show that he is safe and competent to practice medicine" and imposing a $5,000 fine. Berezoski again appealed the order of the Board to the district court, which affirmed. On
appeal to the Texas Court of Appeals, Berezoski argued that the second order was barred by res judicata, collateral estoppel, and "the law of the case." The appeals court disagreed and upheld the Board's second order, noting that res judicata requires a prior final judgment, and that since the district court remanded the case back to the Board, it was not a final judgment. Further, the collateral estoppel claim failed because no specific issue was determined by the district court's judgment. The theory of the "law of the case" which mandates that the ruling of an appellate court on a question of law raised on appeal be regarded as the law of the case in all subsequent proceedings, did not apply here because the remand back to the Board, which was limited to the previously developed record, permitted the Board to "conduct subsequent deliberations." Finally, the appeals court, holding that sufficient evidence regarding the underlying causes of the patient's death had been presented, upheld the district court's affirmation of the Board's second order.


_Neither res judicata, collateral estoppel, nor the "law of the case" will apply where a district court remands a case back to the Board of Medical Examiners a case for further consideration._

**New York High Court Says Dismissed Charges Against Physician Should Be Kept Confidential**

Plaintiff physician was investigated by the New York Department of Health (Department) based on allegations of "willfully harassing, abusing a patient physically," "failure to maintain records," "fraudulent practice," and "practicing beyond the scope." After the investigation, plaintiff was cleared of all charges except for the failure to maintain records, which was characterized as a "technical violation." The Department subsequently posted on its website all of the charges and the outcome of the investigation. Plaintiff petitioned in state trial court for the removal of the posted information from the Internet. The trial court dismissed the petition, the appeals court reversed and the Department appealed. The New York Court of Appeals held that New York law requires physician disciplinary proceedings to be kept confidential where the physician is exonerated of the charges leveled against him or her. Although plaintiff had received a reprimand for failure to maintain records, he had been exonerated of all other charges, and the character of the technical violation was of sufficiently different character and gravity that the charges of which he had been exonerated should not have been posted. The court noted that the Department had discretion whether to maintain confidentiality of exonerated charges in cases of mixed disposition, but that the Department had abused its discretion in posting all of the charges, where the dismissed charges related to abuse of a patient's trust and the sole sustained charge related to a technical violation for failure to maintain a record of the prescription.

Although the State Board of Health has discretion in deciding what to post on its website regarding disciplinary actions where some charges are sustained and some are dismissed, the Board abused that discretion in posting disproved allegations of abuse of patient trust when the only sustained charge was a technical record-keeping violation.

**Court Finds Physician May Sue as Beneficiary of Trauma Services Contract**

Baptist Health (Baptist) and Arkansas Trauma Surgeons, PLLC (ATS), entered into a services agreement (Agreement) under which ATS and its physicians provided on-call coverage for Baptist. A surgeon member of ATS sued Baptist for breach of contract when Baptist sought to have ATS remove the surgeon from the on-call schedule. At issue was whether the surgeon was entitled to sue as a third-party beneficiary of the Agreement.

While the Agreement between the parties did not directly speak to whether the individual physicians of ATS were intended third-party beneficiaries, the surgeon specifically alleged that the agreement and the formation of the ATS stemmed from a discussion between Baptist and the individual physicians and, therefore, that ATS “was formed for the benefit of Baptist and the Services Agreement was entered into for the benefit of the individual physicians.” The court noted the terms of the ATS operating agreement were negotiated with and approved by Baptist and included a designation of Baptist as a third-party beneficiary thereto. In addition, the selection of physicians for membership in ATS was subject to Baptist’s prior approval, while the Agreement provided that each member of ATS would be compensated based upon the number of times each provided call coverage for Baptist. The court stated that “[h]ere, [the surgeon] not only pled that he benefited from the Services Agreement, but he also pled sufficient facts from which a reasonable inference can be drawn that ATS and Baptist intended to benefit him and other individual physicians.”


Arkansas court found that physician who was indirect beneficiary under provider agreement for services provided by small practice group was allowed to sue hospital for breach of contract even if he was not specified as a third party beneficiary because he did indeed benefit from the services agreement.

**Court Rules DHHS Bound by HIPAA When Reviewing NPDB Reports but Physician’s Action Challenging Record Was Time-Barred**

St. John’s Mercy Medical Center (St. John’s) in St. Louis, Missouri, filed an adverse action report with the National Practitioner Data Bank (NPDB) after it summarily suspended an unidentified physician (Plaintiff) for an indefinite period of time as required by the Health Care Quality Improvement Act (HCQIA). Plaintiff objected to the reference to a “positive” psychiatric evaluation in the revised report and asked DHHS to amend the records pursuant to HIPAA. DHHS informed Plaintiff that his only administrative remedy was through the procedures for disputing information contained in the NPDB under 45 C.F.R. § 60.14.
Applying the regulation, the DHHS Secretary concluded that the revised report was inaccurate and amended it to indicate that plaintiff “was not suffering from any type of psychiatric disorder.” However, Plaintiff still objected, arguing that pursuant to HIPAA, the NPDB records should make no reference whatsoever to a psychiatric evaluation.

The U.S. District Court for the District of Columbia held that HIPAA, which requires an agency to “make reasonable efforts” to assure the accuracy, completeness, relevance, and timeliness of records disseminated about an individual, provides more protection than the DHHS regulations for challenging a record submitted to the NPDB. However, the court found that Plaintiff’s HIPAA claims were time-barred under the applicable two-year statute of limitations. The court rejected Plaintiff’s contention that a new cause of action was initiated every time DHHS disseminated the report after he notified the agency of the problem. The critical time period, said the court, is when Plaintiff knew or should have known of the alleged inaccuracy in the NPDB report. Accordingly, the court granted summary judgment in the Secretary’s favor on the ground that the action was time-barred.


This case is significant because it explains when HIPAA’s statute of limitation begins – when the plaintiff become aware of the privacy violation. Furthermore, it explains that the government must adhere to HIPAA’s requirements in processing disputes regarding disputed National Practitioner Data Bank reports because HIPAA is more protective.

Pennsylvania Commonwealth Court Finds Board May Revoke License of Physical Therapist Based on Discipline From Other States

Plaintiff had his license to practice physical therapy revoked by the Pennsylvania Bureau of Professional and Occupational Affairs (Board) on the basis of discipline imposed in eight other states. Plaintiff argued that the Pennsylvania statute required that the Board first find him incompetent, negligent, or abusive, and that none of the discipline he received in the other eight states found that he had ever harmed a patient. The Pennsylvania Commonwealth Court affirmed the Board’s decision, stating that the plain language of the statute did not require the Board to find incompetence, negligence, or abusiveness before a license is revoked. Further, the statute allowed plaintiff’s license to be revoked based on the simple fact that his license had been suspended or revoked in other states; the underlying reasons for the disciplinary actions in the other jurisdictions was irrelevant.


_Pennsylvania court found that the state licensing board may revoke a physical therapist's license based on the mere fact that he has had his license suspended or revoked in other states._
Kansas Appeals Court Holds Board May Enjoin Use of M.D. by Unlicensed Individual

Plaintiff was a licensed dentist in Kansas, who later graduated with a Doctor of Medicine degree. However, he never completed his post-graduate training program or completed any licensing examinations necessary to practice medicine. Nevertheless, plaintiff attaches the designation of M.D. to his name in his dentistry practice. The Kansas State Board of Healing Arts (Board) brought suit seeking to enjoin plaintiff’s use of M.D. and to declare the use of this designation unlawful under the circumstances. Plaintiff won at the trial level, but the state court of appeals reversed and remanded for an injunction.

The court reasoned that plaintiff’s use of M.D. would tend to mislead or confuse the public because an M.D. degree is commonly associated with a certain course of training, which plaintiff did not completely receive. At the same time, however, the court found that the governing state statute was facially overbroad because it also seeks to ban uses of the M.D. designation that are not misleading. Even the Board conceded that the plaintiff should be allowed to use the M.D. designation in "academic or social settings." The court held that the statute should only be applied to an unlicensed M.D. designation in those areas in which the public, patients, hospitals, or other healthcare practitioners could be misled by its use. *State Bd. of Healing Arts v. Thomas*, 97 P.3d 512 (Kan. App. 2004).

*The M.D. designation may not be used in a professional context by an individual in Kansas who is not licensed by the state.*

California Appeals Court Says Trial Court Violated Physician’s Due Process Rights by Imposing Bail Condition Barring Physician From Practicing Medicine

At trial, Dr. Gray was charged with felony counts of unlawfully prescribing and possessing a controlled substance and with misdemeanor counts of possessing child pornography and sexually exploiting a patient or former patient. The Attorney General, on behalf of the Medical Board of California (Board), had appeared at defendant's arraignment and requested that as a condition of bail, Dr. Gray's medical license be suspended. The request was granted, and the defendant appealed, filing a writ of habeas corpus arguing a violation of his procedural due process rights.

A procedural due process claim involves a two-prong test. First, the plaintiff must establish that he has a protected liberty or property interest. Courts have held that physicians do have a protected property interest in their medical license; therefore, they have standing to assert the claim. Second, the court will weigh factors to determine if the individual was provided due process. In this case, the court held that the Board failed to provide Dr. Gray due process because it did not follow any of its notice and hearing procedures before suspending Dr. Gray's license. Further, the court determined that the complaint did not allege sufficient
facts to support the conclusion that allowing Dr. Gray to practice would harm the public.

In addition, the court determined that there was no statute giving the licensing agency the authority to make recommendations about bail conditions in a judicial proceeding; moreover, the court does not have statutory authority to suspend a professional license on the recommendation of a state licensing agency. 


*State medical board must follow its own procedures for limiting, suspending, or revoking a medical license and may not act through the court system to circumvent its policies and procedures.*

**Connecticut Appeals Court Upholds Suspension and Revocation of Physician's License**

Dr. Abraham Solomon (plaintiff) had his medical license revoked after a hearing by the Connecticut Medical Examining Board (Board). The plaintiff appealed the Board's decision and filed suit. The trial court affirmed the Board's decision. Plaintiff appealed his case to the Appellate Court of Connecticut, which affirmed the trial court's holding.

Plaintiff asserted that his due process rights were violated because not all the members on the panel that suspended his license were physicians; a panel member slept through the hearing; each panel member was absent at least one day during the proceedings; and the trial court did not find substantial evidence in the record to support the panel's decision to suspend and revoke plaintiff's medical license. The court rejected the plaintiff's argument because due process does not require that all members of the panel be physicians. Next, the court reviewed the trial transcript and determined that the panel members were attentive and asked questions during the hearing. In addition, the court held that the absence of panel members did not violate due process because each member attested that he had or read the entire record. Lastly, the court affirmed the trial court's holding that there was substantial evidence to support the panel's decision.


*Medical Board's due process procedures need not be perfect, but merely adequate.*

**Illinois Appellate Court Upholds Cease and Desist Order and Suspension of Nursing License**

 Plaintiff Valerie Morris was licensed in Illinois as a nurse, but not as a midwife. Her employer hospital fired her after finding out that she was running an unlicensed midwife practice. Soon afterward, the Department of Professional Regulation (DPR) issued Morris an order to cease and desist from the practice of
midwifery until she was licensed. Morris sued, claiming that the DPR did not have authority to regulate midwives, but the trial court affirmed and she appealed. The DPR then filed a complaint that plaintiff had provided nursing care that she was not licensed to provide and requested that her nursing license be suspended or revoked. The ALJ agreed, recommending a suspension of her license, and the Board of Nursing adopted the ALJ’s recommendations. The plaintiff filed for judicial review, and the trial court affirmed.

On appeal to the Appellate Court of Illinois, the cases were consolidated, and the court affirmed the cease and desist order and the plaintiff’s suspension. As authority, it relied on the state Nursing Act, which provides that a nurse may qualify as a certified midwife if she has a current nursing license and holds a national certification as a nurse midwife. Plaintiff failed to produce such national certification, so the DPR did not err in issuing its cease and desist order. Morris v. Dep’t of Prof’l Reg., 824 N.E.2d 1151 (Ill. App. 2005).

Nursing license suspension was appropriate where licensed nurse failed to meet all the requirements of the state licensing statute in order to practice midwifery.

California Appellate Court Holds Evidentiary and Procedural Standards Were Met in Suspension of Surgeon

The Surgical Policy Committee of Downey Regional Medical Center summarily suspended Dr. Kishore Tonsekar’s privileges pursuant to the hospital bylaws while the Medical Executive Committee (MEC) investigated his treatment of three patients. The bylaws authorize summary suspension when “it appears that failure to take summary action . . . may result in imminent danger to the health of any individual.” The Judicial Review Committee reviewed the decision and ruled that the evidence supported continuing Dr. Tonsekar’s suspension, but felt that the initial suspension was based on a misunderstanding, so it recommended that the Board of Directors (Board) revoke the suspension. The Board declined to do so.

The trial court affirmed the Board’s decision. In affirming the trial court, the appeals court noted that while none of the reviewing bodies used the term “imminent danger” in its rulings, they had concluded in substance that failure to suspend the physician’s privileges would result in the imminent danger to the health of at least one patient. The court also noted that the Board did not have the duty to make an independent determination as to whether failure to suspend Tonsekar’s privileges would result in imminent danger to the health of an individual; it only had to determine whether the MEC made its decision based on sufficient evidence. Tonsekar v. Downey Reg’l Med. Ctr., 2005 WL 477975 (Cal. App. 2005).

A California hospital’s summary suspension of a surgeon’s privileges was proper where it followed the procedural and evidentiary standards of its medical staff bylaws.
Kentucky High Court Finds Lower Court Without Jurisdiction to Order Licensing Board to Provide Hearing for Physician
A circuit court in West Virginia reversed the state medical board’s order revoking Dr. Schaefer’s West Virginia medical license partly because it found that the revocation of her Kentucky medical license was clearly wrong. Based on this reversal, Dr. Schaefer filed a motion in a Kentucky trial court asking it to vacate its prior order revoking her Kentucky medical license, and the trial court ordered the Kentucky Board of Medical Licensure (Board) to conduct a hearing on the issue. The Board appealed and the appellate court denied the Board’s writ petition.

The Kentucky Supreme Court held that the circuit court judge had no jurisdiction to order the Board to hold a hearing, and that the appellate court abused its discretion in denying the Board’s writ petition. The court reasoned that the applicable state statutes limit a court to reviewing final orders of the Board, and that review had already been conducted. Dr. Schaefer was advised that the proper avenue for relief was to seek reinstatement of her license directly from the Board.


The Kentucky Supreme Court held that a court cannot order its state medical board to conduct a review of a physician’s license.

New Jersey Appeals Court Upholds Regulation Requiring Physician Supervision of CRNA’s in Office Setting
The New Jersey Association of Nurse Anesthetists (NJANA) asserted a claim against the New Jersey Board of Medical Examiners (BME), claiming the BME’s regulation requiring a "supervising physician" to be "physically present and available . . . without concurrent responsibilities" when a certified registered nurse anesthetist (CRNA) administered anesthesia was unreasonable, arbitrary and lacked a factual or medical basis. The regulation also included a supervision provision for conscious sedation, requiring a physician’s presence when a CRNA administered conscious sedation but permitting concurrent responsibility for the care of other patients.

The New Jersey Superior Court, Appellate Division, held the provision regulated the practice of medicine, and was thus within the scope of BMEs' authority. The court further held that there are significant differences in training and experience between CRNAs and anesthesiologists and that the BME did not act unreasonably or arbitrarily in promulgating the regulation. In addition, the court held that even though CMS has a rule allowing states to opt out of the supervision requirement, the state of New Jersey has not done so.

Even though a state Board of Medicine regulation has an indirect impact on CRNAs, a regulation requiring physician supervision of CRNA services in an office setting is the regulation of the practice of medicine, and the Board did not exceed its regulatory authority.

III. MEDICAL RECORDS

Court Rules That HIPAA Protections Apply to Records That Predate HIPAA’s Effective Date
In a qui tam action, the U.S. District Court for the District of Columbia applied the privacy protections of the Health Insurance Portability and Accountability Act (HIPAA) in a protective order request to protect records request by the qui tam relator even though the records predated the effective date of HIPAA. The court stated that it would not allow “any disclosures that may violate federal or state law,” rejecting the government’s argument that records existing prior to HIPAA’s effective date should not be protected.


This case is significant because it applies HIPAA’s privacy protections to records that predate its effective date; interestingly, the government argued against such protection.

D.C. Circuit Holds District Court Must Weigh Privilege Before Ordering Production of Medical Records
Plaintiffs, two mentally retarded adult men, are wards of the District of Columbia Mental Retardation and Developmental Disabilities Administration (MRDDA). For several years they lived in a group home where they alleged they were sexually assaulted by the defendant, another resident of the group home and also a ward of MRDDA. Plaintiffs sued the District for violating their civil rights and under other causes of action including negligence. During pre-trial proceedings, plaintiffs moved to compel production of all of the defendant’s medical records. The district court granted the motion. Defendant’s guardian ad litem moved for reconsideration and a more extensive protective order. The district court denied the motion and denied a second request to modify the order. The D.C. Circuit vacated the district court’s order and remanded the case. The appeals court found that the Supreme Court recognized a federal psychotherapist–patient privilege in Jaffee v. Redmond, 518 U.S. 1 (1996). Accordingly, the court held that any “conversations between” defendant and a licensed psychotherapist or social worker are protected from disclosure. Because the district court’s order would subject defendant’s records to disclosure without screening in any way to make sure that they did not contain confidential communications, the court found the district court abused its discretion. The appeals court did not address directly any District of Columbia statutes that afford privileges that would bar disclosure, but held that the district court should look at those provisions and weigh them in
its consideration of whether to compel production of the records under Federal Rule of Civil Procedure 26.
In re Sealed Case (Medical Records), 381 F.3d 1205 (D.C. Cir. 2004).

Courts may not compel production of a defendant’s medical records without first determining whether those records are subject to a federal privilege and weighing the probative value of each non-privileged document against the intrusion into the appellant’s legitimate privacy interest.

Florida Appeals Court Holds No Privacy Limitation on State’s Ability to Obtain Patient’s Medical Records Via Search Warrant
After police in Florida obtained search warrants to obtain certain medical records of Rush Limbaugh as part of an investigation into whether he violated the state “doctor shopping” statute by obtaining prescriptions for controlled substances from various physicians over a five-month period, the state placed the records under seal and notified Limbaugh that his records had been seized. Limbaugh objected to the seizure, asserting a right of privacy in his personal medical affairs under the Florida Constitution. A state trial court denied Limbaugh’s request to quash the search warrants. Limbaugh appealed.

The court held that the constitutional right of privacy in medical records is not implicated by the seizure of such records when seized pursuant to a valid search warrant, nor is the patient entitled to prior notice and a hearing in connection with the search warrant.

Moreover, the appeals court noted, nothing in the search warrant statutes limit the use of search warrants for medical records. Here, the state had the burden of showing probable cause existed that Limbaugh’s medical records were relevant to the commission of a crime in which he might be involved. Search warrants typically do not require prior notice and a hearing because of the potential that the evidence being sought, particularly in a criminal investigation, may be compromised. State prosecutors were within their discretion to determine that, for this reason, a search warrant rather than a subpoena was necessary in this case. Limbaugh v. State, 887 So.2d 387 (Fla. App. 2004).

Court found that a patient’s right to privacy in medical records is not violated by the retrieval of records pursuant to a valid search warrant and Florida search warrant statute does not limit its use for medical records; thus, the patient does not have to be notified of the record’s retrieval nor can the patient challenge such an action on privacy grounds.

Ohio Appeals Court Holds That Hospital Incident Report Was Privileged Under State Statute
Plaintiff sued St. Elizabeth Health Center for negligence after she broke her ankle while being moved from her bed to a wheelchair. The trial court granted her discovery request for an incident report drafted by the hospital staff, reasoning
that the report was a medical record because it did not actually mention the fall. The Ohio Court of Appeals reversed, stating that the plain language of a recently enacted statute, Ohio Rev. Code Ann. § 2305.253, made it clear that incident reports are not discoverable regardless of whether any other statute provides an exception. The court further ruled that its decision did not conflict with prior case law because that case had been decided before the legislature passed § 2305.253.


*New Ohio statute makes it clear that hospital incident reports are absolutely privileged and not subject to discovery requests.*

**California Court of Appeals Holds That Medical Records May be Discovered During Divorce Proceeding When a Child’s Welfare Is At Issue.**

Plaintiff and defendant divorced and sole custody of their son was awarded to the plaintiff. When defendant wished to take their son on a visit, plaintiff was concerned because defendant was still living in a rehabilitation facility and requested discovery of defendant’s psychiatric records based on a joint stipulation they had signed to allow mutual discovery of psychological evidence “through the pendancy” of their divorce action. The trial court held that stipulation had expired at the time the divorce was granted. The Court of Appeals reversed the judgment, relying on *In re Marriage of Armato*, 106 Cal.Rptr.2d 1030 (Cal. App. 2001), which held that a divorce proceeding remains pending after the divorce decree for the purpose of modifying child support orders. The court stated that the lower court’s interpretation of *Armato* was too narrow, as *Armato* should also apply to child support orders, noting that a divorce case remains open and pending while a child is a minor because a court must be able to monitor a child’s welfare.

**In re Marriage of Kreiss,** 19 Cal.Rptr.3d 260 (Cal. App. 2004).

*The California Court of Appeals held that the pendancy of a divorce action remains open while a child is a minor for the purposes of child support and child custody.*

**U.S. Court in Minnesota Says Wife’s Claim to Deceased Husband’s Medical Records Under HIPAA Was Not Sufficient to Confer Jurisdiction**

Mary Johnson decided to sue Parker Hughes Cancer Center (Parker Hughes) and retained an attorney to investigate and pursue a civil action. As her husband’s surviving spouse, she requested that Parker Hughes provide copies of the medical and billing records pertaining to her husband’s treatment. Parker Hughes denied the request claiming she was not in compliance with HIPAA. She argued the state law allowed her to act on behalf of her deceased husband. Parker Hughes argued that HIPAA pre-empts state law. Johnson brought an action seeking declaratory relief clarifying her rights under HIPAA and Parker Hughes moved to dismiss the complaint for lack of subject matter jurisdiction. The U.S. District Court for the District of Minnesota granted the motion to
dismiss, noting that Johnson did not bring a cause of action under HIPAA, but instead sought an order interpreting HIPAA. The court found Johnson’s claim was insufficient to confer subject matter jurisdiction. The court concluded that because there was no private cause of action under HIPAA and there was no other basis to invoke a federal question, subject matter jurisdiction was inappropriate. Accordingly, the court dismissed the complaint for lack of subject matter jurisdiction.


The case reinforces the concept that there is no private right of action under HIPAA.

**Washington Appeals Court Finds Right to Privacy in Medical Records Waived After Workers’ Compensation Beneficiary Requested Return to Work**

Kimberly Mayer filed a worker’s compensation claim for a repetitive stress injury to her hand suffered while she worked at Boeing. When she filed the claim, she signed a broad medical release authorization stating that her treating physician may disclose “any medical records or other information regarding treatment” to her employer. Dr. Judith Hausner was Mayer’s treating physician; she approved her medical leave, opining that continued hand movements would worsen the condition. Several years later, Mayer wished to return to work and petitioned Boeing’s Medical Placement Review Board (MPRB) to reinstate her under a return-to-work provision of her collective bargaining agreement. By then, Dr. Hausner had gone to work for Boeing as their medical consultant, and Dr. Lantsberger replaced her as Mayer’s treating physician. Dr. Lantzberger drafted a letter to the MPRB that Mayer could return to work with certain restrictions, but Dr. Hausner, based on her own experience with the case and other medical charts, disagreed.

Two years later, Mayer was allowed to return to work, but she lost her seniority, and because of this, the following year she was laid off. Mayer sued Dr. Hausner for breach of confidentiality, among other charges. The trial court held, and the Washington Court of Appeals affirmed, that once Mayer put her medical condition at issue, she “effectively waived her confidentiality concerns.” Dr. Hausner’s opinion was relevant to Mayer’s return to work request, and, therefore, came under the scope of the waiver.


When a worker’s compensation recipient requests to return to work, she waives the right to privacy in medical records released to her employer.

**Mississippi High Court Finds Law Firm Lacks Standing to Object to Prices Charged for Medical Record Retrieval**

The Supreme Court of Mississippi held that a law firm lacked capacity to bring an antitrust claim against hospitals and a medical records company for charging
excessive fees to the law firm’s clients for the retrieval of medical records. Owen & Galloway, LLC (the Firm), filed a lawsuit against Smart Corporation, a medical records company (Smart), Gulf Coast Community Hospital, Inc. and Hancock Medical Center (collectively, the Hospitals) alleging that excessive and inconsistent fees were charged by Smart to the Firm for retrieval of medical records with the knowledge of the Hospitals in violation of Mississippi’s antitrust laws. The trial court granted summary judgment to the defendants, finding that the Firm lacked standing because “as a matter of law [the Firm] had no independent right to purchase medical records of its clients.” The Firm appealed. The Supreme Court of Mississippi affirmed, stating that the Firm’s only right to purchase copies of medical records was in its capacity as agent for its clients. The court found that the real party in interest is the clients, not the Firm. 

*Owen & Galloway, LLC v. Smart Corp.,* 2005 WL 674809 (Miss. 2005).

*Only patients/clients, not law firms acting as their agents, have standing to object to any fees associated with the retrieval of their medical records.*

**IV. MEDICAL STAFF ISSUES**

**California Court Finds Hospital May Summarily Suspend Physician Who Is Imminent Threat to Patients**

Dr. Penny Pancoast is a physician with an internal medicine practice who obtained medical staff privileges at Sharp Memorial Hospital (Sharp). Pancoast’s privileges at Sharp were suspended because she had not completed a number of medical records. In the next few months, various attempts to contact Pancoast failed and her psychiatrist and other associates informed Sharp that Pancoast was stressed and possibly suicidal. Pancoast sued Sharp and its chief of staff, alleging that Sharp acted improperly in suspending her privileges and in failing to provide her with a hearing. The trial court granted Pancoast a writ of mandate directing the hospital to either restore her privileges or provide a hearing.

The California Court of Appeal, Fourth District, directed the trial court to vacate its writ. The court first turned to the issue of whether by allowing suspension where there is likely harm to prospective patients, Sharp’s bylaws go beyond the scope of California Business and Professions Code § 809.5. The court found that, read in light of the public interest in protecting patient safety, the statute protects prospective as well as identified patients. Next, the appeals court found that Sharp had an adequate basis upon which to conclude that Pancoast was an imminent threat to patients. Pancoast argued that she did not intend to begin admitting patients to Sharp as soon as her medical records suspension was over; therefore, she was not an imminent threat to patients. However, the appeals court found that the record contained a “great deal” of proof that Pancoast did intend to begin admitting patients.

California court held that doctor whose privileges were summarily suspended by hospital could not maintain action because hospital had adequate basis for finding that doctor posed an imminent threat to patients and, as such, was justified in suspending her privileges without a hearing.

**Court Decides Hospital May Not Exclude Physicians With Staff Privileges**

Three physicians with staff privileges at Monongalia County General Hospital (Hospital) who also were employees and shareholders of Monongalia Anesthesia Associates Inc., which previously provided anesthesia services to the Hospital, challenged the Hospital’s exclusive contract with another provider that covered virtually all general anesthesia services.

The West Virginia Supreme Court rejected the physicians’ position that they had a property interest in their staff privileges and also held that the hospital’s medical staff bylaws did not constitute a contract with the physicians. It distinguished the scope of judicial review in cases involving public and private hospitals, saying that, in public hospitals, physicians do not practice at the will of the hospitals’ governing authorities, but are “entitled to practice,” so long as they stay within the law and conform to all “reasonable” rules and regulations. The court then examined whether the hospital’s decision to enter into the exclusive contract was reasonable, concluding that “the total exclusion of physicians from their hospital practices, and the concomitant complete deprivation of patient choice, simply cannot be justified “by the ends the hospital sought to achieve.

Although the court acknowledged that its decision was contrary to prevailing authority upholding exclusive contracts, it disagreed with those precedents. It found that a preferential contract would have allowed the lead plaintiff access to hospital facilities to treat patients when he was requested, allowed the hospital management the discretion to contract to secure a primary provider of medical services to solve scheduling and staffing problems, and also would have preserved patient choice.


*West Virginia Supreme Court set a new precedent disallowing exclusive provider agreements because such agreements unfairly excluded other physicians, hindered a patient’s right to choose his or her physician and were aimed at solving a problem that could have been addressed by less restrictive means.*

**Eleventh Circuit Finds That Hospital’s Investigation of Physician’s Application for Reappointment Was Consistent With Hospital’s Bylaws**

The Hospital Authority of Colquitt County, Georgia (Hospital), requires physicians with staff privileges to renew those privileges every two years. During the renewal process for Dr. Jerry Lee, the Hospital’s medical director discovered that Dr. Lee had been suspended for three weeks and placed on probation for twelve months at another facility. Thereafter, an ad hoc committee was appointed to
investigate Dr. Lee’s renewal application. The committee referred charts of Dr. Lee’s cases to an outside consultant for review. The consultant expressed concern over the frequency of Dr. Lee’s surgical complications. Based upon that finding, the committee scheduled a meeting with Dr. Lee to discuss their concerns. However, Dr. Lee resigned before the meeting. The Hospital accepted the resignation and the ad hoc committee ceased its investigation. Pursuant to federal law (42 U.S.C. § 11133), the hospital determined that it was obligated to report the results of its inquiry to the NPDB. The Georgia Medical Board was also notified of Dr. Lee’s resignation during the course of an investigation related to patient quality of care issues. Dr. Lee sued the Hospital in federal court claiming the Hospital had failed to follow its own bylaws as required by state law. The court granted summary judgment for the Hospital. Dr. Lee appealed to the Eleventh Circuit, which found no evidence that the Hospital failed to comply with its bylaws or knowingly made a false report to the NPDB. The court also found that the Hospital had not violated Georgia law in its investigation and affirmed the district court’s ruling.

Lee v. Hospital Auth., 397 F.3d 1327 (11th Cir. 2005).

A hospital’s investigation of a physician during the renewal process for staff privileges was not arbitrary or capricious when the hospital complied with its own bylaws and state law.

California Appeals Court Finds Unfair Competition Claim Not Barred by Anti-SLAPP Statute

Plaintiff surgeon Alexander Marmureanu, a non-faculty physician with staff privileges at UCLA Medical Center, sued the Chief of the Division of Cardiac Surgery, Hillel Laks, for unfair competition, restraint of trade, and tortious interference with a contract. Specifically, he alleged that Laks caused the medical center to adopt a policy that only faculty members may supervise patient care; caused the medical center to adopt a privacy policy that restricted access to patient records; and made unfounded complaints about plaintiff’s disclosure of patient information.

Laks filed a special motion to strike plaintiff’s complaint based on the state Anti-SLAPP statute, which provides for a special motion to strike any complaint arising from conduct based on the rights of petition and free speech. The trial court denied the motion, and the California Court of Appeals affirmed the ruling, stating that the Anti-SLAPP statute was inapplicable to the present case. The first element under the statute is that the “challenged cause of action is one arising from a protected activity.” The court stated that the Anti-SLAPP law was intended to protect actions related to official governmental proceedings, and the medical peer review process is not an “official proceeding” within the meaning of the statute. The fact that Dr. Laks may have engaged in conduct protected by the First Amendment was irrelevant because the plaintiff couched his complaint in terms of anti-competition and not the exercise of free speech.

Defendant physician could not rely on the Anti-SLAPP statute to strike a plaintiff’s complaint based on charges that the defendant violated the peer review process.

V. PUBLIC FUNDING OF INDIGENT CARE

Arizona Appeals Court Upholds Reimbursement Award to Hospitals That Provided Emergency Care to Indigent County Residents

As a matter of administrative convenience over two decades, a number of private hospitals (the Hospitals) and Maricopa County (the County) agreed that medical expenses incurred before a patient’s hospital admission were treated as a fixed percentage (twenty-five percent) of hospital charges. As a result, the Hospitals were not required to document charges accumulated prior to hospital admission. The appeals court found a course of dealing between the parties whereby a patient’s income for purposes of determining indigency was reduced by twenty-five percent (spend down) to reflect healthcare expenses incurred prior to admission and that the Hospital reasonably relied on this assumption by not documenting pre-admission charges in its reimbursement claims. The appeals court also found that the Hospitals would suffer substantial detriment if they had to reconstruct pre-hospital admission charge records before they received notice that the County would no longer settle claims. However, the County could require the Hospitals to document pre-admission bills for spend-down claims on a prospective basis.

The appeals court vacated, however, the portion of the court’s judgment refusing to grant the Hospital prejudgment interest. The trial court reached its decision after concluding the Hospitals’ claims were unliquidated because the County’s liability for them was not easily calculable. But the appeals court disagreed, noting that, in fact, the trial court calculated the Hospitals’ award “down to the last penny.” In the appeals court’s view, the amount of the claims at issue “were capable of exact calculation” and therefore, the trial court erred by not awarding prejudgment interest.


A reimbursement award from a county to hospitals for the provision of emergency care for indigent residents should also include prejudgment interest if the claims are capable of exact calculation.

North Carolina Appeals Court Holds Illegal Alien Entitled to Medicaid Coverage for Emergency Medical Condition

Federal and state regulations exclude undocumented aliens from full Medicaid coverage except for care that is necessary to treat an emergency medical condition. An emergency medical condition is described by case law as a condition that causes the onset of severe symptoms that puts the patient’s health
in serious jeopardy absent immediate medical treatment. *Luna v. Division of Soc. Servs.*, 589 S.E.2d 917 (N.C. App. 2004). Hector Diaz, an illegal alien, received several months of treatment for acute lymphocytic leukemia. The North Carolina Division of Social Services (Division) approved Medicaid coverage of the medical services Diaz received for some, but not all, of the hospital admissions. After the Division denied Diaz’s appeals, he sought judicial review. The state trial court held that Diaz was entitled to Medicaid coverage for the treatment of his emergency medical condition, including the services rendered under the standard course of medical treatment. The Division appealed the trial court’s decision. The North Carolina Court of Appeals affirmed the trial court holding that Diaz’s treatment was for an emergency medical condition. However, the appeals court has granted the Division’s request for discretionary review, which remains pending. 


Undocumented aliens may be entitled to full Medicaid coverage in North Carolina for medical care that is necessary to treat an emergency medical condition.

**California Appeals Court Finds Lower Court Improperly Controlled Department’s Discretion in Implementing Medi-Cal Gateway Program**

California’s Gateway Program is an electronic enrollment process that immediately establishes presumptive eligibility at healthcare providers’ offices for two months. Those temporary benefits are automatically terminated at the end of the two months unless an application for benefits has been submitted. However, infants deemed eligible may receive Medi-Cal for one year as long as the child continues to live with his or her mother and the mother remains eligible for Medi-Cal. Baby Doe and his mother filed a petition for writ of mandate alleging the California State Department of Health Services (the Department) was about to illegally terminate Baby Doe’s Medi-Cal benefits because it thought he was presumptively eligible rather than deemed eligible.

The trial court ordered the Department to refrain from terminating benefits of any infant under age one who began receiving Medi-Cal benefits through the Gateway Program and to reinstate benefits for those deemed eligible infants who had fallen through the cracks because of the Gateway Program. The California Court of Appeals, however, found that relevant federal and state law did not require the Department to apply the deemed eligibility and redetermination laws in the operation of its Gateway Program, and, because the Gateway Program did not make final eligibility determinations, the redetermination process did not apply. Therefore, the appeals court reversed the lower court, finding it had improperly controlled the Department’s discretion in implementing the Gateway Program. 

Because relevant law gives the Department discretion to use an electronic enrollment process for enrolling newborns into Medi-Cal, requiring the Department to take actions to identify deemed eligible infants or to reinstate benefits for those infants whose presumptive eligibility period had ended improperly controlled the Department’s discretion.

VI. CREDENTIALING AND PEER REVIEW

U.S. Court in Connecticut Finds PAMII Allows Plaintiff Agency to View Peer Review Records
The State of Connecticut Office of Protection and Advocacy for Persons with Disabilities (OPA) filed suit against Thomas Kirk and other employees of the State of Connecticut Department of Mental Health and Addiction Services (Department) to compel the Department to disclose records relating to the deaths of two former residents of facilities under the Department’s control. OPA based its suit on violation of 42 U.S.C. § 1983 and the Protection and Advocacy for Individuals with Mental Illness Act of 1986, 42 U.S.C. §§ 10801-10827 (PAMII). The Department produced the requested records, except for peer review records related to the incidents in question, citing the state’s peer review statute.

The statutory language at issue states that the Department would have to produce “reports prepared by . . . staff of a facility . . . that describe incidents of abuse, neglect, and injury occurring at such facility.” The Department argued that PAMII was ambiguous with respect to disclosure of peer review records and that the court must distinguish between discoverable factual records and nondiscordable records that evaluate facts. The Department further argued that peer review records covered “evaluations” of facts and not “description” of facts. The court disagreed with the Department, stating that the plain meaning of PAMII is that any report discussing recounting, or “describing” the facts of the incident must be produced.


Peer review records may be compelled in Connecticut under PAMII despite state statutory peer review protections.

Ohio Appeals Court Rules That Peer Review Statute Precludes Trial Court From Requiring Hospital to Identify Documents In Its Files
Hospital that was sued over its credentialing of a physician objected to the production of peer review documents. After an in camera review, the trial court sustained the objection but ordered the hospital to produce a list identifying the documents contained within its peer review committee records that could be obtained from the original source. The hospital appealed.
The Ohio Court of Appeals ruled that the order violated the clear intent of the Ohio Peer Review Statute, which makes all information considered by a peer review committee privileged and non-disclosable from the hospital. The court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files. **Huntsman v. Aultman Hosp.**, 826 N.E.2d 384 (Ohio App. 2005).

Ohio court held that the peer review privilege extends to information that can identify documents in a hospital's peer review and credentialing files.

**Federal Court in West Virginia Dismisses Physician’s Antitrust Claims Against Hospital, but Allows His Conspiracy Claims to go Forward in Connection With Peer Review Activities**

Dr. Wahi sued Charleston Area Medical Center (CAMC) on various claims arising out of the hospital's peer review activities against him. The U.S. District Court for the Southern District of West Virginia allowed the physician's private conspiracy claims under 42 U.S.C. §§ 1985-86 and his civil rights claim under 42 U.S.C. § 1983 to continue, stating that CAMC acted in concert with state officials (i.e., the Board of Medicine) in an effort to have Dr. Wahi's license revoked. Further, the court refused to dismiss the case based on several arguments set forth by CAMC, including that the action should be stayed under the primary jurisdiction doctrine and sent back to the peer review committee for an initial determination. The court stated that a private hospital is not an administrative agency, and although the peer review body was formed under the HCQIA, the statute "simply has not created the type of regulatory scheme traditionally designed to foster national uniformity" to bring peer review claims within the primary jurisdiction doctrine. The court distinguished between independent federal or state agencies and "a quasi-administrative body that is essentially attached to one of the parties." Also, the court refused to dismiss the complaint based on CAMC's presumptive immunity under HCQIA, stating that plaintiff was not required to plead lack of presumptive immunity as part of a well-pleaded complaint.

The court, however, dismissed several of the physician's claims, including antitrust claims under the Sherman Act because the plaintiff did not allege how the CAMC's actions affected interstate commerce. Also, the physician's Due Process Clause claims were dismissed because CAMC did not act under the color of law simply by reporting the physician to the NPDB. **Wahi v. Charleston Area Med. Ctr.**, 2004 WL 2418316 (S.D. W.Va. 2004).

A U.S. District Court in West Virginia held that a hospital peer review body is not an administrative body entitled to primary jurisdiction over peer review claims, and a hospital does not act under the color of the law simply by reporting a physician to the National Practitioner Data Bank.
Louisiana Supreme Court Holds That Revocation of Recommendation for Physician Who Graduated From Otolaryngology Residency Program Implicated Due Process Property and Liberty Interests
Dr. Peter Driscoll completed the Otolaryngology program at Louisiana State University Health Sciences Center (LSUHSC) and was provided a final written evaluation/exit letter. Driscoll also received letters of recommendation from Dr. Fred Stucker, program director and chairman of the residency program at LSUHSC. Thus, Driscoll was board eligible and entitled to sit for the board certification examination of the American Board of Otolaryngology (Board). Driscoll was offered a three-year contract with the Minden Medical Center (MMC) with an annual salary of $360,000. MMC also granted Driscoll temporary privileges while he contemplated the offer and became qualified to become a member of MMC.

Driscoll later admitted he had once performed a medical procedure on a friend, but asserted that he had generated a medical chart for the procedure and not charged the friend. Because of this admission, Stucker sent a letter to the Board recommending that it “consider removing Peter Driscoll from the individuals scheduled to sit for [the examination].” Driscoll was informed that he would not be permitted to sit for the examination because the Board no longer had the required recommendation from his program director. Because he was no longer board eligible, Driscoll could not accept the offer of employment from MMC and thus accepted a one-year fellowship for $12,000. Driscoll filed suit against LSUHSC and Stucker claiming breach of contract and denial of due process. The trial court granted partial summary judgment in favor of Driscoll and awarded him $780,000 in lost wages and $75,000 in general damages, along with interest and court costs.

The appeals court affirmed the trial court in all respects, but reduced the damages for lost wages to $540,000. The appeals court found that: (i) the defendants’ actions were not entitled to peer review immunity because their actions were not peer review as defined by the state statute, (ii) Driscoll possessed a property and liberty interest subject to due process procedures in receiving the letter of recommendation, and (iii) there was no credible evidence of wrongdoing on Driscoll’s part and no written policy against his actions. The defendants again appealed. The Supreme Court of Louisiana reversed the lower courts’ judgments as to the individual liability of Stucker, but affirmed in all other respects.


The revocation of the residency program director’s letter of recommendation given on behalf of the plaintiff (a graduate of a residency program) that resulted in the denial of the plaintiff’s eligibility for board certification and thus prevented plaintiff from obtaining employment, was sufficiently akin to a peer review action to require due process. Because defendants could not produce evidence of a violation of any bylaw, rule or regulation by plaintiff, the revocation of the letter of Recommendation by the program director was sufficiently similar to a peer review action to require due process.
recommendation was not made in good faith and blatantly violated the plaintiff’s due process rights. Therefore, peer review immunity was not available and the court affirmed the award of monetary damages to the plaintiff.