

# AMERICAN HEALTH LAWYERS ASSOCIATION

## Year in Review 2009-2010

The following paper summarizes the key court rulings and regulatory developments in health law over the past twelve months. For more detailed information about any case discussed in this paper or for a complete compilation of the health law cases for the year, please go to <http://www.healthlawyers.org/Members/Resources/YearinReview/Pages/default.aspx>. Note that the topic of healthcare reform is not included in this paper, as it is discussed separately in the first part of this presentation.

### Antitrust

Although final healthcare reform legislation (Pub. L. No. 111-148) did not include a provision banning so-called “pay-to-delay” payments as part of patent settlements between brand and generic drug companies, courts continued to grapple with the issue of anti-competitive conduct affecting the entry of generic drugs into the marketplace.

The U.S. District Court for the Eastern District of Pennsylvania refused to dismiss a case alleging Cephalon, Inc. and several generic drug manufacturers entered into unlawful “reverse payment” patent settlements that delayed the market entry of cheaper-priced generics in violation of the antitrust laws. According to plaintiffs, Cephalon, Inc. paid generic drug manufacturers millions of dollars so that the companies would refrain from selling a generic version of Provigil®.

The court first noted that the Third Circuit has not established a framework for analyzing reverse payment patent settlements. Accordingly, the court turned to a lengthy review of case law from the Sixth Circuit, which found a reverse payment settlement to be a per se violation of the Sherman Act, and the Second, Eleventh, and Federal Circuits, which adopted “a scope of the patent test.”

The court ultimately opted to follow the latter approach, saying a “reflexive conclusion that the agreements in question are per se antitrust violations,” as urged by plaintiffs and the Federal Trade Commission (FTC), fails to recognize that “a patent grants its owner the lawful right to exclude others.” In the court’s view, the “scope of the patent” framework strikes the appropriate balance between competing patent and antitrust principles, allowing the latter to apply where the agreements in question improperly afford more rights than those granted under the patent.

“Today’s decision seems to reflect a growing understanding—first in Congress now in the courts—that brand name drug companies must not be allowed to make pay-offs to their generic competitors to keep low-cost generic drugs off the market. These deals are costing American consumers \$3.5 billion a year in higher drug costs,” said FTC Chairman Jon Leibowitz in a statement following the district court’s decision. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-cv-07197 (E.D. Pa. Mar. 29, 2010).

Direct purchasers of an antidiuretic medication used by certain diabetics have standing to assert antitrust claims against two drug makers—Ferring and Aventis—for allegedly abusing the patent system to unlawfully maintain a monopoly over the drug, according to a Second Circuit ruling.

Ferring developed the drug at issue, desmopressin acetate tablets (sold under the name DDAVP), and owns the '398 patent. Ferring granted Aventis an exclusive license to market and sell the patented tablets under the DDAVP name. In 2002, Ferring filed a patent infringement suit against Barr Laboratories, Inc. after Barr filed an Abbreviated New Drug Application (ANDA) for a generic version of the compound. As part of the ANDA, Barr filed a "paragraph IV" certification stating the '398 patent was invalid, unenforceable, and/or would not be infringed by Barr's generic product.

In an earlier ruling, the appeals court had found that the Patent Trademark Office's (PTO's) decision to grant the '398 patent was based in part on declarations of two individuals who failed to disclose their prior affiliations with Ferring, and therefore was unenforceable. Following the ruling, plaintiffs, retail pharmacies and wholesalers that were direct purchasers of DDAVP, sued Ferring and Aventis, alleging their conduct regarding the '398 patent also violated the antitrust laws.

The appeals court concluded that plaintiffs had antitrust standing to bring the claim. As purchasers alleging they were forced to pay "supra-competitive prices" resulting from defendants' anticompetitive conduct, plaintiffs established the requisite antitrust injury, the appeals court said.

The appeals court ultimately declined to decide whether purchaser plaintiffs per se have standing to raise *Walker Process* claims, finding in the instant action antitrust standing was appropriate because plaintiffs were challenging "an already tarnished patent" that was unenforceable due to inequitable conduct. *In re DDAVP Direct Purchaser Antitrust Litig.*, No. 06-5525-cv (2d Cir. Oct. 16, 2009).

In other antitrust litigation, the Tenth Circuit ruled that a hospital has no antitrust duty to share its facilities with a physician at the expense of its own nephrology practice, rejecting a physician's action against Mercy Medical Center of Durango for alleged monopolization or attempted monopolization.

Southern Ute Indian tribe and Mercy sought for many years to convince Dr. Mark Bevan to provide kidney dialysis and other nephrology services in Durango. Ultimately, given the high prevalence of kidney disease in the area, Mercy and the tribe recruited another nephrologist, Dr. Mark Saddler, who in 2005 agreed to come to Durango. The hospital and tribe anticipated the new nephrology practice would lose money initially and set aside up to \$2.5 million to cover the expected losses. Under Mercy's bylaws, when Saddler became a full-time active nephrologist, Bevan's consulting privileges were automatically terminated, although he was allowed to remain a member of the hospital's courtesy staff.

Bevan and one of his associates filed an application to become a member of the hospital's active staff. Mercy decided to designate its nephrology practice under Saddler as the sole provider of nephrology services to the hospital. According to Mercy, it made this decision out of concern that granting active staff membership to Bevan and his associates would reduce the volume of patients for Saddler and his partner, potentially causing them to leave, and would exacerbate the losses already expected with its existing nephrology practice.

Bevan sued Mercy, claiming its decision to exclude him and other nephrologists from admitting patients amounted to the unlawful monopolization, or attempted monopolization, of the market for "nephrology physician services" in Durango in violation of Section 2 of the Sherman Act and the Colorado Antitrust Act. The Tenth Circuit affirmed the trial court's summary judgment in Mercy's favor, finding Mercy's refusal to deal with Bevan was not anticompetitive conduct within the meaning of federal and state antitrust law.

"Having made a substantial investment in developing its own nephrology practice—indeed, having even tried to secure Dr. Bevan's services for that practice—Mercy is entitled to recoup its investment without sharing its facilities with a competitor," the appeals court said.

The appeals court also held that Bevan failed to show an antitrust injury. The relief Bevan sought in addition to damages was an order directing Mercy to grant him privileges.

"Whatever injury he may have suffered, then, it is not one the antitrust laws protect because 'a producer's loss is no concern of the antitrust laws, which protect consumers from suppliers rather than suppliers from each other,'" the appeals court noted. *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango*, No. 08-1231 (10th Cir. Sept. 29, 2009).

The Eighth Circuit dismissed an antitrust action brought by the Little Rock Cardiology Clinic (clinic) against Baptist Health, insurer Blue Cross and Blue Shield of Arkansas (Blue Cross), and various affiliates, agreeing with the district court that the clinic failed to define a valid relevant product or geographic market.

The clinic and certain cardiologists (plaintiffs) initially sued Baptist Health, which operates five hospitals in Arkansas, in November 2006. The alleged wrongdoing began after the 1997 opening of the Arkansas Heart Hospital in Little Rock, whose part owners were cardiologists who practiced at the clinic. Before that time, these cardiologists participated in the Arkansas FirstSource network and were on staff at the Baptist Hospital in Little Rock. According to plaintiffs, after Arkansas Heart Hospital opened, the clinic and the physicians who practiced there were excluded from the FirstSource network, allegedly to protect Baptist Health from competition. In May 2003, Baptist Health adopted an "economic credentialing policy" to prohibit any physician from having or maintaining staff privileges at any of its facilities if they held an interest in a competing hospital. The complaint defined the relevant product market as, among other things, "the market for cardiology procedures obtained in hospitals by patients covered by private insurance."

According to the appeals court, proposing a market limited by how consumers pay for cardiology procedures "lacks support in both logic and law." The relevant inquiry, the Eighth Circuit said, is whether there are alternative patients available to the cardiologists. Plaintiffs argued the product market should be limited to patients with private insurance because private insurance and government insurance were not reasonably interchangeable. But the appeals court pointed out that "the patients able to pay their medical bills, regardless of the method of payment, are reasonably interchangeable from the cardiologist's perspective—the correct perspective from which to analyze the issue in this case." Thus, the appeals court concluded "as a matter of law, in an antitrust claim brought by a seller, a product market cannot be

limited to a single method of payment when there are other methods of payment that are acceptable to the seller.”

Plaintiffs also argued Little Rock was the relevant geographic market because it was the location to which cardiology patients had to travel for such services. But according to the appeals court, the proposed geographic market failed to take into account Baptist Health’s entire trade area, which extended well beyond Little Rock. Plaintiffs’ complaint fell short, the appeals court continued, because they failed to allege a geographic market in which the defendant supplier drew a sufficiently large percentage of its business.

The appeals court concluded:

We hold only that where, as here, an antitrust plaintiff alleges that a firm competes in and draws its customers from a specified geographic area, it cannot then limit the relevant geographic market to a location smaller than that area based solely on the fact that consumers must travel to that smaller area to obtain the relevant service or product.

*Little Rock Cardiology Clinic, P.A. v. Baptist Health*, No. 08-3158/09-1786 (8th Cir. Dec. 29, 2008).

## **Employment and Labor**

Weighing in on an issue that splits the federal circuits, the Ninth Circuit ruled that Section 504 of the Rehabilitation Act is not limited to employers and employees as defined in Title I of the Americans with Disabilities Act (ADA), but rather applies to independent contractors and the entities that hire them. The appeals court concluded that Congress intended the Rehabilitation Act to have a broader scope and therefore held the statute covered discrimination claims by independent contractors.

Dr. Lester Fleming, an anesthesiologist who suffers from sickle cell anemia, sued Yuma Regional Medical Center after it informed him that the hospital would not be able to accommodate his operating room and call schedules. Fleming alleged breach of his employment contract and employment discrimination in violation of Section 504 of the Rehabilitation Act.

While the Sixth and Eighth Circuits have concluded that the Rehabilitation Act, like the ADA, requires an employee-employer relationship, the Tenth Circuit has held that only the *standards* of Title I, and not Title I itself, should be used to determine whether a claim for employment discrimination under the Rehabilitation Act can stand. The Ninth Circuit agreed with the Tenth Circuit, emphasizing the Rehabilitation Act’s broad scope in covering any “otherwise qualified individual” who has been “excluded from the participation in, or denied the benefits of, or subjected to discrimination under any program or activity receiving Federal financial assistance.” *Fleming v. Yuma Reg’l Med. Ctr.*, No. 07-16427 (9th Cir. Nov. 19, 2009).

## EMTALA

A hospital cannot violate the duty to stabilize under the Emergency Medical Treatment and Labor Act (EMTALA) unless it actually transfers a patient, according to a First Circuit ruling. Moreover, the appeals court asserted, a physician's order that a patient be transferred as soon as possible was not a "transfer" under EMTALA.

Adalberto Martinez Lopez came to Ryder Memorial Hospital's emergency room complaining of chest pain and bleeding from a femoral dialysis catheter site. Physicians examined him and eventually admitted him but were unable to stop the bleeding. The next day physicians ordered a blood transfusion and determined that Martinez required surgery and recommended he be transferred to another hospital for a specific procedure. Martinez died before he was transferred to the other hospital.

According to the appeals court, the statute is clear in defining a "transfer" as "the movement (including the discharge) of an individual outside a hospital's facilities." In addition, EMTALA clearly defines "to stabilize" as "to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur *during the transfer of the individual from a facility*." The stabilization requirement "plainly applies only where transfer occurs," the appeals court observed. *Torres v. Ryder Mem'l Hosp.*, No. 08-2351 (1st Cir. Sept. 4, 2009).

EMTALA does not apply to hospital outpatients, according to a Third Circuit ruling. The appeals court held EMTALA's requirements are not triggered when an individual already is a hospital patient (which includes outpatients) even if during the outpatient encounter they are later found to have an emergency medical condition.

Honey Toretta, who previously was treated for pre-term labor and suffered from insulin dependent diabetes among other things, was 34 weeks pregnant when she went to a testing center adjacent to Paoli Memorial Hospital (Paoli) where her obstetrician Dr. Andrew Gerson performed a scheduled fetal non-stress test. At the time, Toretta said she was experiencing contractions and Gerson told her husband to take her to Lankenau Hospital where his practice delivered babies. Gerson later testified that he did not believe an ambulance was necessary because Toretta was not an acute emergency. Toretta also testified that she did not believe her condition to be an emergency at that point.

Toretta's son was born at Lankenau later that day; he suffered permanent mental and physical damage. Toretta, her son, and her husband (plaintiffs) sued Main Line Hospitals, Inc., which owns and operates Paoli, alleging the hospital was liable under EMTALA for transferring her without stabilizing her emergency medical condition. Plaintiffs also asserted state law medical malpractice claims.

The appeals court said the issue could be resolved by considering federal regulations, which reasonably interpret the statute as not applying to scenarios involving outpatients like Toretta. Those regulations specify that EMTALA is triggered only where an individual with an emergency medical condition "comes to the emergency department" if that person is not already a patient, the appeals court explained.

The appeals court rejected plaintiffs' argument that EMTALA was triggered because Toretti came to Paoli for "what was, from the inception, a potential 'emergency medical condition.'" Toretti came to Paoli for her scheduled, bi-weekly appointment for routine monitoring and did not present as an emergency to the Paoli medical staff. Toretti's own testimony indicated that she did not believe she was in an emergent state until after she began monitoring at Lankenau Hospital. Nor did the fact that she had a high-risk pregnancy turn each scheduled visit to Paoli into something that would qualify as a presentment of an emergency medical condition to trigger EMTALA coverage. *Toretti v. Main Line Hosps., Inc.*, No. 08-1525 (3d Cir. Sept. 2, 2009).

## **Food and Drug Law/Life Sciences**

As has been the case in previous years, court rulings in this area focused on access to prescribing data, failure to warn claims, and drug pricing.

In Vermont, a federal district court refused to enjoin enforcement of a Vermont law regulating the collection and use of data identifying healthcare providers' prescribing patterns pending the appeal of a decision upholding the statute. *IMS Health Inc. v. Sorrell*, No. 1:07-CV-188 (D. Vt. June 5, 2009). In an earlier ruling, the same court had refused to strike down the law as unconstitutional. (*IMS Health Inc. v. Sorrell*, No. 1:07-CV-188 (D. Vt. Apr. 23, 2009)). The law, which was passed in 2007, went into effect July 1, 2009.

Vermont is one of three states (in addition to Maine and New Hampshire) that have enacted laws aimed at regulating so called "data mining" of physicians' and other providers' prescribing habits, which is then used by pharmaceutical manufacturers for their marketing activities, known as "detailing." The U.S. Supreme Court declined June 29, 2009 to review a First Circuit decision ruling a New Hampshire law regulating the use of prescription data did not amount to an unconstitutional restriction on commercial speech. *IMS Health Inc. v. Ayotte*, No. 08-1202 (U.S., cert. denied June 29, 2009). In December 2007, a federal district court agreed to preliminarily enjoin the enforcement of the Maine statute that was set to go into effect January 1, 2008.

In an opinion dealing with the federal preemption of state failure-to-warn laws, the Fifth Circuit in a January 8, 2010 opinion rejected a generic drug manufacturer's bid to dismiss a state tort action against it on those grounds. In so doing, the Fifth Circuit joined the Eighth Circuit in ruling that the federal regulatory regime for generic drugs does not preempt state law failure-to-warn claims, relying heavily on the U.S. Supreme Court's recent decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), which found no preemption in an action that involved brand-name drugs.

Although Actavis, Inc., which manufactures metoclopramide, the generic version of the anti-reflux drug Reglan, sought to distinguish federal regulation of generics from brand-name drugs, the appeals court rejected its arguments, finding instead that generic drug manufacturers had similar avenues for strengthening warnings and that this served the underlying purpose of advancing safety and effectiveness in the nation's drug supply. *Demahy v. Actavis, Inc.*, No. 08-31204 (5th Cir. Jan. 8, 2010).

Similarly, the Seventh Circuit held that federal law does not preempt a state law negligence action against SmithKline Beecham Corp., d/b/a GlaxoSmithKline (GSK), by plaintiffs whose daughter committed suicide while taking GSK's anti-depressant Paxil. Reversing a lower court ruling that granted summary judgment in GSK's favor on federal preemption grounds in 2008, the Seventh Circuit also examined the case in light of the Supreme Court's subsequent decision in *Wyeth v. Levine*.

The plaintiff in *Levine* lost her arm to gangrene after she was injected with Phenergan using the "IV-push" method. The majority of the Court held federal preemption would only be triggered if *clear evidence* existed that the Food and Drug Administration (FDA) would have rejected a proposed change to the drug's label to warn of the risks associated with that method of injection. After reviewing the evidence presented in *Levine* on this issue, the Seventh Circuit concluded that the majority had set a high bar for the "clear evidence" standard.

"Taking *Levine* as a whole, it is clear from the ample administrative record that the FDA strongly considered a similar warning to the one the plaintiff proposed and the Court still did not find preemption," the appeals court observed. *Mason v. SmithKline Beecham Corp.*, No. 08-2265 (7th Cir. Feb. 23, 2010).

In the area of drug pricing, there were several significant rulings over the past year. Notably, in the average wholesale price (AWP) litigation (a massive nationwide multi-district class action brought against over 40 drug makers involving the pricing of pharmaceutical drugs that were reimbursed by Medicare, private insurers, and patients based on AWP between 1991 and 2003), the First Circuit issued a ruling involving Class 2 and 3 plaintiffs (third-party payors and certain consumers). According to plaintiffs, the published AWP's for the drugs, including AstraZeneca's Zoladex, among numerous others, did not reflect the discounts and rebates that the various drug manufacturers offered to physician providers.

In June 2007, the district court in this case concluded that AstraZeneca violated the Massachusetts deceptive trade practices act, by "[u]nscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup." In November of the same year, the court assessed damages on AstraZeneca totaling nearly \$13 million.

On appeal, the First Circuit rejected AstraZeneca's argument that the Massachusetts consumer protection law conflicted with or was preempted by federal Medicare law. Noting that express preemption was not at issue, the appeals court also found "[a] state consumer protection law that covers as severe a form of price manipulation as this cannot be said to be contrary to Congress' intent in establishing and administering the Medicare program." The appeals court upheld the district court's finding that AstraZeneca violated the Massachusetts consumer protection act by engaging in "unfair or deceptive" business practices. *In re Pharmaceutical Ind. Average Wholesale Price Litig.*, No. 08-1065 (1st Cir. Sept. 23, 2009).

In further AWP litigation developments, the First Circuit vacated September 28, 2009 a final judgment entered in Johnson & Johnson's (J&J's) favor in the case and remanded to the district court to explain its ruling and for further proceedings if necessary. (*In re Pharmaceutical Ind. Average Wholesale Price Litig.*, No. 08-1002 (1st Cir. Sept. 28, 2009).

In another case that is part of the AWP litigation, the U.S. District Court for the District of Massachusetts refused to dismiss relator Ven-A-Care of the Florida Keys, Inc.'s (Ven-A-Care's) qui tam action under the False Claims Act (FCA) alleging drug makers engaged in a scheme to report inflated pricing information for certain drugs leading to substantial overpayments by public programs. The court found Ven-A-Care was an "original source" of the allegations in its complaint and therefore the FCA public disclosure bar did not apply. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, No. 1456 (D. Mass. Feb. 1, 2010).

## **Fraud and Abuse**

The most noteworthy area of activity in fraud and abuse litigation over the past year was the numerous and substantial settlements entered into following allegations of fraudulent conduct. The following list summarizes the key settlements in 2009-2010.

- The state of New York and New York City agreed to pay \$540 million to settle allegations that they knowingly submitted, or caused to be submitted, false claims for reimbursement for school-based healthcare services, the Department of Justice (DOJ) announced July 21, 2009. The case arose from two lawsuits filed by a whistleblower under the False Claims Act. The settlement is a record federal recovery by DOJ for the Medicaid program, the agency said.
- Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. agreed to pay a \$2.3 billion settlement to resolve charges that the company illegally promoted its drug Bextra, DOJ announced September 2, 2009. The settlement is the largest healthcare fraud settlement in the history of DOJ, the agency said.
- Omnicare Inc., the largest nursing home pharmacy in the U.S., and IVAX Pharmaceuticals, a drug manufacturer, reached an agreement to pay the federal government \$112 million to resolve allegations of participating in a kickback scheme in violation of the federal False Claims Act, DOJ announced November 3, 2009.
- Teva Pharmaceuticals Industries, Ltd. announced February 5, 2010 that several of its U.S. subsidiaries had reached a settlement in principle to resolve allegations of Medicaid drug pricing fraud. The settlement, if finalized and approved by the court, would resolve a civil lawsuit involving federal contributions to all state Medicaid programs and claims of Texas, Florida, and California relating to their Medicaid programs, according to the company's press release.
- Recently, in April 2010, AstraZeneca LP and AstraZeneca Pharmaceuticals LP agreed to pay \$520 million to the government for off-label drug marketing of its anti-psychotic drug Seroquel. That settlement marks the largest amount ever paid by a company in a civil-only settlement of off-label marketing claims, Attorney General Eric Holder said at a press briefing announcing the settlement.

There were also a number of significant court rulings interpreting various provisions of the False Claims Act.

The U.S. Supreme Court held June 8, 2009 that when the United States has declined to intervene in a privately initiated FCA action, it is not a "party" to the litigation; thus, the 30-day time limit for filing a notice of appeal in Fed. R. App. P. 4(a)(1)(A) applies. Writing on behalf of the unanimous Court, Justice Clarence Thomas explained that, although the United States is the real party in interest in FCA actions, it is not a "party" to the qui tam action unless it decides to intervene and therefore parties in such cases must file a notice of appeal within 30 days. *United States ex rel. Eisenstein v. City of New York*, No. 08-660 (U.S. June 8, 2009).

More recently, in March 2010, the U.S. Supreme Court held that a public disclosure as defined under the FCA, 31 U.S.C. § 3730(e)(4), includes "administrative" reports, audits, and investigations from state and local sources as well as federal sources. In holding that the public disclosure bar applied to a whistleblower action that was based on a state audit report, the 7-2 decision, which overturns a Fourth Circuit ruling, resolves a split in the federal courts on this issue.

At the same time, the majority opinion, written by Justice John Paul Stevens, acknowledged the recently enacted Patient Protection and Affordable Care Act changes the FCA landscape in this regard, specifically providing that a public disclosure only encompasses federal sources of information. See Pub. L. No. 111-148, 124 Stat. 119, § 10104(j)(2).

"The legislation makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners' claimed defense to a qui tam suit," Stevens wrote in a footnote. *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson*, No. 08-304 (U.S. Mar. 30, 2010).

That same month, the Fourth Circuit held that a pre-filing release is enforceable with respect to a subsequent qui tam action under the FCA where the government had knowledge of the alleged fraudulent conduct before the suit was filed. Specifically, the appeals court found a release relator Mark Radcliffe executed as part of a severance package with his former employer, Purdue Pharma, L.P. and Purdue Pharma Inc. (collectively, Purdue), prevented him from subsequently bringing a qui tam action alleging Purdue misrepresented to physicians the relative potency of its pain medication OxyContin, causing higher reimbursement from federal and state healthcare programs.

The Fourth Circuit held the district court erred in refusing to enforce the release, saying the focus of the inquiry, as argued by the government in an amicus brief filed in the case, should be on whether the allegations were properly disclosed to the government, not on the completeness of the government's investigation. According to the appeals court, the government was aware of the claims before the suit was filed and therefore "the public interest has been served and the Release should be enforced." *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, No. 09-1202 (4th Cir. Mar. 24, 2010).

In an issue of first impression involving the FCA, the Ninth Circuit ruled that qui tam defendants may bring certain third-party claims under that statute. Accordingly, a biotechnology company that received incorrect information from an

outside Medicare reimbursement consultant that led to the company submitting false claims may pursue third-party indemnification claims against the consultant, the appeals court said.

Cell Therapeutics, Inc. (CTI) developed a cancer drug called Trisonex, which was approved by the FDA in September 2000 for the treatment of leukemia. CTI then hired Documedics Acquisition Co., Inc. to handle Medicare reimbursement and serve as a reimbursement consultant. Documedics mistakenly advised CTI, and in turn Medicare carriers and medical providers, that off-label uses for Trisonex were reimbursable by Medicare.

The government began investigating CTI and the Lash Group, Documedics' successor in interest, in the fall of 2004. Two years later, James Marchese, a CTI employee, filed a qui tam action against CTI and Lash. In 2007, the government intervened in the suit as to CTI but not as to Lash. CTI immediately settled with Marchese and the government for \$10.6 million. While the qui tam suit was pending, CTI sued Lash alleging claims of breach of contract and indemnification, among other things.

The Ninth Circuit noted it had not previously addressed the issue of whether a defendant that settles with the government and the relator may then seek recovery against a third-party for contractual indemnity and independent claims under the FCA. In this case, the appeals court ruled, the district court erred in concluding that the settlement effectively established FCA liability and thus barred CTI's claims against Lash. In support of its ruling, the appeals court highlighted that the "government signed on to a settlement that specifically disclaimed CTI's liability and Lash was not even a party to the settlement." Moreover, "the district court's presumption that a settlement with the government is equivalent to a finding of liability would chill the settlement process, signaling to future qui tam defendants that the only way to preserve potentially legitimate claims would be to secure a litigated judgment in court." *Cell Therapeutics Inc. v. Lash Group Inc.*, No. 08-35619 (9th Cir. Nov. 18, 2009).

In June 2009, the U.S. District Court for the District of Delaware held that the recent amendments to the FCA cannot be applied retroactively. Under 31 U.S.C. § 3729(a)(2), the court observed, the Third Circuit requires that "a plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." See *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004). In this particular case, the government alleged 1,495 of defendant's claims were false, but in fact they had been denied prior to payment. Because the government did not allege that any false claims were actually paid, it failed to state a claim under Section 3729(a)(2), the court held.

The court next turned to the question of whether the Fraud Enforcement and Recovery Act of 2009 (FERA), which was enacted in May 2009 and eliminates the actual payment requirement, could be applied retroactively to the case. Although Congress did not unambiguously preclude retroactive application of the False Claims Act amendments, the court found the law could not be applied retroactively. To do so would cause retroactive effects, which Congress directed against, the court said. *United States v. Aguillon*, No. 08-789-SLR (D. Del. June 24, 2009).

Similarly, a federal district court in Ohio ruled that the retroactive application of FERA violates the Ex Post Facto Clause of the U.S. Constitution. Specifically, the court found retroactive application of the FERA amendments was unconstitutional because Congress intended the FCA to be punitive and because sanctions under the statute are punitive in purpose and effect.

FERA amended Section 3729(a)(2) to provide that any person who "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable under the FCA. The FERA includes a retroactivity clause that provides the Section 3729(a)(2) amendment "shall take effect as if enacted on June 7, 2008 and apply to all *claims* under the False Claims Act . . . that are pending on or after that date." (Emphasis added).

The court ruled that the plain language of the retroactivity clause, which refers to "claims," not "cases," did not make the FCA amendments retroactive to the instant case. "This 'case' claiming violation of the FCA has been pending since 1995, but the 'claims' upon which this 'case' is based were paid in the late 1980s and early 1990s and were no longer pending on June 7, 2008," the court observed. "Since the Defendants in this case had no 'claims' pending on June 7, 2008, the retroactivity clause does not apply to them," the court continued. In addition, the court held FERA's retroactivity clause ran afoul of the Ex Post Facto Clause "because retroactive application of the amendments to the FCA would impose punishment for acts that were not punishable prior to enactment of the amendments." *United States ex rel. Sanders v. Allison Engine Co., Inc.*, No. 1:95-cv-970 (S.D. Ohio Oct. 27, 2009).

In December 2009, a federal district court in New York refused to dismiss an FCA whistleblower action alleging a professor of psychiatry and a medical college submitted false claims to obtain federal research funds from the National Institutes of Health. The case involved allegations that progress reports submitted by the professor and the college to support funding renewal applications contained false claims about the program.

The U.S. District Court for the Southern District of New York refused to dismiss the case, citing a number of unresolved material questions of fact regarding the adequacy and accuracy of information contained in the reports and applications. The court noted no dispute that the fellowship program as implemented differed from the program described in the grant application. "The question is whether those differences are material," the court said.

The court also noted a split of authority on whether damages to the United States are a required element of an FCA claim, again observing that the Second Circuit had not ruled on the issue. According to the court, "the most reasonable interpretation of the statutory language is that damages to the United States are not a required element of an FCA claim." *United States ex rel. Feldman v. van Gorp*, No. 03 CIV. 8135 (WHP) (S.D.N.Y. Dec. 7, 2009).

Finally, the perennial issue of whether Stark law and Anti-Kickback statute violations can trigger liability under the False Claims was the subject of ruling by the U.S. District Court for the Middle District of Pennsylvania in March 2010. In this case, the district court found factual disputes concerning whether defendants had "knowledge" of the alleged Anti-Kickback and Stark Law violations for purposes of triggering False Claims Act liability; thus, precluding disposition of the case at the

summary judgment stage. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, No. 1:05-CV-2184 (M.D. Pa. Mar. 31, 2010).

## **Health Information Technology**

In one of the fastest growing and most active areas of healthcare law, health information technology, there were a number of significant regulatory developments that are worth noting.

In August 2009, the FTC issued a final rule requiring certain businesses to notify consumers when the security of their electronic health information is breached. Two days later, the Department of Health and Human Services (HHS) issued an interim final rule on breach notification requirements applicable to healthcare providers, health plans, and other entities covered by the Health Insurance Portability and Accountability Act (HIPAA). Both rules implement the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA).

The FTC rule applies to vendors of personal health records and entities that offer third-party applications for personal health records—i.e., non-HIPAA covered entities. According to the FTC, such applications could include devices like blood pressure cuffs or pedometers whose readings consumers can upload into their personal health records. The final rules specify the timing, method, and content of the required notification, and in the case of certain breaches involving 500 or more people, require notice to the media. 74 Fed. Reg. 42962 (Aug. 25, 2009), codified at 16 C.F.R. pt. 318.

Under the HHS rule, breaches involving fewer than 500 individuals must be reported to the Secretary annually. Business associates of covered entities also must notify the covered entity of any breaches pursuant to the regulations. HHS also issued as part of the regulations updated guidance on technologies and methodologies to secure health information and prevent harm by rendering health information unusable, unreadable, or indecipherable to unauthorized individuals. 74 Fed. Reg. 42740 (Aug. 24, 2009), codified at 42 C.F.R. pts. 160 and 164.

The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) issued regulations December 30, 2009 aimed at further implementing electronic health record (EHR) incentives under ARRA.

The HITECH Act provisions of ARRA offer incentive payments to “meaningful users” of certified EHR technology for both Medicare and Medicaid providers. The CMS proposed rule defines the central concept of “meaningful use” of EHRs (75 Fed. Reg. 1844 (Jan. 13, 2010)) and the ONC interim final rule sets initial standards, implementation specifications, and certification criteria for EHR technology (75 Fed. Reg. 2014 (Jan. 13, 2010)). According to a CMS fact sheet, the proposed Stage 1 criteria for meaningful use focus on electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.

The interim final rule issued by ONC describes the standards that must be met by certified EHR technology to exchange healthcare information among providers and between providers and patients. The rule includes standard formats for clinical summaries and prescriptions; standard terms to describe clinical problems, procedures, laboratory tests, medications, and allergies; and standards for the secure transportation of such information using the Internet.

As was the case last year, the Red Flags Rule, which imposes new obligations on “creditors” to detect, prevent, and mitigate identity theft, continued to generate a good deal of uncertainty with respect to its reach and its date of implementation. The American Bar Association (ABA) filed a complaint in August 2009 seeking a declaration that the FTC’s application of the Red Flags Rule to lawyers was unlawful and exceeded the agency’s statutory authority. On October 30, 2009, the U.S. District Court for the District of Columbia ruled that the FTC could not apply the Red Flags Rule to attorneys, granting partial summary judgment to the ABA. In addition, at the end of May 2010, several medical groups, including the American Medical Association, filed a lawsuit seeking to block the application of the Red Flags Rule to physicians.

In October 2009, attempting to address the concerns of these groups, the House passed legislation (H.R. 3763) aimed at narrowing the application of the Red Flags Rule. The House bill would amend the Fair Credit Reporting Act to exclude certain small businesses—specifically those healthcare, accounting, and legal practices with 20 or fewer employees—from the Red Flags Rule.

Inevitably, the FTC further delayed enforcement of the “Red Flags Rule” until June 1, 2010. On May 28, 2010, FTC extended the June 1, 2010 deadline to December 31, 2010. FTC said it decided to delay enforcement again while Congress considers legislation that would affect the scope of entities covered by the Rule. These new deadlines mark the fourth and fifth time that the FTC has delayed enforcement of the Red Flags Rule.

## **HIPAA**

HIPAA, which will soon celebrate its 15th year in existence, remains a complex area of compliance for healthcare providers and the attorneys that represent them. Developments in 2009-2010 further emphasized the importance of this statute in the broader area of health information technology and management.

On August 3, 2009, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius announced that the authority to administer and enforce the HIPAA Security Rule had been delegated to the Office for Civil Rights (OCR). Enforcement authority previously resided with CMS.

In October 2009, the Departments of Health and Human Services, Labor, and Treasury issued an interim final rule with request for comments implementing Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). 74 Fed. Reg. 51644 (Oct. 7, 2009).

On the same day, OCR also issued a notice of proposed rulemaking with a 60-day comment period that would modify the HIPAA Privacy Rule pursuant to GINA Title I to prohibit health plans from using or disclosing genetic information for underwriting purposes. OCR’s proposed rule would also modify the HIPAA Privacy

Rule to clarify that genetic information is health information. The proposal also would prohibit the use and disclosure of genetic information by covered health plans for eligibility determinations, premium computations, applications of any pre-existing condition exclusions, and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits. 74 Fed. Reg. 51698 (Oct. 7, 2009).

Later that month, HHS issued an interim final rule (74 Fed. Reg. 56123) implementing provisions of the HITECH Act that significantly increase the penalty amounts the Secretary may impose for violations of HIPAA.

Prior to the HITECH Act, the Secretary could not impose a penalty of more than \$100 for each violation or \$25,000 for all identical violations of the same provision. However, Section 13410(d) of the HITECH Act strengthened the civil money penalty scheme by establishing tiered ranges of increasing minimum penalty amounts, with a maximum penalty of \$1.5 million for all violations of an identical provision. In addition, HHS said, under prior law, a covered healthcare provider, health plan, or clearinghouse could bar the Secretary's imposition of a civil money penalty by demonstrating that it did not know that it violated the HIPAA rules. Under the new rule, a covered entity can no longer avoid the imposition of a civil money penalty for an unknown violation unless it corrects the violation within 30 days of discovery.

## **Insurance/Managed Care**

### *Post-Claim Rescissions*

The issue of post-claim rescissions was at the forefront of managed care case law and regulatory activity in California last year.

A California superior court judge ruled in favor of Blue Shield of California in an action alleging the health plan improperly rescinded a subscriber's health insurance policy. The case involved Cindy and Steve Hailey, who filed the action against Blue Shield after it informed the Haileys that their health insurance coverage had been retroactively canceled. The policy cancellation came after Steve was hospitalized following an automobile accident that resulted in substantial medical bills, including the ongoing need for physical therapy and nursing care.

The case previously had been reviewed by a California appeals court after the trial court granted summary judgment to Blue Shield on the ground that the Haileys' misrepresentations and omissions on their application justified rescission. The California Court of Appeal, Fourth Appellate District, reversed, saying a health services plan must show a willful misrepresentation or omission *or* that it made reasonable efforts to ensure a subscriber's application was accurate and complete as part of the pre-contract underwriting process in order to lawfully rescind the contract later. *See Hailey v. California Physicians' Serv.*, No. G035579 (Cal. Ct. App. Dec. 24, 2007).

The judge on remand granted Blue Shield a directed verdict in the case after the Haileys stipulated that they had willfully omitted and willfully misrepresented material information to obtain insurance coverage, according to published reports.

A California appeals court held that local prosecutors could pursue unfair competition and false advertising claims against Anthem Blue Cross of California, Inc. (Blue Cross) for their rescission practices. The lawsuit alleged that Blue Cross engaged in

the illegal practice of “post-claims” underwriting, or rescinding coverage after consumers began submitting claims for expensive medical care. The Knox-Keene Act makes post-claims underwriting unlawful and therefore such conduct may be enjoined under the state’s unfair competition and false advertising laws, the appeals court held. The appeals court noted the Knox-Keene Act contained no provision preventing such a result. *Blue Cross of Cal., Inc. v. Superior Court of Los Angeles County*, No. B215035 (Cal. Ct. App. Dec. 15, 2009).

In June 2009, California unveiled regulations that take aim at post-claim rescissions by health insurers, a practice that has drawn increasing scrutiny from state regulators. The regulations, among other things, set clear and rigorous standards that insurers must meet before issuing a health insurance policy, including completing the underwriting process; require insurers to ask clear and unambiguous health history questions to avoid confusing applicants; encourage the use of personal health records where available instead of potentially confusing health history questionnaires to underwrite applicants; and provide fair due process protections for consumers who are being investigated for possible rescission.

Ultimately, the adoption of the healthcare reform law, which contains a ban on rescissions except in cases of fraud or intentional misrepresentation of fact, prompted several major insurance companies to announce in late April 2010 that they would implement that requirement ahead of the September 2010 deadline set forth in the statute. WellPoint, Inc. became the first insurer to announce early implementation of the rescission ban effective May 1, 2010.

### *Mental Health Parity*

Long-awaited regulations implementing the mental health parity legislation were issued by the Departments of Health and Human Services, Labor, and the Treasury in January 2010. 75 Fed. Reg. 5410. The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 requires insurance companies and employers offering mental health coverage to provide it on par with the coverage offered for other physical illnesses.

Shortly thereafter, in April 2010, a coalition of managed behavioral healthcare organizations filed a lawsuit in federal district court seeking to invalidate the recently issued regulations. The U.S. District Court for the District of Columbia refused to issue a temporary restraining order to prevent enforcement of the regulations, finding plaintiffs failed to show they would suffer irreparable injury. While the regulations have an April 5, 2010 effective date, they are not generally applicable to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.

The underlying complaint alleges the agencies failed to engage in required notice and comment rulemaking before issuing the interim final rules in violation of the Administrative Procedure Act. The complaint also alleges the rules are so ambiguous that they preclude uniform compliance and will likely lead to higher costs, administrative delays, and the risk of dropped or reduced mental health coverage.

### **Long Term Care**

In the area of long term care, there are several court rulings and regulatory developments that are worthy of mention.

The Third Circuit ruled a Medicaid recipient has a private right of action under 42 U.S.C. § 1983 to sue a nursing home for violating the Federal Nursing Home Reform Amendments (FNHRA). Reversing a lower court decision granting the nursing home's motion to dismiss, the appeals court found the language of the FNHRA is sufficiently rights-creating and that Section 1983 provided the right avenue for relief.

Congress enacted FNHRA to provide for the oversight and inspection of nursing homes that participate in Medicaid and Medicare, including satisfying certain standards. The Third Circuit found "no question" that the FNHRA was intended to benefit Medicaid recipients and nursing home residents, noting the amendments were directly concerned with whether each individual placed in a nursing home receives proper care.

Next, the appeals court held the rights asserted in this case were not so "vague or amorphous" that their enforcement would strain judicial resources—noting the provisions at issue repeatedly used mandatory language like "must provide," "must maintain," and "must conduct." The Third Circuit found FNHRA "replete with rights-creating language," noting both the use of mandatory requirements and of the word "residents" throughout the amendments. "The plain purpose of these provisions is to protect rights afforded to individuals," the appeals court said. *Grammer v. John J. Kane Reg'l Ctrs.*, No. 07-2358 (3d Cir. June 30, 2009).

In an emergency hearing held in February 2010, a federal court in Illinois found that a nursing facility was not entitled to a temporary restraining order enjoining the HHS Secretary from revoking its Medicaid certification. Because nothing in the Medicaid statute or implementing regulations requires a pre-termination hearing, the facility had received all of the process it was due under the Constitution after a federal survey found serious compliance issues, the appeals court held. Further, the facility had not shown that it would suffer irreparable harm as a result of its certification being terminated because a pending expedited appeal before an administrative law judge could allow it to recover any lost funds. *Somerset Place, LLC v. Sebelius*, No. 10-cv-764 (N.D. Ill. Feb. 5, 2010).

## **Medicaid**

In an interesting constitutional challenge to Maine's "free care" laws, the First Circuit held that these laws, which require hospitals to provide free services to patients eligible for charity care, do not amount to an unconstitutional taking. Specifically, the laws require hospitals to provide free medically necessary inpatient and outpatient hospital services to state residents who earn incomes at or below 150% of the federal poverty level. The state enforces compliance through fines and suits brought by the Maine Attorney General. A hospital may avoid liability by showing that its "economic viability would be jeopardized by compliance."

The appeals court found while the state's free care laws "adjust the benefits and burdens of economic life," they essentially "leave the core rights of property ownership intact." Maine's free care laws require hospitals to treat low-income patients, but they otherwise allow the hospitals to set the terms on which they provide access to their facilities and services, the court stated. The First Circuit also rejected the hospitals' claim of an unconstitutional taking based on the state's alleged failure to pay reasonable reimbursement rates under its Medicaid program, MaineCare. *Franklin Mem'l Hosp. v. Harvey*, No. 08-2550 (1st Cir. Aug. 5, 2009).

According to a ruling by the Eighth Circuit, CMS' disapproval of a state plan amendment to Iowa's Medicaid program involving multiple-source drugs was not arbitrary, capricious, or an abuse of discretion. CMS properly concluded the state's plan to pay pharmacies for multiple source drugs without reference to the federal upper limit

did not conform with applicable law and regulations, the court declared. *Iowa Dep't of Human Servs. v. Centers for Medicare and Medicaid Servs.*, No. 08-3284 (8th Cir. Aug. 19, 2009).

In March 2010, a federal court in Alabama refused to dismiss in its entirety the state's challenge to a letter issued by CMS to state health officials concerning state Medicaid fraud recoveries. Taking the allegations in the complaint as true, the U.S. District Court for the District of Alabama held the state could proceed with its claim that the letter amounted to an invalid substantive regulation because it was not subject to notice-and-comment rulemaking. *Alabama v. Centers for Medicare and Medicaid Servs.*, No. 2:08-cv-881-MEF-TFM (D. Ala. Mar. 30, 2010).

In the way of noteworthy regulatory developments affecting Medicaid, the CMS published in the April 30, 2010 *Federal Register* a final rule (75 Fed. Reg. 23068) giving states more flexibility in designing their Medicaid programs. The rule, which implements provisions of the Deficit Reduction Act of 2005 (DRA), revises a final rule published on December 3, 2008 (73 Fed. Reg. 9714) giving states "increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid-eligible individuals." The final rule is effective July 1, 2010.

CMS issued May 28, 2010 in the *Federal Register* (75 Fed. Reg. 30244) a final rule that allows states more flexibility to impose premiums and cost sharing on certain Medicaid recipients. The final rule, which implements provisions of the DRA and the Tax Relief and Health Care Act of 2006, revises the one issued November 25, 2008 (73 Fed. Reg. 71828). The final rule is effective July 1, 2010.

## **Liability and Medical Malpractice**

An Illinois appeals court held that a hospital was not entitled to relief from a jury verdict holding it vicariously liable for the negligence of an emergency room (ER) physician who was an independent contractor. Although the hospital's consent form, signed by the patient in the case, expressly indicated ER physicians were independent contractors, the appeals court found a jury, based on the totality of the circumstances, reasonably could have found the hospital held out the physician as its agent and the patient justifiably relied on the hospital, not the physician, to provide the specific medical care.

Judith Spiegelman sued Victory Memorial Hospital and several physicians, including ER physician Dr. Murray Keene, to recover for injuries she sustained as a result of misdiagnosis of bacterial meningitis. Before receiving treatment in Victory Memorial's ER, Spiegelman signed a one-page consent form titled "Consent for Emergency Treatment." The multi-part consent form included an acknowledgment that the ER physicians were independent contractors and not agents or employees of the hospital.

Keene, who was employed by Emergency Specialists of Illinois, P.C., subsequently examined Spiegelman. He did not suspect that Spiegelman was suffering from bacterial meningitis nor start her on prophylactic antibiotics. By the time she was diagnosed, she had sustained permanent brain injury.

In deciding this case, the appeals court relied on the Illinois Supreme Court decision in *Gilbert v. Sycamore Municipal Hosp.*, 622 N.E.2d 788 (Ill. 1993), which held that a hospital may be liable for the negligent actions of a physician under the theory of

apparent agency even where the physician is an independent contractor, unless the patient knows, or should have known, of the physician's status. The appeals court found Victory Memorial's consent form, which explicitly stated ER physicians were independent contractors, did not necessarily defeat the "holding out" element of a vicarious liability claim based on apparent agency.

Instead, the appeals court said, a number of factors created an issue of fact as to whether the hospital held the physician out as its agent. For example, the appeals court highlighted that Victory Memorial's consent form utilized a multi-part format and contained various provisions unrelated to the independent contractor disclaimer; the form itself was titled "Consent for Emergency Treatment"; the signature line was below a separate unnumbered paragraph concerning the release of property; and it contained potentially confusing language about hospital employees.

The appeals court also held Spiegelman had satisfied the "reasonable reliance" element of the apparent agency claim by showing she relied on the hospital to provide medical care, rather than a specific physician. Finally, the court pointed to evidence of an advertisement lauding the healthcare the hospital offered, observing that "[t]he Hospital cannot have it both ways. It cannot advertise it has the best doctors in the community and then tell a jury that there is no evidence that emergency department doctors were its employees." *Spiegelman v. Victory Mem'l Hosp.*, No. 1-07-3195 (Ill. App. Ct. June 5, 2009).

Several courts addressed various tort reform provisions in state statutes. For example, in September 2009, the Washington Supreme Court struck down that state's certificate of merit requirement in medical malpractice cases, finding it violates the right of access to courts and conflicts with the judiciary's inherent power to set court procedures. "When the activity of one branch invades the prerogatives of another, there is a violation of the doctrine of separation of powers," the high court said in finding the statute unconstitutional.

Plaintiff Kimme Putman sued Wenatchee Valley Medical Center and several of its employees, alleging they negligently failed to diagnose her ovarian cancer. The trial court dismissed Putman's claims because she failed to file a certificate of merit as required by Washington's medical malpractice litigation statute, WASH. REV. CODE. 7.70.150. Putman appealed, arguing the certificate of merit statute is unconstitutional.

The state high court found that the statute unduly burdens access to the state's courts, noting that collecting the evidence necessary to obtain a certificate of merit may not be possible prior to discovery. Requiring plaintiffs to submit evidence supporting their claims prior to the discovery process violates the plaintiffs' right of access to courts, the high court declared.

The high court also concluded that the certificate of merit statute conflicts with civil rules regarding notice pleading. "The certificate of merit requirement essentially requires plaintiffs to submit evidence supporting their claims before they even have an opportunity to conduct discovery and obtain such evidence," the high court held. "For that reason, the certificate of merit requirement fundamentally conflicts with the civil rules regarding notice pleading—one of the primary components of our justice system." *Putman v. Wenatchee Valley Med. Ctr.*, No. 80888-1 (Wash. Sept. 17, 2009).

In Illinois, the state supreme court held that the state's statutory limit on noneconomic damages in medical malpractice actions is unconstitutional on its face. The

high court agreed with an earlier ruling by a state court that the cap violated the separation of powers clause of the Illinois Constitution.

The case was initially brought by plaintiffs Abigaile Lebron, a minor, and her mother, Frances Lebron, who sued Gottlieb Memorial Hospital, a physician, and a nurse for medical malpractice. Plaintiffs sought a judicial determination and declaration that the statutory caps (\$500,000 for actions against physicians and \$1 million for actions against hospitals) were unconstitutional.

Relying on the Illinois Supreme Court's opinion in *Best v. Taylor Machine Works*, 179 Ill.2d 367 (1997), the circuit court found the cap unconstitutional, holding it "operates as a legislative remittitur in violation of the separation of powers clause." After reviewing its decision in *Best*, the high court agreed that the statutory caps were facially invalid. While acknowledging that the statute at issue in *Best* was much broader than the one at issue in the current litigation, the high court nonetheless found "the encroachment upon the inherent power of the judiciary the same." *Lebron v. Gottlieb Mem'l Hosp.*, Nos. 10575-41, 105745 (Ill. Feb. 4, 2010).

Similarly, the Georgia Supreme Court struck down the state's statutory noneconomic damages caps in medical malpractice actions, finding that the provision violates the right to a jury trial under the Georgia Constitution. The high court also held that its decision invalidating the caps should be applied retroactively.

Affirming a lower court decision finding the caps unconstitutional, the high court said the threshold at which the caps applied, in this case \$350,000, under GA. CODE ANN. § 51-13-1, could not save the statute from constitutional attack because any limit, regardless of the amount, would violate the right to a jury trial.

According to the high court, the noneconomic damages limits in Section 51-13-1 unconstitutionally infringe on this right because the statute requires the court to nullify the jury's findings of fact regarding damages and "thereby undermines the jury's basic function."

"[W]e conclude that at the time of the adoption of our Constitution of 1798, there did exist the common law right to a jury trial for claims involving the negligence of a health care provider, with an attendant right to the award of the full measure of damages, including noneconomic damages, as determined by the jury," the high court said. While the high court acknowledged that the legislature has the authority to modify or abrogate the common law, "we do not agree with the notion that this general authority empowers the Legislature to abrogate *constitutional* rights that may inhere in common law causes of action."

The high court also refused to liken the caps to the courts' exercise of their remittitur power. "Judicial remittitur, the power to reduce a damages award deemed clearly excessive, is a corollary of the courts' constitutionally derived authority to grant new trials under . . . the Georgia Constitution." Moreover, the high court said, judicial remittitur is a carefully circumscribed power, whereas damages caps are automatically triggered when a damages award exceeds the threshold amount.

Finally, the court found retroactive application of its decision would not result in substantial inequitable results, noting no evidence that the defendant medical provider's litigation strategy would have been any different had the caps not been in effect. *Atlanta Oculoplastic Surgery, P.C. v. Nestlehutt*, No. S09A1432 (Ga. Mar. 22, 2010).

However, the Georgia Supreme Court upheld a state law that requires a gross negligence standard of liability for certain emergency room physicians in medical malpractice cases. The high court rejected the malpractice plaintiffs' constitutional challenges to the law under the uniformity clause, the due process clause, and the equal protection clause of the state constitution.

Carol and Robert Gliemmo (plaintiffs) brought a medical malpractice action against emergency room physician Mark Cousineau, Emergency Medical Specialists of Columbus, P.C., and St. Francis Hospital, Inc. (collectively, defendants). During the suit, plaintiffs challenged the constitutionality of a state law that establishes a gross negligence standard of liability only for certain emergency care providers, GA. CODE ANN. § 51-1-29.5. In particular, they argued that the law violates the uniformity clause of the Georgia Constitution because it sets forth a gross negligence standard only for certain emergency care providers.

The high court found the provision does not violate the uniformity clause. It explained that, to establish a violation of the uniformity clause, "the statute in question must either be a general law which lacks uniform operation throughout the state or a special law for which provision has been made by existing general law." See *Lasseter v. Georgia Public Serv. Comm.*, 253 Ga. 227, 229 (1984). However, the high court found the law at issue "is not a special law affecting only a limited activity in a specific industry during a limited time frame." Rather, the high court said, "it is a general law because it operates uniformly upon all health care liability claims arising from emergency medical care as provided in the statute."

The court also rejected plaintiffs' argument that the statute violates the Georgia equal protection guarantee because it only applies to malpractice actions involving emergency medical care in a hospital emergency department, and does not include actions arising from medical care provided outside of hospital emergency departments. Although Section 51-1-29.5 (c) raises the burden of proof in certain cases, it does not deprive plaintiffs of the right to a jury trial or any other fundamental right, the high court said.

The statute was passed as part of the Tort Reform Act of 2005, which is aimed at promoting affordable liability insurance for healthcare providers and hospitals, and thereby advancing the availability of quality healthcare services. These are legitimate legislative purposes, the high court said, finding it "entirely logical to assume that emergency medical care provided in hospital emergency rooms is different from medical care provided in other settings, and that establishing a standard of care and a burden of proof that reduces the potential liability of the providers of such care will help achieve those legitimate legislative goals."

The high court also rejected plaintiffs' argument that the law violates due process because it does not define "gross negligence" and is thus unconstitutionally vague. The high court found the term gross negligence "has a commonly understood meaning, and needs no specific definition within the statute." See *Rouse v. Department of Natural Resources*, 271 Ga. 726, 729 (1999).

*Gliemmo v. Cousineau*, No. S09A1807 (Ga. Mar. 15. 2010).

In the area of vaccine injury litigation, several rulings deserve mention. In June 2009, the Federal Circuit held the correct standard of proof of causation for recovery under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) is "simple preponderance of the evidence; not scientific certainty." The decision reversed the lower

court's finding that plaintiffs "failed to meet their burden to show a logical sequence of cause and effect."

Enrique and Sonia Andreau, on behalf of their son Enrique, sued the HHS Secretary alleging the diphtheria, whole-cell pertussis, and tetanus (DPT) vaccine Enrique received on October 31, 1995, when he was eight weeks old, induced a seizure disorder. The key issue at trial was whether the seizure disorder was "caused in fact" by the DPT vaccine.

The Federal Circuit noted that this is a "matter of considerable debate" among clinicians and went on to reject the government's argument that causation was lacking because Enrique's clinical picture was inconsistent (somewhat less severe) with toxic injury to the brain from the DPT vaccine. The appeals court applied the *Althen* causation test, which requires plaintiff to show: (1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the cause of the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. See *Althen v. Secretary of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

The second prong, cause and effect, was at the heart of the dispute in this case. "[D]etermination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain," the appeals court said. "[T]reating physicians are likely to be in the best position to [make this determination] . . ." The unequivocal testimony of Enrique's treating physician, that "there is no other explanation for Enrique's seizure disorder and encephalopathy [brain injury] other than the DPT vaccination," was sufficient to establish a logical sequence of cause and effect, the appeals court found. *Andreu v. Secretary of Health & Human Servs.*, No. 2008-5184 (Fed. Cir. June 18, 2009).

In another important vaccine injury-related development, the Federal Circuit issued a decision May 13, 2010 that dealt another blow to claims that vaccines cause autism, and the corresponding claim to payments from the \$3 billion Vaccine Injury Compensation Trust Fund. The case affirmed the decision of Special Master Campbell-Smith (Feb. 12, 2009), already affirmed by the Court of Federal Claims (July 24, 2009), that vaccines did not cause autism in the case of Yates Hazelhurst, the petitioner.

Rolf and Angela Hazlehurst filed a claim in 2003 for their son, Yates, seeking compensation under the Vaccine Act alleging the measles, mumps, and rubella vaccine, which was administered to Yates just before his first birthday, caused him to develop regressive autism.

The case was consolidated as part of the Omnibus Autism Proceeding, an effort to identify and adjudicate certain test cases as a means of addressing the roughly 5,000 autism claims that have been filed under the Vaccine Act. This case was considered with two others in one of the groups of test cases.

The Federal Circuit's decision dealt with two evidence issues, whether the Special Master improperly: (1) relied on evidence that should have been excluded, or (2) disregarded other evidence that should have been considered. In a unanimous decision, the Federal Circuit affirmed the decision of the Court of Federal Claims on both issues.

The Federal Circuit wrote:

Compensation under the Vaccine Act is limited to those individuals whose injuries or deaths can be linked causally . . . to a listed vaccine. The

special master concluded that the Hazlehursts' evidence failed to demonstrate the necessary causal link, and the petitioners have not identified any reversible error in the special master's decision reaching that conclusion.

*Hazelhurst v. Secretary of Health and Human Services*, No. 2009-5128 (Fed. Cir. May 13, 2010).

## Medicare

Court rulings dealing with Medicare issues focused on a number of prominent topics, including the disproportionate share hospital (DSH) adjustment, medical education expenses, the validity of the hospice cap regulation, medical education expenses, bad debt, the wage index, and depreciable assets.

### *DSH Cases*

The U.S. District Court for the District of Columbia dismissed for lack of mandamus jurisdiction St. Agnes Medical Center's suit seeking to require the HHS Secretary to recalculate its DSH adjustment for fiscal year 1991. The court found the cost report at issue was outside the three-year window for reopening as dictated by 42 C.F.R. § 405.1885(b) where an intermediary has notice that a decision was "inconsistent with the applicable law." This case is related to an issue previously litigated before the federal district court and D.C. Circuit in *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001), and *In re Medicare Reimbursement Litig.*, 414 F.3d 7 (D.C. Cir. 2005).

Those cases found intermediaries had a clear duty enforceable through mandamus to reopen Notices of Program Reimbursement (NPRs) issued for the three years prior to the Secretary's issuance of HCFAR 97-2. The Health Care Financing Administration (HCFA), the predecessor of CMS, issued HCFAR 97-2 in 1997 after several court rulings found interpretative regulations for calculating hospitals' DSH adjustment were inconsistent with the Medicare Act. HCFA intended HCFAR 97-2 to be prospective only, but the courts held that because the ruling amounted to "notice" under Section 405.1885(b), it created a nondiscretionary duty to reopen NPRs decided under the rescinded regulation within the three years prior to its issuance. The court found in the instant case, however, that St. Agnes was not entitled to reopening of its 1990 cost report, which the intermediary issued a NPR for in 1992, because it fell outside the three-year window under Section 405.1885(b). *St. Agnes Med. Ctr. v. Sebelius*, No. 06-0820 (PLF) (D.D.C. June 25, 2009).

In September 2009, a federal court in New Jersey ruled that CMS' interpretation of the Medicare DSH provision as excluding "patient days" under the New Jersey Charity Care Program (NJCCP) is a permissible construction of an ambiguous statute. At issue in the case was the "Medicaid fraction" of the disproportionate share percentage calculation and in particular a CMS program memorandum indicating that for a day to be counted in the Medicaid fraction, the patient must be eligible on that day for Medicaid.

Applying *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court first found the Medicare statute was ambiguous. In the second-step of its *Chevron* analysis, the court held the Secretary's interpretation of the ambiguous statute—i.e. that only patients who are eligible for traditional Medicaid are included in the fraction—was reasonable. Finally, the court rejected hospital's argument that the Secretary's interpretation of the Medicare DSH provision was not entitled to *Chevron* deference because it was an informal interpretation that deviated from the agency's past position. "The agency decision here is sufficiently formal to warrant

deference to the agency's statutory interpretation under *Chevron*." *Cooper Univ. Hosp. v. Sebelius*, No. 08-3781 (JBS/JS) (D.N.J. Sept. 28, 2009).

Similarly, in March 2010, the U.S. District Court for the District of Columbia upheld the HHS Secretary's exclusion of certain "charity care patient days" from a Massachusetts hospital's DSH adjustment. Under Massachusetts' Medicaid program, MassHealth, hospitals may qualify for a *Medicaid* DSH adjustment for providing uncompensated care to charity care patients. In this case, the hospital's fiscal intermediary, and later the Secretary, concluded the charity care patients were not "eligible for medical assistance under a state [Medicaid] plan," and therefore refused to include them in the hospital's *Medicare* DSH calculation.

Applying *Chevron* deference to the Secretary's interpretation of the Medicare statute, the court agreed that the charity patient days were properly excluded. According to the court, the charity care patients at issue "cannot receive 'medical assistance' as that phrase is defined in the Medicaid statute."

The hospital also contended that the Medicaid DSH payments it received included federal matching funds; therefore, the charity care patients must have been eligible for "medical assistance." Rejecting this argument, the court said "[i]t is undisputed that the charity care patients at issue here do not come within one of th[e] thirteen categories of people eligible for Medicaid."

Also at issue here were patient days for individuals who had elected a Medicare+Choice (M+C) plan under Medicare Part C and who were eligible for Medicaid. The question of whether these patient days should be included in the DSH calculation turned on whether the patients were still "entitled to benefits under [Medicare] Part A" even though they elected to enroll in an M+C plan. The court concluded that once an individual enrolls in an M+C plan, they are no longer entitled to Medicare Part A benefits; thus, the Secretary erred in excluding these days based on the finding that the patients were entitled to Medicare Part A benefits. The court also concluded the Secretary improperly excluded the days associated with labor and delivery services attributable to Medicaid-eligible patients. *Northeast Hosp. Corp. v. Sebelius*, No. 09-0180 (D.D.C. Mar. 31, 2010).

An HHS regulation requiring that Medicare-exhausted dual eligible patient days be included in the Medicare, rather than Medicaid, fraction of the DSH calculation is invalid because it violates the clear language of the statute, according to a recent ruling by federal court in Michigan.

A hospital's DSH adjustment is calculated based on the sum of the Medicare and Medicaid fractions. The Medicare fraction is based on the number of patient days for individuals "entitled to" Part A and Supplemental Security Income (SSI) (excluding patients who received state assistance only) divided by the number of days for patients "entitled to" Part A. The Medicaid fraction is based on the number of patient days for individuals "eligible for" Medicaid, but not "entitled to" Medicare Part A, divided by the number of all patient days.

Before October 1, 2004, the Medicare fraction regulation, 42 C.F.R. § 412.106(b), provided that the numerator was the number of "covered" days furnished to patients who were "entitled to" both Medicare Part A and SSI. In August 2004, CMS published a final rule deleting the word "covered" from the regulation. According to CMS, as a result of this change, days of care provided to dual eligible patients who had exhausted their Medicare Part A hospital benefit were now to be counted in the Medicare, rather than Medicaid, fraction.

Citing the Sixth Circuit's decision in *Jewish Hosp. Inc. v. HHS*, 19 F.3d 270 (1994), the U.S. District Court for the Western District of Michigan agreed with the hospital that the CMS regulation conflated "eligibility" with "entitlement." While the Medicare fraction speaks of "entitlement," the Medicaid fraction deals with "eligibility" only. HHS' reliance on the general definition of who is "entitled to" Medicare Part A benefits, 42 U.S.C. § 426(a), fails to consider the more specific statutory language applicable to the DSH Medicare fraction, which first refers to the "hospital's patient days" and to patients who were entitled to Medicare benefits "for such days."

"In calculating the DSH Medicare Fraction, the statute places no significance whatsoever on whether the patient, at the time of the hospital stay, might have still been entitled to benefits for (not exhausted coverage for) other services outside the hospital," the court explained. *Metropolitan Hosp. Inc. v. United States Dep't of Health and Human Servs.*, No. 1:09-cv-128 (W.D. Mich. Apr. 5, 2010).

### *Medical Education Expenses*

The U.S. District Court for the District of Columbia held that the CMS Administrator properly determined a hospital was not entitled to have resident time performed at non-hospital settings included in its resident count for purposes of determining its indirect graduate medical education (IME) and direct graduate medical education (GME) payments. In so holding, the court found it reasonable for the Secretary to require a contemporaneous written agreement with the non-hospital setting, although the relevant statutory language did not include such a requirement. The court also held the hospital had been given notice through a payment rule published in the *Federal Register*, a program memorandum, and other correspondence that it had to submit Medicare "encounter data" directly to its fiscal intermediary for additional IME and GME payments authorized by the Balanced Budget Act of 1997 for Part C claims. *Cottage Health Sys. v. Sebelius*, No. 08-098 (JDB) (D.D.C. July 7, 2009).

In Michigan, a federal district court affirmed the Secretary's decision denying reimbursement for certain medical education costs under Medicare, finding the plaintiff hospital did not comply with Medicare regulations.

The court noted that during the relevant period, Medicare regulations required hospitals seeking reimbursement for the costs of training residents offsite to have a written agreement in place with each nonhospital site. See 42 C.F.R. §§ 412.105(f)(1)(ii)(C). The hospital first challenged the validity of the regulation, arguing that the written agreement regulation is invalid because it conflicts with the language of the Medicare Act, which only has two requirements for reimbursement of medical education costs: (1) the costs are for "patient care"; and (2) the hospital has incurred "all, or substantially all, of the costs for the training program."

But the court disagreed with this argument, finding the regulation, "which is intended to ensure that a hospital has actually incurred all or substantially all of the costs it seeks, is not arbitrary, capricious, or manifestly contrary to the Medicare Act." The court also found the fact that the regulation was ultimately rescinded in 2004 "has no bearing on its validity while it was in effect." Finally, the court rejected the argument that because the hospital and the offsite training facility are related parties, the written agreement regulation did not apply, finding the related parties provision and the written agreement provision were not inconsistent. *Covenant Med. Ctr., Inc. v. Sebelius*, No. 07-15108 (E.D. Mich. Sept. 10, 2009).

HHS incorrectly interpreted a regulation governing whether certain residents involved in educational research may be included in the IME full-time equivalent (FTE)

residents count, according to a ruling by the U.S. District Court for the Northern District of Illinois. In so holding, the court said the term "portion" in the relevant regulation clearly has a geographic meaning and does not refer to the function the resident is performing, as the Secretary argued.

The court first explained that under the regulation at issue, 42 C.F.R. § 412.105(g)(1), in order for a resident to be included in Medicare's IME payment, two requirements must be met: (1) the resident must be enrolled in an approved teaching program, and (2) the resident must be assigned to a "portion" of the hospital subject to the prospective payment system (PPS). While the hospital contended the term "portion" unambiguously refers to a geographical location within a hospital, the Secretary argued that "portion" unambiguously refers to a function a resident is performing within a hospital, regardless of that resident's physical location. However, the court found the meaning was clear in the regulation using common rules of statutory construction. "The Secretary's interpretation of the regulation does not persuade this Court because, as the Hospital correctly contends, the term 'portion' unambiguously refers to a geographical location," the court held.

The court turned next to the Secretary's argument that a resident's research must directly relate to a patient's care for the resident to be included in the hospital's IME FTE resident count. The court found no such requirement mandated by the regulation, noting "the regulation makes no mention of a direct patient care limitation on research." *University of Chicago Med. Ctr. v. Sebelius*, No. 07 CV 7016 (N.D. Ill. Aug. 3, 2009). For a similar ruling, see also *Henry Ford Health Sys. v. Sebelius*, No. 2:09-cv-10195-SFC-MJH (E.D. Mich. Dec. 30, 2009).

In a North Dakota case, a federal court ruled October 13, 2009 that the HHS Secretary acted arbitrarily and capriciously in disallowing the direct and indirect costs incurred by two hospitals in training their residents at a non-hospital family practice center.

The U.S. District Court for the District of North Dakota granted summary judgment to the hospitals, finding the Secretary's decision was arbitrary and capricious because it retroactively applied a 2003 interpretation of the Medicare Act that amounted to a change in policy, not a clarification of existing requirements.

Under the relevant Medicare statutory provisions, 42 U.S.C. §§ 1395ww(d)(5)(B) and 1395ww(h)(4)(E), all the time a resident spent in training under an approved medical residency training program, regardless of setting, counted towards FTE resident counts for purposes of GME and indirect GME so long as (1) the resident was involved in patient care activities and (2) the hospital incurred "all, or substantially all of the costs for the training program" in the non-hospital setting. At issue in the instant action was the second statutory requirement—i.e., whether the hospitals met the requirement to incur "all, or substantially all of the costs for the training program," which is not defined by statute.

The dispute arose primarily over whether a hospital has to incur "all, or substantial all" of the costs for the entire residency training program, or for training only the residents claimed on its cost reports. According to the court, the CMS Administrator concluded 1998 regulations set forth a clear policy that one entity, either a hospital or a qualified non-hospital provider, must incur all or substantially all of the costs for the entire resident training program to obtain Medicare reimbursement.

The Secretary argued these regulations provided plaintiffs with notice that they could not split the costs of a residency training program for purposes of obtaining

Medicare reimbursement. But the court disagreed, saying the 1998 regulations governed Medicare payments to qualified *non-hospital* providers and are more stringent than those regulations that apply to *hospitals*. These regulations did not address a situation in which two or more hospitals split the total costs of a medical residency training program, with each hospital paying for the costs incurred in training its own residents. Accordingly, the court concluded, at no time before 2003 had the Secretary published his intent to require a single hospital to incur the costs for the full complement of residents at a non-hospital setting. *Medcenter One Health Sys. v. Leavitt*, No. 1:-08-cv-063 (D.N.D. Oct. 13, 2009).

### *Hospice Cap*

The validity of an HHS regulation implementing a statutory cap on hospice care was litigated in several cases over the past year. In July 2009, a federal court in California found the regulation was arbitrary and capricious. The regulation at issue, 42 C.F.R. § 418.309(b), ran counter to the clear congressional directive for calculating the annual provider cap.

Under the statute, the amount paid for hospice care for an accounting year is limited to a "cap amount" for the year "multiplied by the number of Medicare beneficiaries in the hospice program in that year." The statute provides that the number of Medicare beneficiaries for purposes of this calculation should be "reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year . . ."

The implementing regulation, Section 418.309(b), however, calculates each hospice's cap amount using "the number of Medicare beneficiaries who elected to receive hospice care during the cap period." Plaintiff argued the regulation was invalid because it includes an individual in a single accounting year depending on when the individual filed an election to receive hospice care rather than requiring a proportional adjustment as the statute specifies.

The court found the regulation did not pass muster under the standards set forth in *Chevron*. "Here, the answer under the *Chevron* analysis is plain and the Court need not proceed beyond the initial inquiry required there under," the opinion said. "Congress unquestionably required that the number of Medicare beneficiaries be reduced to reflect 'the proportion' (not simply a proportion or an estimate) . . . of hospice care that 'each such individual' (not individuals in the aggregate) 'was provided in a previous or subsequent accounting year,'" the court said. *Los Angeles Haven Hospice, Inc. v. Sebelius*, No. CV-08-4469 (C.D. Cal. July 13, 2009).

More recently, a federal court in Texas issued a similar ruling. The court enjoined HHS from enforcing overpayment determinations against the plaintiff hospice provider calculated by using the invalid regulation and from using the regulation to calculate the plaintiff's payment cap for past, present, or future accounting years. The Texas court specified that it need not proceed beyond the first step of the *Chevron* analysis because Congress was clear in the statute about how the "number of beneficiaries" should be calculated.

"By its plain language, the statutory requirement that the number be 'reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year' can only be accomplished in one way: each such individual who was also provided care in other accounting years must be counted toward the 'number of beneficiaries' in that year as a fraction," the court explained.

"Section 418.309(b)(1) clearly does not follow the method described in § 1395f(i)(2)(C)," the court held. According to the court, "rather than merely to 'reduce' the number of individuals who were provided care in a particular accounting year, the regulation completely excludes individuals who did not elect benefits in that accounting year . . ." *Lion Health Servs., Inc. v. Sebelius*, No. 4:09-CV-493-A (N.D. Tex. Feb. 22, 2010).

The court in the above cases also ruled that the plaintiffs had standing to challenge the validity of the regulation. *See also Compassionate Care Hospice v. Sebelius*, No. 5:09-cv-00028-C (W.D. Okla. July 10, 2009).

### *Medicare Bad Debt*

The Sixth Circuit affirmed the dismissal of claims brought by several hospitals alleging the HHS Secretary's regulation implementing a 1997 amendment to the Medicare Act that reduced bad debt reimbursement violated the prohibition on cross-subsidization. The appeals court found the two provisions were not at odds and held the statutory text was clear on its face in not allowing the exception sought by the hospitals.

Plaintiff hospitals provide services to patients under both Medicare and Medicaid. They alleged that the Secretary's regulation implementing Congress' 1997 amendment to the Medicare Act, which provides a percentage reduction of the amount of bad debt that would be reimbursed by Medicare, was invalid. Under the amendment, providers can make up for the remaining loss by continuing collection efforts against Medicare beneficiaries, except when the beneficiaries also are covered by Medicaid, as the Medicaid Act disallows such efforts. However, because the Medicare Act also states that the Secretary will promulgate regulations to ensure the costs of Medicare will not be borne, or cross-subsidized, by individuals not covered by Medicare, plaintiffs alleged the regulation violated the Medicare Act's cross-subsidization ban.

The Third Circuit dismissed the challenge to the regulation's validity because the statutory scheme is clear on its face and provides no exceptions to the bad debt reimbursement reduction for qualified Medicare beneficiary bad debt. The bad debt reimbursement reduction can be viewed as an overall reduction in payment rates for patients who are covered under both Medicare and Medicaid, which does not violate the cross-subsidization ban at 42 U.S.C. § 1395x(v)(1)(A), the appeals court held. Congress' decision to limit bad debt reimbursement may be characterized not as cross-subsidization, but simply as a setting of Medicare payment rates closer to Medicaid payment rates, the appeals court explained. *Detroit Receiving Hosp. and Univ. Health Ctr. v. Sebelius*, No. 08-1920 (6th Cir. July 30, 2009).

The D.C. Circuit upheld the HHS Secretary's disallowance of "bad debts" arising from plaintiff-skilled nursing facilities' (SNFs') provision of therapy services paid under Medicare Part B, finding the decision in line with controlling Medicare law and regulations. The appeals court found the refusal to reimburse the SNFs for uncollectible deductibles and coinsurance did not "contravene" the Medicare statute's "prohibition against cross-subsidization," as well as implementing regulations to that effect. Rather, the appeals court said it was reasonable for the Secretary to conclude that this provision applies only to reimbursement based on reasonable costs, and not to reimbursements based on reasonable charges or on a fee schedule.

Applying *Chevron* deference, the appeals court first noted the statute was silent on the subject of bad debt and therefore open to interpretation. The appeals court then

held it was reasonable for the Secretary to interpret the anti-cross-subsidization provision as applying only to reimbursement systems based on “reasonable costs.”

Plaintiffs also contended the Secretary had not applied the stated “long-standing” policy consistently, noting that Medicare reimburses providers for bad debt under Part A, which is a PPS, and under the fee schedule for ambulatory surgical centers. But the appeals court said those payment systems were still based on costs rather than on charges like the Part B physician fee schedule applicable to SNFs. Finally, the appeals court rejected the SNFs’ argument that the denial of reimbursement for bad debts was at odds with the implementing regulation, 42 C.F.R. § 413.80, for the anti-cross-subsidization provision. The appeals court found it “perfectly reasonable” for the Secretary to interpret this regulation in the same manner as the statute as only applying to cost-based reimbursement systems. *Abington Crest Nursing and Rehabilitation Ctr. v. Sebelius*, No. 08-5120 (D.C. Cir. Aug. 4, 2009).

### *Wage Index*

The HHS Secretary’s prior policy of excluding the wage data of reclassified hospitals in urban areas was a reasonable interpretation of the ambiguous Medicare statutory provision, 42 U.S.C. § 1395ww(d)(3)(E)(i), a federal district court held August 26, 2009.

Applying *Chevron* review, the court first determined that Section 1395ww(d)(3)(E)(i) did not speak to the precise question at issue—i.e., whether the Secretary had to include the wage data of reclassified hospitals in the calculation of the wage index. Plaintiffs argued Section 1395ww(d)(3)(E)(i) was clear and unambiguous because it defined the wage index to reflect “the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.”

But the U.S. District Court for the District of Columbia disagreed, discounting plaintiffs’ reliance on two cases: *Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163 (2d Cir. 2006), and *Anna Jacques Hosp. v. Leavitt*, 537 F. Supp. 2d 24 (D.D.C. 2008). According to the court, *Bellevue* actually undermined plaintiffs’ position because in that case the Second Circuit emphasized that Section 1395ww(d)(3)(E)(i) left to the Secretary’s discretion to define the term “geographic area.” Moreover, the *Anna Jacques* case addressed a different part of Section 1395ww(d)(3)(E)(i), one related to the *collection* of wage-index data rather than the *calculation* of a wage index after the data has been gathered. The court also noted the statutory framework reinforced its conclusion that Section 1395ww(d)(3)(E)(i) did not unambiguously require the Secretary to include reclassified hospitals in the geographic area where they are physically located, given that other provisions specifically included such protections for rural hospitals.

Next, the court found the Secretary’s interpretation was a permissible construction of Section 1395ww(d)(3)(E)(i). On this issue, plaintiffs argued the Secretary’s shift in position starting with fiscal year 2002—i.e., to include the wage data of reclassified hospitals—without a change to the statutory or regulatory framework indicated Section 1395ww(d)(3)(E)(i) required such an approach all along. The court disagreed, ruling that because the statute was silent on this issue, the agency was not only permitted to change its practice but was required to do so when it acquired additional information. *St. Michael’s Med. Ctr. v. Sebelius*, Nos. 07-2036 and 07-1484 (D.D.C. Aug. 26, 2009).

The D.C. Circuit reversed a federal district court decision granting summary judgment in favor of various Massachusetts hospitals challenging a change in the government’s method to calculate their area wage index. The action against HHS

Secretary Kathleen Sebelius in her official capacity asserted she exceeded her statutory authority by deciding to exclude wage data from hospitals that had become critical access hospitals (CAHs) from the wage index for fiscal year 2005.

The D.C. Circuit disagreed with the trial court in this case that the relevant statutory provision, Section 1395ww(d)(3)(E)(i), required the Secretary to include data collected from every subsection (d) hospital in the survey, finding the statute is silent about whether she must use all of the survey data. "Under the statute the Secretary has the discretion to remove some data from the survey so long as the remaining data constitute the principal component of the final wage index calculation," the appeals court said.

The appeals also found the Secretary acted reasonably in deciding to no longer include survey data from hospitals that had since been designated as CAHs. According to the appeals court, the change comported with the Secretary's long-standing policy of scrubbing aberrant data that failed to meet her criteria for reasonableness. Finally, the appeals court held plaintiffs failed to support their argument that the Secretary acted arbitrarily because she included data from other non-subsection (d) hospitals in the wage index calculation. *Anna Jacques Hosp. v. Leavitt*, No. 08-5407 (D.C. Cir. Sept. 11, 2009).

### *Depreciable Asset Cases*

Several courts also addressed the issue of whether a merger is a bona fide sale for the purposes of declaring a loss on the merged entity's depreciable assets.

In September 2009, the U.S. District Court for the District of Columbia upheld the HHS Secretary's finding that a statutory merger was not a bona fide sale and thus the surviving entity could not recover a loss on the merged entity's depreciable assets. According to the court, the regulation at issue, 42 C.F.R. § 413.134(f), allows for the realization of gains or losses only upon a "bona fide sale." The court noted that the actual sale "price" in this merger had nothing to do with the reasonable value of the hospital's long term assets.

"If a merger involved the assumption of liabilities that closely mirrored the true value of depreciable assets, or involved competitive bidding for those assets, it might satisfy the bona fide sale requirements, even if it involved a non-profit entity," the court explained. "But where, as here, even the plaintiff agrees that the 'price' provides no reasonable estimate of market value, it would be odd indeed for Medicare to treat the liabilities assumed as a better estimation of market price than the assets' net book value."

The court also rejected the argument that the Secretary's interpretation was a post hoc rationalization departing from a previous policy that all statutory mergers automatically trigger the reassessment of depreciable assets. Rather, the court endorsed the view "that agencies may change their informal interpretations at any time, so long as their new position is adequately explained." *St. Luke's Hosp. v. Sebelius*, No. 08- 0883 (D.D.C. Sept. 30, 2009). See also *Provena Hosps. v. Sebelius*, No. WMN-08-1054 (D.D.C. Oct. 12, 2009), and *Forsyth Mem'l Hosp. Inc. v. Sebelius*, No. 1:07-cv-01828-CCB (D.D.C. Nov. 5, 2009).

However, the Third Circuit reversed a district court's finding that the HHS Secretary properly denied nonprofit UPMC-Braddock Hospital (UPMC) Medicare reimbursement for depreciation losses that allegedly occurred during a statutory merger.

Under Medicare regulations, a statutory merger may result in a depreciation adjustment—a reassessment of the value of assets—but only if the merger was between “unrelated parties” and constituted a “bona fide sale.” The appeals court found the Secretary’s interpretation of the Medicare related party regulations as requiring examination of whether the parties were related pre- *and* post-merger was contrary to the plain language of the regulations.

The case arose after Braddock Medical Center (BMC) and University of Pittsburgh Medical Center System (UPMC) entered into a statutory merger. BMC, a nonprofit corporation operating an acute care inpatient hospital, merged with UPMC in 1996, with UPMC the surviving corporation. Under the terms of the merger, UPMC’s board of directors would consist of six members appointed by the Heritage Health Foundation (Foundation), which undertook fundraising and other charitable activities for BMC. Pursuant to the merger, UPMC received roughly \$27 million in assets from BMC—including over \$10 million in monetary assets from BMC and an additional \$3 million from the Foundation—while assuming almost \$13 million in debt.

UPMC attempted to treat the absence of consideration paid for the depreciable assets as evidence that the assets had depreciated to nothing. It therefore claimed a near total “loss” and sought a Medicare depreciation adjustment pursuant to 42 C.F.R. § 413.134(f). The U.S. District Court for the Western District of Pennsylvania upheld the Secretary’s decision to disallow the depreciation adjustment, based on the finding that the merger did not meet the criteria for a “bona fide sale”; it did not, therefore, address the argument that BMC and UPMC were related parties. *See UPMC-Braddock Hosp. v. Leavitt*, No. 07-1618 (W.D. Pa. Sept. 29, 2008).

The Third Circuit first held the lower court’s finding of a discrepancy of about \$13 million between the value of the transferred assets and the value of the consideration was in error. Taking this error into account, “the reasonable consideration question becomes much closer, with UPMC-Braddock receiving \$16.4 million in assets while assuming \$12.9 million in liabilities,” the appeals court explained. That leaves only a \$3 million discrepancy, the appeals court noted, adding that a question also remained about the accuracy of that number. Accordingly, the appeals court remanded on the issue of whether the transaction was a bona fide sale, instructing the lower court to consider whether the merger was negotiated at arm’s length as part of its analysis of that issue.

The appeals court then turned to the question of whether the entities were related parties. The Secretary argued that the relationship of the parties must be assessed both *pre-* and *post-*merger. On that issue, there was no doubt that the parties were unrelated pre-merger, the appeals court said. Therefore, the sole issue before the court “is whether the *post-*merger relationship between BMC and UPMC-Braddock is relevant to the ‘related parties’ inquiry.”

The relevant regulation states that “[i]f the statutory merger is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the merged corporation(s) acquired by the surviving corporation may be revalued.” 42 C.F.R. § 413.134(l)(2)(i). The appeals court concluded that the only permissible reading of the regulation is that “between” means “pre-merger.” A corporation formed as part of the merger is not a party to the merger; it is the surviving corporation, the appeals court noted. Thus, the appeals court concluded that the parties were not related. “Because the parties were not related, the only issue to be decided on remand is whether the merger was a ‘bona fide sale,’ since both prongs must be satisfied in order for the merger to qualify for the depreciation adjustment,” the appeals court explained. *UPMC-Braddock Hosp. v. Sebelius*, No. 08-4247 (3d Cir. Jan. 20, 2010).

## *Regulatory Developments*

CMS issued a final rule (74 Fed. Reg. 47458) that prohibits Medicare from recouping provider and supplier overpayments during the first level of appeal—the redetermination—if the provider or supplier files a timely request for appeal. The final rule implements a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that required certain changes to the recoupment process and became effective on November 16, 2009.

The fee-for-service appeal process consists of redetermination by a Medicare contractor; reconsideration by a Qualified Independent Contractor (QIC); a hearing before an administrative law judge; followed by the Department of Appeals Board; and finally federal district court review. In the final rule, CMS said it included revisions to make clear that it was implementing the statutory requirement to limit recoupment during reconsideration (the second level of appeal), as well as limiting recoupment during redetermination (the first level of appeal). Providers or suppliers must file a first-level appeal within 41 days and a second-level appeal within 60 days to halt recoupment. The final rule also specifies that if an overpayment determination is overturned in administrative or judicial appeals, above the QIC level of appeal, CMS is liable for interest on recouped overpayments that has accrued since the original determination. 42 C.F.R. pt. 405.

In other significant regulatory activity, CMS issued a final rule revising certain policies and “technical” requirements for the Part C Medicare Advantage (MA) program and Part D prescription drug benefit. The final rule is aimed at strengthening beneficiary protections, ensuring plan offerings include “meaningful differences” among plans, improving plan payment rules and processes, strengthening various program participation and exit requirements, improving data collection for oversight and quality assessment, and implementing a new Part D formulary policy, according to an agency fact sheet.

The final regulations, published in the April 15 *Federal Register* (75 Fed. Reg. 19678), became effective June 7, 2010. In practice, however, because health and drug plans under Parts C and D operate under contracts with CMS that are effective on a calendar year basis, the provisions will not have an effect before contract year January 1, 2011, unless otherwise specified in the rule.

Under the final rule, the agency will only approve a bid submitted by an MA organization or Part D sponsor if the plan benefit package or cost structures differ substantially from those of other plans offered by the organization or sponsor for key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. MA organizations and Part D sponsors will have two-years after completing a merger or acquisition to ensure their plans meet the “substantially different” requirement. The final rule also makes clear that Parts C or D plans without a significant number of enrollees over a sustained period of time may not see their contracts renewed.

The new regulations include a number of beneficiary protections, including cost-sharing thresholds for certain Part A and Part B services identified as particularly likely to have a discriminatory impact on sicker beneficiaries such as inpatient catastrophic days, inpatient short stay days, inpatient mental health days, and SNF days. In addition, the final rule establishes a mandatory out-of-pocket limit, or MOOP, on overall cost-sharing for Parts A and B services. MA organizations will continue to have the option of adopting a lower voluntary MOOP limit with greater flexibility in Parts A and B cost sharing than if they had elected to design their benefit packages using the higher, mandatory MOOP limit. Other provisions include a risk adjustment data validation appeals process and a

deeming option for fraud, waste, and abuse training of Parts C and D plans' downstream entities. 42 C.F.R. pts. 417, 422, 423, and 480.

CMS' final calendar year (CY) 2010 outpatient prospective payment system (OPPS) rule with comment period (74 Fed. Reg. 60316) revises payment policies and updates the payment rates for services furnished to beneficiaries during CY 2010 in hospital outpatient departments under the OPPS. In addition, and most significantly, the final rule revised several current policies in the area of physician supervision, designed to ensure that hospital outpatient services are appropriately supervised by qualified practitioners while not impeding beneficiary access to these services

Under these revisions, CMS will allow certain nonphysician practitioners—specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and licensed clinical social workers—to provide direct supervision for all hospital outpatient therapeutic services that they are authorized to personally perform according to their state scope of practice rules and hospital-granted privileges.

For purposes of on-campus hospital outpatient therapeutic services, the rule defines "direct supervision" to mean that the physician or nonphysician practitioner must be present anywhere on the hospital campus and immediately available to furnish assistance and direction throughout the performance of the procedure. For services furnished in an off-campus provider-based department, "direct supervision" would continue to mean that the physician or nonphysician practitioner must be present in the off-campus provider-based department and immediately available to furnish assistance and direction throughout the performance of the procedure, according to the agency.

The rule also requires all hospital outpatient diagnostic services furnished directly or under arrangement, whether provided in the hospital, in a provider-based department, or at a nonhospital location, follow the Medicare physician fee schedule physician supervision requirements for individual tests. 42 C.F.R. pt. 410.

CMS issued May 28, 2010 a transmittal clarifying the agency's policies under the OPPS rule requiring physician supervision of diagnostic and therapeutic services provided to hospital outpatients. The transmittal further defines the term "immediately available," and clarifies the credentials, knowledge, skills, ability, and privileges that the supervisory practitioner must possess to be qualified to perform a given service or procedure. *CMS Transmittal 128*, Pub. 100-02, Medicare Benefits Policy Manual.

## **Physicians**

On March 18, 2010, the Joint Commission issued the revised medical staff standard MS.01.01.01, formerly known as MS.1.20, which addresses the medical staff's self-governance and its accountability to the governing body for the quality and safety of patient care. The revised standard goes into effect March 31, 2011, which will provide hospitals and their medical staff a year to come into compliance with the revised requirements, as well as an opportunity for the Joint Commission to answer any questions, the group said.

The Seventh Circuit found July 24, 2009 that a physician could not maintain a claim for tortious interference against the hospital where he did his residency and several other physicians who worked there after another hospital denied his application for privileges. The appeals court found no evidence the hospital where the physician sought privileges relied on or was influenced by information provided

by defendants in making its credentialing decision. *Botvinick v. Rush Univ. Med. Ctr.*, No. 08-1966 (7th Cir. July 24, 2009).

According to a Florida appeals court decision, the Health Care Quality Improvement Act of 1986 (HCQIA) does not impliedly preempt a constitutional amendment passed by Florida voters that gives patients the right to access information from healthcare providers about adverse medical incidents. Amendment 7 was approved by Florida voters in 2004 and provides that "patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident."

Defendant hospital in the medical malpractice case, West Florida Regional Medical Center, Inc., argued that conflict preemption existed in that the amendment interfered with HCQIA's purpose of promoting effective peer review. In rejecting this argument, the Florida District Court of Appeal, First District, noted that Congress did not provide for confidentiality of peer review records or communications in HCQIA, but did provide that participants in peer review actions would be immune from liability for damages in connection with their participation in such actions.

After finding no HCQIA preemption, the appeals court next held the application of Amendment 7 in this case did not violate the Contract Clause of the U.S. Constitution by preventing the hospital from honoring the confidentiality provisions in its medical staff bylaws. Noting the state heavily regulates the medical profession, the appeals court said hospitals and physicians could not shield themselves from state regulations through private contracts. *West Fla. Reg'l Med. Ctr., Inc. v. See*, Nos. 1D09-1055, 1D09-1144 (Fla. Dist. Ct. App. Sept. 25, 2009).

The HCQIA does not require a hospital to conduct its own fact-finding investigation to corroborate the accuracy of the facts found by a previous facility's peer or disciplinary review proceedings for immunity purposes, an Indiana appeals court has ruled. According to the appeals court, the hospital was entitled to rely on the accuracy and veracity of another hospital's peer review findings in denying the physician privileges absent any indications that the report was unreliable or suspect, which was not the case here. *W.S.K. v. M.H.S.B.*, No. 71A03-0903-CV-106 (Ind. Ct. App. Mar. 10, 2010).

In October 2009, the Oregon Court of Appeals found that an on-call physician's telephone call with an emergency room physician gave rise indirectly to a physician-patient relationship between the on-call physician and the patient.

Plaintiff Cynthia Lynn Mead arrived at Legacy Good Samaritan Hospital's emergency room unable to walk due to severe low back pain and weakness in her legs. She was examined by Dr. Aviva Zigman, the emergency room physician, who ordered an MRI. The results of the test led Zigman to believe plaintiff may be suffering from a serious neurological condition so Zigman called Dr. David Adler, the on-call neurosurgeon. Zigman and Adler disagreed about the contents of the phone conversation, but Adler ultimately recommended that Mead be admitted for one day for pain management and then released. Mead was kept in the hospital as her condition deteriorated and Adler performed surgery four days later. Plaintiff suffered permanent impairment.

Plaintiff sued Legacy, Adler, and others for medical malpractice. Defendant Adler asserted that he had no liability to plaintiff because the two had not entered into a physician-patient relationship at the time of the alleged negligent conduct. In a special

verdict, the jury found there was no physician-patient relationship in existence when the phone call to Adler was made.

According to the appeals court, other courts to consider the issue have found that a physician-patient relationship can arise by implied consent of the physician based on indirect contact through telephone communication between a hospital emergency room physician and an on-call physician if the on-call physician affirmatively participates in the care of the patient. Here, Adler testified that he said plaintiff should be admitted for pain management and was likely not a neurosurgical candidate.

Thus, the appeals court concluded that,

in light of defendant's on-call status, in analyzing the information provided to him by the resident and providing a medical opinion—albeit in part implicit—that plaintiff's condition did not require surgery and that she should be admitted for observation and pain management, defendant made affirmative medical decisions concerning plaintiff's care that constituted diagnosis and treatment and thereby implicitly consented to a physician-patient relationship.

*Mead v. Legacy Health Sys.*, No. A130969 (Or. Ct. App. Oct. 28, 2009).

## **Quality of Care/Patient Safety**

In August 2009, the Joint Commission issued a new Sentinel Event Alert that urges administrative and clinical leaders to ramp up efforts for preventing medical errors. The alert recommends a series of 14 steps for the governing body, chief executive officer (CEO), senior managers, and medical staff leaders to implement such as establishing an organization-wide safety culture that includes a code of conduct for all employees and making the organization's overall safety performance a key, measurable part of the evaluation of the CEO and other leadership. Healthcare trustees, executives, and physician leaders should adopt a "zero-defect" approach used in other high-risk industries such as aviation and nuclear energy, The Joint Commission said.

New Jersey hospitals will have to publicly report their patient safety performance and rates of serious medical errors under legislation signed by state Governor Jon S. Corzine on August 31, 2009. Under the bill, S2471/A1264, the New Jersey Department of Health and Senior Services will publish annual hospital performance reports, which include hospital-specific results on 14 patient safety measures. The legislation also prohibits hospitals from charging consumers and their insurance companies for serious medical errors.

## **RICO**

The Eleventh Circuit affirmed summary judgment in favor of Tenet Healthcare Corp. in an action brought by plaintiff Boca Raton Community Hospital alleging Tenet violated the Racketeer Influenced and Corrupt Organizations Act (RICO) by engaging in a scheme with its affiliated hospitals to increase outlier payments from Medicare. The appeals court agreed with the U.S. District Court for the Southern District of Florida that Boca Raton failed to offer any evidence of injury (i.e. lower reimbursement from Medicare) from Tenet's alleged conduct—an essential element of its RICO claim. *In re Neurontin Marketing and Sales Practices Litig.*, MDL No. 1629 (D. Mass. Jan. 8, 2010).

The Sixth Circuit held that a group of out-of-network providers cannot pursue claims against a health insurance company pursuant to RICO based on allegations that

the company illegally denied or reduced payments for services the providers rendered to the company's insureds.

Plaintiff Riverview Health Institute LLC and other co-plaintiffs are out-of-network providers of healthcare services that do not maintain any provider agreements with health insurance carriers. In other words, plaintiffs operate exclusively on an out-of-network basis, taking compensation for their services "by direct patient payments and private insurance proceeds to the extent patients' insurance provides out-of-network coverage," the appeals court explained. Plaintiffs alleged defendant Medical Mutual of Ohio (Medical Mutual) committed RICO violations by systematically delaying, diminishing, or denying payment of claims submitted by them on behalf of the company's insured patients "through a scheme or artifice, utilizing the U.S. Mail."

The Sixth Circuit agreed with the trial court that plaintiffs' claims were reverse preempted by the McCarran-Ferguson Act. First, the appeals court held plaintiffs' federal RICO claims related to the "business of insurance" as the allegations involved "the actual performance of the insurance contract between Medical Mutual and its insureds."

Next, the appeals court found application of the federal RICO statute in this instance would "impair" Ohio's insurance regulatory scheme. Specifically, the appeals court noted that Ohio's Prompt Pay Act regulates the timely processing and payment of insureds' healthcare claims, the exact practices at issue in the instant litigation. Moreover, Ohio's insurance scheme does not afford a private right of action, a violation of the Prompt Pay Act does not constitute "corrupt activity" under Ohio's RICO statute, and the treble damages available under the federal RICO statute would greatly exceed the administrative remedies available under Ohio law, the appeals court said. *Riverview Health Inst. LLC v. Medical Mut. of Ohio*, No. 08-4431 (6th Cir. Apr. 7, 2010).

## **Tax**

In June 2009, a three-judge panel of the Eighth Circuit upheld the Internal Revenue Service's (IRS') regulation providing that medical residents who work 40 hours per week are not students within the statutory student exception under the Federal Insurance Contributions Act (FICA); therefore, in the tax periods in question, the residents' compensation for healthcare and patient services was subject to FICA taxes. The appeals court found the statute is "silent or ambiguous" on the question of whether a medical resident working for the school full-time is a "student" for purposes of the exemption and thus the IRS may promulgate a reasonable interpretation of that term. Accordingly, the appeals court concluded, the full-time employee regulation is a permissible interpretation of the statute.

At issue in the consolidated case is the exception under FICA for "service performed in the employ of . . . a school, college, or university . . . if such service is performed by a student who is enrolled and regularly attending classes at such school, college, or university." 26 U.S.C. § 3121(b)(10). The appeals court held "that the statute is silent or ambiguous on the question whether a medical resident working for the school full-time is a 'student who is enrolled and regularly attending classes' for purposes of 26 U.S.C. § 3121(b)(10)." Thus, the Treasury Regulation is appropriate as long as it "is a permissible interpretation of the statute," the appeals court said.

The appeals court next held the regulation was consistent with the student exception's origin and purpose, rejecting the argument that the full-time employee provision is of recent vintage and is inconsistent with the IRS Commissioner's "prior longstanding interpretation" of the statute. The court found instead that "the historical record reflects a consistent substantive policy applying the generally worded 'incident to'

regulation as not including full-time student employees." *Mayo Found. for Med. Educ. and Research v. United States*, Nos. 07-3242, 08-2193 (8th Cir. June 12, 2009). The Supreme Court granted certiorari June 1, 2010 to review the case. No. 09-837 (U.S. June 1, 2010).

In a closely watched case across the country, the Illinois Supreme Court held March 18, 2010 that Provena Covenant Medical Center (PCMC) was not entitled to a property tax exemption for the 2002 tax year. The high court agreed with an appeals court ruling that Provena Hospitals, which owns and operates PCMC, failed to show it qualified for either the charitable or religious exemption to the state property tax.

The dispute arose after the Illinois Department of Review (IDOR) refused to grant Provena's renewal application for a property tax exemption. The IDOR found Provena did not qualify for the charitable institution tax exemption under Illinois' property tax statutes because it failed to sufficiently show it used the property exclusively for charitable purposes. The Illinois appeals court sided with the IDOR, finding "no clear error" in the decision to deny Provena's exemption from property taxes.

The Illinois Supreme Court found PCMC's owner, Provena Hospitals, a subsidiary of Provena Health formed through the consolidation of four Catholic-related healthcare organizations as a not-for-profit corporation, did not qualify as a charitable institution under the factors identified in *Methodist Old Peoples Home v. Korzen*, 39 Ill. 2d 149 (1968). While Provena met some of the factors for a charitable institution, the high court emphasized that it plainly failed to meet one important criterion—its funds are not derived mainly from private and public charity; rather, "[t]hey are generated, overwhelmingly, by providing medical services for a fee." In other words, the vast majority of Provena's revenue is not derived from charitable contributions, the high court

In addition to charitable ownership, an organization seeking a charitable exemption also must show the property is "actually and exclusively used for charitable or beneficent purposes." According to the high court, Provena also failed to satisfy this charitable use requirement.

The high court wrote,

While Illinois law has never required that there be a direct, dollar-for-dollar correlation between the value of the tax exemption and the value of the goods or services provided by the charity, it is a *sine qua non* of charitable status that those seeking a charitable exemption be able to demonstrate that their activities will help alleviate some financial burden incurred by the affected taxing bodies in performing their governmental functions.

The high court said it was impossible to determine from the record whether PCMC's use of the property lessened the burdens on the relevant taxing bodies that they would otherwise have been required to bear. On the contrary, the court found that there was ample evidence that PCMC's property was not "actually and exclusively" used for charitable purposes. In that regard, the court noted, the number of uninsured patients receiving free or discounted care, and the dollar value of the care received, were de minimus, and, in fact, the property was, with little exception, devoted to providing care to patients with Medicare, Medicaid, and private insurance for compensation. The high court also pointed out that Provena did not advertise the availability of charitable care at PCMC, unpaid bills were automatically referred to collection agencies, and hospital charges were discounted or waived only after it was determined that a patient had no insurance and no other resources with which to pay.

Finally, the high court held Provena did not qualify for a religious exemption because, despite the religious component of Provena's mission, advancing religion was not its dominant purposes (which the high court again emphasized was providing medical care to patients for a fee). "We note, moreover, that no claim has been made that operation of a fee-based medical center is in any way essential to the practice or observance of the Catholic faith." *Provena Covenant Med. Ctr. v. Department of Revenue*, No. 107328 (Ill. Mar. 18, 2010).